SCIENTIFIC OPINION

Scientific Opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs: Part I – Exposure assessment[1]

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

TABLE OF CONTENTS

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ASSESSMENT

1. Introduction

Bisphenol A (BPA) is an industrial chemical that is widely used as a monomer or additive for the manufacture of polycarbonate (PC) plastics and epoxy resins and other polymeric materials and also certain paper products (e.g. thermal paper). The properties of PC, e.g. rigidity, transparency and resistance, make these plastics particularly suitable for many technical applications. PC is used for food and liquid containers, such as tableware (plates and mugs), microwave ovenware and reservoirs for water dispensers, and non-food applications such as toys and pacifiers with PC shields. BPA-based epoxyphenolic resins are used as protective linings for food and beverage cans and as a coating on residential drinking water storage tanks. BPA is also used in a number of non-food-related applications, e.g. epoxy resin-based paints, medical devices, surface coatings, printing inks, thermal paper and flame retardants and also in plastic materials such as CDs, DVDs and parts of electronic products.

The scientific opinion on BPA deals with the assessment – by the EFSA CEF Panel –- of the risks to public health associated with BPA exposure. It consists of three separate documents: Executive summary; Part I – Exposure assessment, Part II – Toxicological assessment and risk characterisation. This document refers to Part I.

For the sake of clarity, it should be noted that when the text makes reference to another section (or Appendix) of the opinion, this generally refers to a section included in the same part of the opinion, unless otherwise stated. In this latter case, the specific part of the opinion (i.e. Executive summary, Part I or Part II), to which the mentioned section belongs, is clearly mentioned.

1.1. EU and national provisions regarding BPA

BPA was first evaluated in 1984 by the Scientific Committee on Food (SCF, 1986[4]) for use in plastic materials and articles intended to come into contact with foodstuffs and established a Tolerable Daily Intake (TDI) of 0.05 mg/kg bw. It was subsequently listed as a permitted monomer in Annex II of Commission Directive 90/128/EEC[5] with a specific migration limit (SML) of 3 mg/kg food. In 2002, the SCF reduced the TDI (SCF, 2002[6]) and a lower SML total (T) of 0.6 mg/kg was subsequently set to reflect this in Commission Directive 2004/19/EC[7]. This Directive was an amendment to the then Commission Directive 2002/72/EC[8] relating to plastic materials and articles intended to come into contact with foodstuffs, which also authorised its use as an additive. In 2006, EFSA reduced the uncertainty factor, establishing a TDI of 0.05 mg/kg bw, although the SML(T) remained at 0.6 mg/kg.

In 2011, Commission Directive 2011/8/EU[9] placed a restriction on the use of BPA in the manufacture of PC infant feeding bottles as from 1 March 2011 and the placing on the market of these feeding bottles as from 1 June 2011, on the basis of the precautionary principle. This was subsequently

[4] Reports of the Scientific Committee for Food (Seventeenth series). http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_17.pdf.

[5] Commission Directive of 23 February 1990 relating to plastic materials and article intended to come into contact with foodstuffs (90/128/EEC). OJ L 75, 21.3.1990, p. 19 – 40.

[6] Opinion of the Scientific Committee on Food on Bisphenol A (Expressed on 17 April 2002). http://ec.europa.eu/food/fs/sc/scf/out128_en.pdf

[7] Opinion of the Scientific Committee on Food on Bisphenol A (Expressed on 17 April 2002). http://ec.europa.eu/food/fs/sc/scf/out128_en.pdf

[8] Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs. L 220, 15.8.2002, p. 18 – 58.

[9] Commission Directive 2011/8/EU of 28 January 2011 amending Directive 2002/72/EC as regards the restriction of use of Bisphenol A in plastic infant feeding bottles, OJ L 26, 29.1.2011, p. 11–14.

reflected in Commission Implementing Regulation (EU) No 321/2011[10] amending Commission Regulation (EU) No 10/2011/EU[11] on plastic materials and articles intended to come into contact with foodstuffs. This latter Regulation was introduced as a replacement to the previous Commission Directive 2002/72/EC and continues to authorise BPA for use as a monomer subject to the specified restrictions.

Bans on the use of BPA for food packaging intended for young children (zero to three years old) have been proposed by several European Union (EU) Member States.

In May 2010, Denmark banned the use of BPA in infant feeding bottles and all food contact materials of foods particularly intended for children between zero and three years of age and it is now included in the Bekendtgørelse om fødevarekontaktmaterialer 579/2011.[12]

Sweden has decided to ban the use of BPA or compounds containing BPA in varnishes or coatings for packaging for food intended for children between the age of zero and three years (Regulation SFS 2012:991[13]). The ban entered into force on 1 July 2013.

On 24 December 2012, France adopted a law suspending the manufacturing, import, export and putting on the market of all food contact materials containing BPA. This law will apply gradually with an application date of 1 January 2013 for food contact materials coming into contact with food intended for children between zero and three years of age and an application date of 1 January 2015 for all food contact materials. In the meantime, once a decree with specifications is adopted, labelling requirements for pregnant women, breastfeeding women and small children will apply.[14]

In September 2012, Belgium published an amendment to its national law concerning the protection of consumer health, regarding food commodities and other products, banning the marketing or putting on the market and manufacture of containers for food commodities, containing BPA, particularly intended for children between zero and three years of age.[15] This amendment was based on the opinion of the Belgium Superior Health Council, issued on 3 November 2012. The law entered into force on 1 January 2013.

On 6 October 2011, Austria published a decree forbidding the use of BPA in pacifiers and soothers.[16]

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.[17]

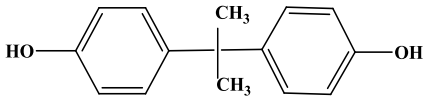
2. Physical and chemical characterisation

BPA is an organic chemical synthesised by condensation of 2 mol phenol with 1 mol acetone in the presence of an acid catalyst. It has the chemical formula $C_{15}H_{16}O_2$, with a molecular mass of

[10] 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.
[11] 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
[12] Bekendtgørelse om fødevarekontaktmaterialer 579/2011 (§ 8, stk. 2): https://www.retsinformation.dk/Forms/R0710.aspx?id=136917&exp=1
[13] Regulation No 991/2012 of 20 December 2012 amending the Food Regulation No 813/2006, Svensk författningssamling (SFS), 4.1.2013, p. 1.
[14] Regulation No 1442/2012 of 24 December 2012 aiming at banning the manufacture, import, export and commercialisation of all forms of food packaging containing bisphenol A. OJ of the French Republic (OJFR), 26.12.2012, text 2 of 154.
[15] Loi du 4 septembre 2012 modifiant la loi du 24 janvier 1977 relative à la protection de la santé des consommateurs en ce qui concerne les denrées alimentaires et les autres produits, visant à interdire le bisphénol A dans les contenants de denrées alimentaires publiée au Moniteur Belge le 24 septembre 2012
[16] Verordnung: Verbot der Verwendung von Bisphenol A in Beruhigungssaugern und Beißringen: http://www.ris.bka.gv.at/Dokumente/BgblAuth/BGBLA_2011_II_327/BGBLA_2011_II_327.pdf
[17] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ L 342, 22.12.2009, p. 59–209.

228.29 g/mol. It has the CAS (Chemical Abstracts Service) No 80-05-7 and EC No 201-245-8 (European Chemical Substances Information System (EINECS) number).

Chemical structure:



IUPAC name:
4,4'-Dihydroxy-2,2-diphenylpropane
2,2-bis(4-Hydroxyphenyl)propane
4-[2-(4-Hydroxyphenyl)propan-2-yl]phenol

EINECS name:
4,4′-Isopropylidenediphenol

CAS name:
Phenol, 4,4′-(1-methylethylidene)bis-

Other names:
Bisphenol A
Bis(4-hydroxyphenyl)dimethyl methane
4,4′-Dihydroxydiphenyl propane
Diphenylolpropane

BPA is a white solid available as crystals or flakes (Lewis, 2001; O'Neil, 2006). It crystallises as prisms from dilute acetic acid and as needles from water (Lide and Milne, 1994) and has a mild phenolic odour under ambient conditions (O'Neil, 2006). It has a melting point of 150–158 °C, a boiling point of 360–398 °C (at 101.33 kPa, (IUCLID, 2000; Cousins et al., 2002) and a density of 1.195 kg/dm^3 at 25 °C (IUCLID, 2000; Lewis, 2001). The vapour pressure is 5.3×10^{-6} Pa at 25 °C (Cousins et al., 2002).

BPA is a moderately hydrophobic compound with an octanol–water partition coefficient (log *P*ow) of 3.32 (Hansch et al., 1995), with a slight polarity owing to the two hydroxyl groups. It is soluble in acetic acid (Lide and Milne, 1994) and soluble in aqueous alkaline solution, alcohol, acetone (O'Neil, 2006), benzene and diethyl ether (Lide, 2004). It is has a fairly low solubility of 120–300 mg/L in water at 25 °C (Dorn et al., 1987, Cousins et al., 2002).

The pKa value of BPA is between 9.59 and 11.30 (Cousins et al., 2002); thus BPA will be present mainly in its non-ionised form in liquid media with a pH lower than 7. The BPA molecule has a fairly strong fluorophore and it can be detected by its fluorescence. Its chromophore is relatively weak, and the sensitivity of ultraviolet (UV) detection is much lower than that of fluorescence detection.

The Cousins report cited above also summarised environmental information as follows: BPA does not persist in the environment, although it is fairly stable in its solid form. Aerobic biodegradation is the dominant loss process for BPA in river water and soil, with a degradation half-life of approximately 4.5 days (Cousins et al., 2002). Its loss process in the atmosphere is due to the rapid reaction with hydroxyl radicals, and the photo-oxidation half-life for BPA in air is about four hours (Cousins et al., 2002).

3. Potential sources of exposure

3.1. Materials and uses

3.1.1. Polycarbonate plastics

PCs are a group of thermoplastic polymers produced by the condensation polymerisation reaction of BPA and carbonyl chloride or by melt-transesterification reaction between BPA and diphenylcarbonate. The production of PC is the main use for BPA. PC plastics are amorphous, transparent polymers with high levels of impact strength and ductility, stability and heat resistance and useful engineering properties over a wide temperature range, as well as good resistance to ultraviolet (UV) light (CEH, 2008; IHS, 2013). Because of these properties PC plastics and PC blends with, for

example, polybutylene terephthalate and acrylonitrile–butadiene–styrene (ABS) polymers are used in numerous applications (BPF, 2013). PC and PC blends may be used in the manufacture of consumer products such as CDs and DVDs, jars/containers, identity cards and toys. PC plastics are also used in the automotive industry, in glazing (e.g. greenhouses) and in optical media including lenses for glasses, as well as in food contact materials and articles and in medical devices.

Until 2011 PC plastics were used in the manufacture of infant feeding bottles. However, this application was withdrawn in the EU following the introduction of Commission Directive 2011/8/EU of 28 January 2011, which restricts the use of BPA in these articles[18]. Other PC food contact applications include water coolers with refillable PC reservoirs (PC coolers), tableware, chocolate moulds, kettles and kitchen utensils. The migration of residual BPA in the polymer, present because of incomplete polymerisation and migration of the BPA released by hydrolysisof the polymer from these PC materials into the foods and beverages with which they come into contact, has the potential to provide a source of dietary exposure to BPA.

Some toys may be made with PC plastics (KEMI, 2012). Mouthing of the toys by children may result in exposure to any BPA leaching from these articles into the saliva (KEMI, 2012). For baby pacifiers a large Danish retailer of pacifiers estimated that for 10–20 % on the Danish market in 2010 the shield and ring were made of PC plastics (Lassen et al., 2011). Since the saliva of a baby is spread around the mouth during sucking and may then be ingested, the shield may represent a source of oral exposure to BPA.

About 3 % of total PC production is reported to be used for the manufacture of medical devices (Beronius and Hanberg, 2011). Some BPA-containing medical devices may have direct and/or indirect contact with patients (e.g. autotransfusion apparatus, filters, bypasses, tubing, pumps, instruments, surgical equipment, blood pathway circuits and respiratory tubing circuits, dialysis equipment). It has also been reported that breast milk pumps are made from PC plastics (Beronius and Hanberg, 2011). The transfer of BPA from these PC plastics into the biological human matrices with which they come into contact or the migration of BPA into human milk to be consumed by an infant can result in exposure to BPA.

3.1.2. Epoxy resins

Epoxy resins are thermosetting polymers that have good mechanical properties, as well as high temperature and chemical resistance. As such, these resins have a wide range of applications, including use as coatings applied to metal substrates in food contact materials, in dental fillings, in electronics/electrical components, in high-tension electrical insulators, in fibre-reinforced plastic materials, in structural adhesives and in the relining of aged water pipes (KEMI, 2013).

Epoxy resins are produced by the reaction of BPA with BPA diglycidyl ether (commonly abbreviated to BADGE, made from BPA and epichlorohydrin), which are the primary chemical building blocks for the broad spectrum of materials generally referred to as epoxy resins. Alkoxylated BPA may also be used to prepare epoxy resins.

Epoxy resins represent the second largest use for BPA. Epoxy resins may be cross-linked with phenolic resins, amino resins, acrylic resins or anhydride resins producing epoxy phenolic, epoxy amino, epoxy acrylic and epoxy anhydride can coatings. All of these are used for can coatings, but there are also other coatings not containing epoxy resins, such as polyesters.

Following a request from EFSA, industry noted that "the content of the statement on epoxy phenolic resins in the EFSA opinion of 2006 is still correct, but that BPA based phenolics stopped being used in Europe a few years ago." (email from PlasticsEurope to EFSA on 5 February 2013). As well as canned food and beverages, epoxy-based coatings have been reported to be used in other food contact

[18] Commission Directive 2011/8/EU of 28 January 2011 amending Directive 2002/72/EC as regards the restriction of use of Bisphenol A in plastic infant feeding bottles, OJ L 26, 29.1.2011, p. 11–14.

applications including re-usable drinks bottles and wine vats. They may also be used in construction products, such as and storage tanks and water reservoirs, or for the restauration of domestic water pipes.

Epoxy resins may also be used as stabilisers (hydrochloric acid scavengers) and as plasticisers in polyvinylchloride (PVC) organosol coatings that may be used for cans and metal lids applied to glass jars. Residual BPA in the cured coating has the potential to migrate into the food or beverage with which it comes into contact, thereby providing a potential source of dietary exposure.

As for plastic food contact materials and articles, the extent of the migration from the coating, and hence the potential exposure, is dependent on contact surface, time and temperature. With the high-temperature processing conditions and the long shelf life of canned foods the migration of any residual BPA will occur, resulting in dietary exposure.

Epoxy resins may also be reacted with ethylenically unsaturated monocarboxylic acids to form vinyl esters, and it has been stated that these too may be used in food contact applications (email from PlasticsEurope to EFSA on 5 February 2013).

Epoxy resins may further be used in non-food contact applications including flooring and non-food tanks and pipes. The cross-linking of epoxy resins with phenol gives rise to a higher molecular weight solid epoxy resin known as a phenoplast (WUR, 2001). These resins are used as materials in the construction sector and as such are considered to constitute a source of exposure through indoor air and dust (see Section 4.3.3).

3.1.3. Thermal paper

Thermal paper consists of a smooth paper to which a coating is applied. This coating is made from a leuco dye and a phenol developer such as BPA. The leuco dye exists in two forms, one of which is colourless. On printing, a thermal head causes the coating components to melt and react with each other, causing the dye to become dark (Biedermann et al., 2010; Mendum et al., 2011). Exposure from this source can occur via dermal contact, in particular for cashiers handling receipts, as BPA can be transferred from the paper surface to the skin (Biedermann et al., 2010), but also for consumers. Thermal papers containing BPA were identified in different applications, such as bus tickets, airline tickets, cash receipts and papers for laboratory use (Liao and Kannan, 2011a, b). The European Thermal Paper Association states that BPA is still used in thermal paper and that in 2012 80 % of thermal paper used was point-of-sales grades, which are mainly used for supermarket and shop receipts and not for tickets for transport (bus/boarding passes) or tickets for lotteries (email from European Thermal Paper Association to EFSA from 17 June 2013).

3.1.4. Recycled paper

Recycled paper and board may contain BPA if paper products that contain BPA (e.g. thermal papers) are included in the recycling feedstock and if the is not removed during the recycling decontamination process. Thermal paper was estimated to be a major source for the contamination of recycled paper with BPA (Gehring et al., 2004). BPA is listed as an evaluated monomer permitted for use in printing inks in the Swiss Ordinance of the FDHA on articles and materials (RS 817.023.21[19]). The use of BPA as an ingredient in inks is no longer widespread, but its presence as an impurity in ink formulations cannot be excluded (email from PlasticsEurope to EFSA on 5 February 2013). Food contact papers and cartons include fast-food and snack wrappers and boxes, paper cups, paper plates and food cartons, such as pizza boxes. These may include a recycled component within the food-packaging material and so may provide a source of exposure to BPA. BPA was detected in 45 % of the take-away food cartons tested with higher levels in cardboard than in paper (Lopez-Espinosa et al., 2007). In this study all but one of the 40 samples tested contained recycled fibres. Any migration from the recycled

[19] Ordinance No 817.023.21 of 25 November 2005 on materials and articles. Swiss Federal Department of Home Affairs (FDHA), 1.4.2013, p. 1–96

paper or board into food will result in dietary exposure to BPA. BPA was also detected in toilet paper (Gehring et al., 2004) and in kitchen towels (Ozaki et al., 2006) made from recycled paper.

3.1.5. Polyvinyl chloride

PVC is the third most widely produced plastic, after polyethylene and polypropylene. PVC is produced by polymerisation of the monomer vinyl chloride. BPA has been used historically as (i) a production aid to stabilise vinyl chloride monomer; (ii) in the polymerisation of PVC plastics; and (iii) as an antioxidant in plasticisers used in PVC. According to the European Council of Vinyl Manufacturers, the use of BPA for polymerisation and as a stabiliser for storage of vinyl chloride monomer was discontinued in Europe from December 2001 (email from PlasticsEurope to EFSA on 5 February 2013). Additionally, the use of BPA as an additive for food contact plastics, including PVC, is not permitted in the EU according to Regulation (EU) No 10/2011.

PVC has a very low market share (less than 5%) in polymers used for food packaging (Howick 2007)". However, BPA may still be used in the production of PVC, e.g. for toys, and, therefore, exposure may occur by the transfer of BPA through the saliva. Also, the use of BPA as a production aid in PVC cannot be excluded, as such use as a polymer production aid is outside the scope of Regulation (EU) No 10/2011.

3.1.6. BPA methacrylate-containing resins

BPA-containing resins may be used in dental sealants. BPA is not used directly in dental materials, but BPA glycidyl methacrylate (bis-GMA) and other acrylate-based derivatives (BPA dimethacrylate) of BPA are used. Any BPA that is present as an impurity in the used methacrylate derivative or is released from the dental sealant by degradation of the polymer has the potential to contribute to oral exposure to BPA (Van Landuyt et al., 2011).

3.1.7. Polyetherimides

Polyetherimides (PEIs) are synthesised by the melt condensation of BPA bis(phthalic anhydride) with a diamine, usually *m*-phenylenediamine. PEIs find use in food contact applications, e.g. microwave cookware, in blends with PCs (FAO/WHO, 2011) as a consequence of their high heat stability. PEIs may also be used in medical applications, in electronic components and in aircraft interiors. The ether linkage of polyetherimides has good thermal and hydrolytic stability and so migration of BPA, if any, would be limited to any unreacted BPA in the dianhydride starting substance.

3.1.8. Polysulphone resins

Polysulphone resins are made by condensation of the disodium salt of BPA with 4,4-dichlorodiphenyl sulphone. They exhibit thermal stability, toughness, transparency and resistance to degradation by moisture (FAO/WHO, 2011). They are used in electrical components, appliances, transport, medical equipment, pumps, valves and pipes (FAO/WHO, 2011).

3.1.9. Polyarylates

Polyarylates are amorphous polymers that may be formed by co-polymerisation of BPA with aromatic dicarboxylic acids (mainly terephthalic and isophthalic acids). Polyarylates have excellent thermal resistance and toughness, in combination with clarity and stability to UV light, and compete with traditionally less expensive engineering plastics for applications in the automotive, electronics, aircraft and packaging industries. If used in food packaging applications, the migration of BPA from these into food or beverage provides a potential source of exposure. However, according to the FAO/WHO report, high cost, poor chemical resistance and a tendency to yellow have prevented polyarylates from gaining wider acceptance, and so exposure from these materials is not considered likely (FAO/WHO, 2011).

3.1.10. Flame retardants

BPA may be used in the production of two flame retardants, tetrabromobisphenol A (TBBPA) and BPA bis(diphenyl phosphate) (CEH, 2010). TBBPA is used to impart flame resistance to epoxy resins used in printed circuit boards, to PC, to ABS resins and, to a lesser extent, to unsaturated polyester resins and other engineering thermoplastics. TBBPA is also used as an intermediate in the production of other flame retardants, such as brominated epoxy oligomers and brominated carbonate oligomers. BPA bis(diphenyl phosphate) is used as a flame retardant in polyphenylene oxide and PC/ABS blends. The latter are not used in food contact applications and so any exposure to BPA from this source will occur through dermal contact, air or dust (see Section 3.2).

3.1.11. Other uses

The presence of BPA has also been reported in tablecloths and mittens (VKM, 2008). However, the material type (other than plastic) was not specified in the report. BPA was also detected in low amounts in cosmetics on the European market (Cacho et al., 2013). BPA is not permitted for use in cosmetics in the EU,[20] but it may migrate from packaging materials into the cosmetics or be present as an impurity in the cosmetic ingredients. Therefore, cosmetics may constitute a source of exposure through dermal contact (see Section 4.3.3).

Other uses have also been reported, such as the use of BPA in polyester resins such as bisphenol fumarates formed by reacting BPA with propylene oxide to form a glycol, which is then reacted with fumaric acid to produce a resin mainly used for its exceptional corrosion resistance in a caustic environment (e.g. AOC, 2013). Typical applications of bisphenol fumarate resins are fibre-reinforced tanks and piping. BPA may also be used as an additive in polyamide materials used mainly in electrotechnical applications (ECB, 2010).

The use of BPA as a monomer in plastic food contact materials other than PC cannot be excluded. BPA is subjected to an SML of 0.6 mg/kg food (Regulation (EU) No 10/2011).

3.2. Environmental sources

The general population can be exposed to BPA via food or via the use of non-food consumer products such as thermal paper, toys, etc. (see Section 3.1). The general population can also be exposed to BPA from environmental sources such as surface water (during swimming) and outdoor air (inhalation of aerosols). In addition, the release of BPA from epoxy-based floorings, adhesives, paints, electronic equipment and printed circuit boards is reported to be a source of contamination of indoor air (including airborne dust) and dust (Loganathan and Kannan, 2011). Environmental sources therefore can potentially contribute to oral, inhalation and dermal exposure to BPA (see Section 4.3.3).

4. Exposure assessment

4.1. Scope of the exposure assessment

The scope of the exposure assessment is to assess average and high chronic exposure to BPA through different sources and routes of exposure in the EU population, in order to inform risk assessment. For BPA, the toxicologically relevant form is unconjugated BPA. In the conjugated form (e.g. glucuronidated) BPA has no oestrogen receptor affinity and is therefore of less toxicological concern if at all (see Part II – Toxicological assessment and risk characterisation of this opinion). The fraction of an external dose of BPA that reaches the bloodstream in the unconjugated state is dependent on the route (and source) of exposure: after oral uptake first-pass metabolism takes place in the liver where BPA is rapidly and extensively conjugated before reaching the systemic circulation. For the dermal and inhalation routes, absorbed BPA directly enters the systemic circulation. Therefore, route-specific

[20] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ L 342, 22.12.2009, p. 59–209.

exposure levels have to be used in risk assessment. For the dermal route, source-specific exposure levels need to be distinguished as well, because the absorption fractions differ by source (s. below).

The route/source-specific external exposure levels were calculated by multiplying source concentrations with the corresponding use frequency (e.g. intake of amounts of food, handling conditions of thermal paper, application of amounts of cosmetics, inhalation of quantity of air), which is commonly referred to as source-to-dose modelling or forward exposure modelling (Figure 1A).

In order to evaluate the reliability of the forward-modelled exposure estimates, they were compared with urinary biomonitoring data. For this comparison, the route/source-specific external exposure is converted to internal exposure to total (unconjugated plus conjugated) BPA (i.e. the total absorbed dose) by applying route- and source specific uptake fractions (Figure 1B). For BPA absorption from oral sources and inhalation an absorption fraction of 1 was used. For BPA from thermal paper and cosmetics, source-specific absorption fractions of 0.1 and 0.5 were used, respectively (see Section 4.6.5). Since in humans all BPA that is systemically available will be eliminated via the kidneys, the internal exposure to total BPA can be compared with daily excretion rates of total BPA calculated from urinary levels of total BPA and daily urinary outputs (backward exposure modelling).

Note that the estimate of interal exposure to total BPA cannot be used directly for risk assessment, because it refers to unconjugated plus conjugated BPA and not specifically and only to the toxicologically relevant unconjugated BPA. For the use in risk assessment, these route and source-specific exposure values have to be transformed to human equivalent oral doses (HEDs), since for oral exposure the most extensive toxicological data are available. This transformation uses human-equivalent oral dose factors that are based on serum levels of unconjugated BPA and is not included in the exposure part of the opinion, but is described in Part II of this opinion entitled–Toxicological assessment and risk characterisation.

Another consequence of the route dependency in the toxicology of BPA is that it is not very practical to compare exposures via different routes. For example, external oral exposure to BPA could amount to 75 mass units/day and dermal exposure could amount to 19 mass units/day, or, in other words, oral contributes 80 % and dermal contributes 20 % to the total *external* exposure. Given the very efficient first-pass effect for BPA for the oral route, even under the condition that 100% of an oral dose is absorbed, only approximately 0.75 mass unit/day would "count" as toxicologically relevant, while for the dermal route (assuming 10 % dermal absorption) 1.9 mass unit/day would "count" as toxicologically relevant. In other words, from a toxicological perspective, dermal and oral would each count for 28 or 72 % of the toxicologically relevant (*internal*) exposure to unconjugated BPA, respectively. In contrast, when looking at urinary excretion, all 75 mass units ingested, but for the dermal route only the 1.9 mass unit that is actually absorbed, will end up in the urine. That means that for the urinary excretion of total BPA content 97.5 % (i.e 100*75/76.9 comes from oral exposure and 1 % (i.e. 100*1.9/76.9) comes from dermal exposure. Hence, a comparison of the contribution of routes to exposure to BPA is meaningful only if it is explicitly stated for which kind of exposure estimates this comparison is being made (external, internal to total BPA inclujding urinary estimates, or *internal* to the toxicologically relevant unconjugated BPA). Because of this complication, in this Part or in Part II of this opinion –Toxicological assessment and risk characterisation, the "contributions of the various routes of exposure to the total exposure" have not been calculated.

Specific scenarios were developed to cover the exposure patterns in the different age classes and vulnerable groups (infants and children and pregnant and breastfeeding women). Scenarios to assess acute exposure to BPA, BPA exposure in specific disease states or occupational exposure of workers handling BPA-containing products were not developed in this opinion.

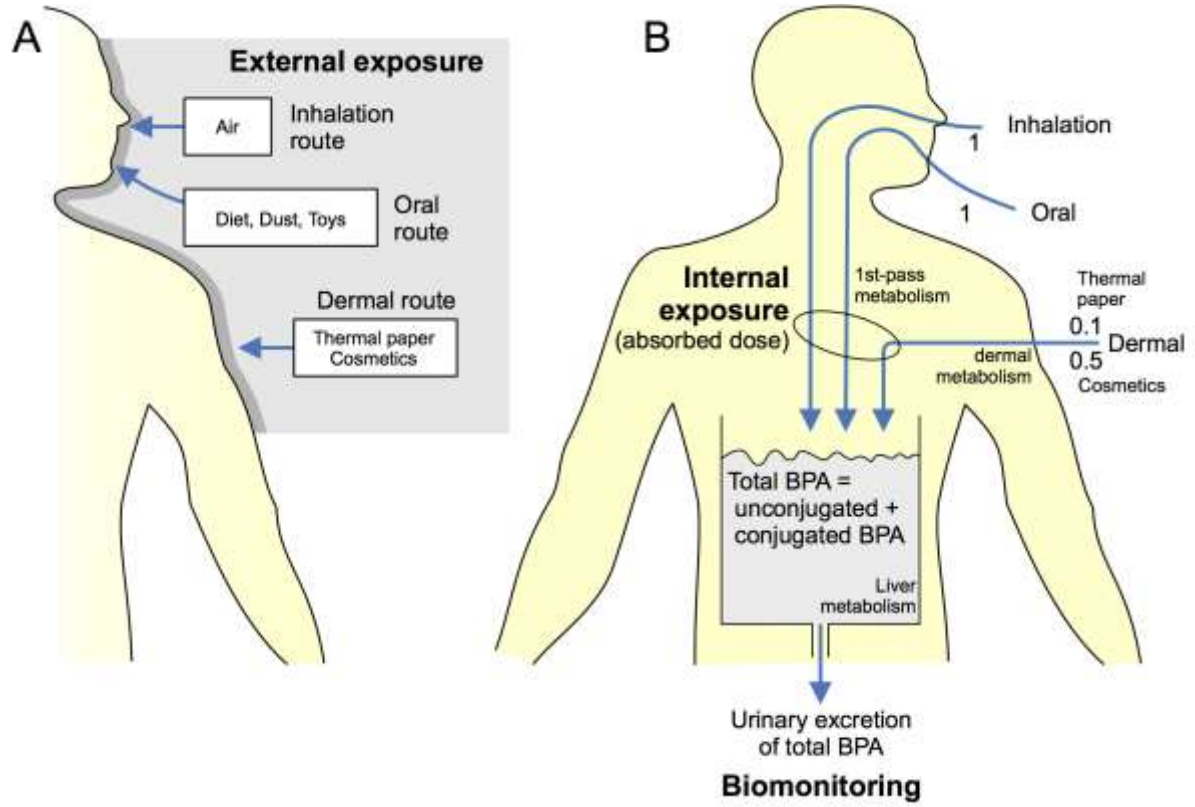


Figure 1: Difference in route-specific external exposure (A) and internal exposure to total BPA (i.e. absorbed dose) by applying route-specific and source-specific uptake fractions (B)

4.2. Methodology applied for data retrieval and for performing the exposure assessment and comparison with biomonitoring data

The methodology to perform exposure assessment and the comparison with the biomonitoring data are explained and summarised in this section. Reference is made to other sections and appendices where additional relevant information is given. For the (forward) exposure assessment/modelling, analytical/experimental BPA concentrations in food (including human milk) were combined with food consumption (including human milk) data to estimate dietary exposure. In addition, analytical/experimental BPA concentrations in non-food sources were combined with behavioural patterns (associated with the handling of these non-food sources) to estimate non-dietary exposure. For the backward exposure modelling via biomonitoring data, analytical/experimental BPA concentrations in urine were combined with urinary volumes to determine the excreted BPA levels.

4.2.1. Approaches followed to collect concentration data for use in the exposure assessment and biomonitoring comparison

Whereas EFSA has created a comprehensive European Food Consumption Database (EFSA, 2011), concentration data for BPA in food and non-food sources were not readily available. Following the terms of reference, which suggest that an exposure assessment should be carried out on the basis of the occurrence data available in the public domain and other occurrence data that may be available, EFSA has performed a literature search, as well as published a call for data on its website. The EFSA terms of reference also state that biomonitoring data should be taken into account when assessing the exposure and the results should be compared with the calculated exposure, and so EFSA has also performed a literature search to obtain biomonitoring data.

4.2.2. Literature search in bibliographic databases

A thorough literature search was the basis for retrieving scientific studies reporting occurrence data herein. This work was outsourced under Contract NP/EFSA/FIP/2012/05. The search of a number of bibliographic databases was conducted from August 2012 to November 2013 by an independent contractor, and the following databases were searched:

- ISI Web of Knowledge—Web of Science (WoS) including:
  - Web of Science (1945 to present)
  - Biological Abstracts (1969 to present)
  - MEDLINE (1950 to present)
- Elsevier Science Direct (SciVerse)
- Elsevier Scopus
- EBSCOhost—OmniFile Full Text Select (H.W. Wilson)
- SpringerLink
- Taylor & Francis online
- Wiley Interscience

A number of different electronic bibliographic databases was used for the search because (i) no single database is fully comprehensive; (ii) despite overlap in coverage of the scientific literature with different databases, different search engines potentially may perform differently; and (iii) some journals are not accessible through mainstream databases. The above choice ensured that the highest coverage for relevant articles was achieved.

Initially searches were conducted using the search term "bisphenol" and a specific year. In total there were 9 649 hits from all databases within Web of Knowledge and 13 062 hits from Science Direct in the period of the searches from January 2006 until November 2013 (see Table 1). These hits contained mainly articles dealing with toxicological studies and not occurrence data, therefore the search was refined by adding additional terms such as "food" or "migration". This led to fewer hits (see Table 1) but excluded publications such as those reporting BPA in urine and BPA in non-food materials such as banknotes and environmental samples. It was therefore found necessary for a specified time window to scan the titles of all publications containing "bisphenol" within the content of the article. The screening using "food" and "migration" as additional terms was useful as a "double check" that all publications had been found, but it was not broad enough to be used exclusively.

This search strategy was very sensitive and led to scanning a large number of titles and abstracts for relevance, but this was ultimately judged to be the most reliable way of ensuring that no relevant articles were missed. All Elsevier articles that were found in the search using Science Direct in principle should also have been found by searching Web of Science. However, the timing of entry of articles into the two databases appeared to be different, with articles being available sooner from Science Direct, often as "author's uncorrected" or "in press" articles before their appearance in Web of Science. Parallel searches by two individuals in the same time window recovered more or less the same relevant articles.

Abstracts were scrutinised on a yearly basis from 2006 until the end of 2012, and from January until November 2013 on a monthly basis, around the 10th of each month. An overview of the number of hits using "bisphenol" as a broad search term and subsequent refined searches, by restricting the search, is shown in Table 1.

Table 1: Searching statistics: searching results

	2006	2007	2008	2009	2010	2011	2012	Jan. to Nov. 2013	2006 to Nov. 2013
Web of Knowledge									
Keyword: BPA	1 010	978	1 175	1 159	1 333	1 450	1 186	1 358	9 649
Combined with "food"	57	57	75	88	102	128	106	158	771
Combined with "migration"	21	12	20	22	40	25	21	17	178
Combined with "water"	257	291	323	371	405	445	352	477	2 921
Science Direct									
Keyword: BPA	1 030	1 130	1 300	1 372	1 469	1 837	2 302	2 622	13 062
Combined with "food"	347	342	446	471	529	698	932	1 083	4 848
Combined with "migration"	105	117	140	139	174	216	288	207	1 386
Combined with "water"	801	844	1 009	1 074	1 159	1 427	1 809	2 144	10 267
Summary of number of selected studies									
Contractor—individual I	50	34	40	42	50	72	85	138	511
Contractor—individual II	53	38	42	40	54	71	87	140	525
Number of studies provided to the CEF Panels WG BPA Exposure for consideration	**48**	**32**	**38**	**40**	**50**	**69**	**80**	**136**	493

The final numbers of publications selected as containing information potentially relevant for this opinion, i.e. those that could be assigned to the eight categories given below ranged from 48 articles for the year 2006 to 136 articles for the year 2013. Online versions of articles were increasingly found to be published ahead of the cover issue date, and thus in the searches until the end of November 2013 three relevant articles were found with 2014 publication dates. For the period 2006–2013 a total of 493 peer-reviewed articles were selected as relevant by the contractor and were passed to the CEF Panel's Working Group on BPA Exposure and were assigned to the eight categories listed below:

- analytical methods for BPA in food;
- human biomonitoring of BPA;
- migration of BPA from food contact materials;
- occurrence of BPA in drinking water;
- occurrence of BPA in food contact materials;
- occurrence of BPA in food;
- occurrence of BPA in non-food materials such as indoor air, dust, thermal printed paper, dental materials and medical devices;
- occurrence of BPA in the environment.

Some articles were found to contain information covering more than one category, e.g. a publication describing an analytical method for the determination of BPA in canned foods might also contain occurrence data from a small survey and so was assigned to both relevant categories. In total, 611 publications were assigned by category and by year.

As mentioned above, all articles from the literature search were screened by two individuals, and if the title of an article appeared relevant, then the abstract was examined more closely to confirm this. Articles reporting methods of analysis for food and containing survey data for food were rather easy to identify. However, there were many method papers relating to BPA in water and environmental samples, which were exclusively analytical method related papers and did not contain any relevant survey (concentration) data. For these articles, it was frequently necessary to look at them in more depth to see whether or not the article should be considered.

As result of the screening process applying the above-described method of working, two lists of articles were produced (one by each individual). They were compared and a final list agreed between the two individuals. Differences in the number of articles selected between the two independent searches were small and these were easily reconciled by discussion between the two individuals, if necessary removing any articles that were of marginal interest. Differences were usually because the initial search had failed to remove articles that were not relevant.

In addition to the literature search carried out by the contractor, members of the CEF Panel's Working Group on BPA Exposure searched the scientific literature for additional relevant information, e.g. parameters used to estimate skin absorption and physiological data, etc.

4.2.3. Eligibility criteria for assessing publication relevance

The publications provided by the contractor to the Working Group on BPA Exposure were further assessed to confirm their relevance to the exposure and biomonitoring assessments. Only primary research studies (i.e. studies generating new data) were considered. Language, publication period, geographical origin of the samples and sample type were considered, according to the criteria defined below.

4.2.3.1. Language

The search of scientific literature databases was focused only on scientific studies with at least an abstract in English. All papers provided to the CEF Panel's Working Group BPA Exposure by the contractor were in English. However, data and non-English reports from other sources, e.g. Swedish data for toys and water pipes and French risk assessment reports, each published in the native language were considered, but not in a systematic manner/way.

4.2.3.2. Publication period

As a general rule only data published from January 2006 until December 2012 were considered. For food, data published before 2006 have already been reviewed in the 2006 EFSA assessment of the dietary exposure to BPA. The pattern of use of BPA in food packaging has changed in the meanwhile and therefore there was a need to provide an up-to-date assessment of the occurrence of BPA in food in order to estimate current dietary exposure. Although they were not considered in the EFSA opinion of 2006, the same criterion, i.e. data published from 2006 onwards, was applied to the other fields (food contact materials and non-food sources of exposure). This criterion was applied, as in more recent years there has been a lot of effort to improve the performance of analytical determinations of BPA in terms of increased sensitivity and reduced BPA contamination; therefore, more recent data should be of better quality than older data. As mentioned above, the literature search carried out by the contractor covered the period January 2006 to November 2013. However, owing to the timing of the public consultation, only papers to December 2012 were considered. Papers published after this date were considered only if they provided data in areas where no or very few data were available (e.g. data on human milk) or to complete the European dataset (e.g. biomonitoring data).

Similarly, for biomonitoring, only studies published from January 2006 until December 2012 were considered. Since 2006, substantial methodological improvements have been achieved, in terms of both sensitivity and specificity, by using mass spectrometry (MS)-based analytical techniques. Moreover, increased efforts have been implemented to preserve sample integrity and to reduce external contamination; therefore, more recent data should be of higher quality than older data. Furthermore, the more recent data will provide an up-to-date indication of the current exposure to BPA. Papers published after this date were considered only where there were gaps in the data as a consequence of only a small number of publications being available. For the biomonitoring studies this included BPA concentration data for colostrum and mature breast milk.

4.2.3.3. Geographical origin of the samples

A specific inclusion criterion for data on occurrence in food, food contact materials and non-food sources and for migration data from food contact materials reported in the scientific literature was that only samples purchased in the European region (EU and non-EU) should be included in the exposure assessment. Only for those sample classes for which no or only limited European data were available, data from products produced and sold elsewhere in the world, were included in the assessment.

A specific inclusion criterion for biomonitoring data on urinary BPA was that the studies have been performed in the European region to enable the estimation of the daily exposure to BPA for different age groups of European populations. In addition, biomonitoring data on BPA concentration in breast milk were assessed to provide information for the estimate of dietary exposure in breastfed infants. However, as only limited European data for human milk were available, data from samples from elsewhere in the world were included in the assessment. Also, in the case of biomonitoring data, for which no or only limited European data were available, data from elsewhere in the world were included.

4.2.3.4. Sample type

Data for composite samples with canned and non-canned food combined together were not included in the assessment.

For food contact materials papers describing migration data for food-packaging materials such as can coatings and paper and board were not considered, as exposure from packaged foodstuffs is included in the exposure assessment for foods themselves. Publications describing migration from food contact articles, specifically those made of PC (PC kettles, water coolers, filters and tableware), and from articles to which non-stick coatings had been applied were included in the assessment of exposure from food contact materials.

4.2.4. Methodological appraisal of the included publications

Appendix I, in which all of the publications provided by the contractor are listed, provides an assessment of their evaluation against the above criteria. Those publications that met these criteria were further scrutinised to ensure that the methods used to determine the concentration and migration data were of acceptable quality. The quality criteria applied to the analytical methods are given in Appendix A. The method characteristics and sample descriptions are summarised in Appendix I for all papers that met the criteria on language, publication date and geographical origin. A final evaluation of whether or not the data reported in the papers are included, and the associated reasoning for that (based on all criteria: publication date, origin of samples and method quality), is also given in Appendix I.

4.2.5. Grey literature and other sources of information

Beyond the thorough search of the primary scientific literature, other sources of information were also considered: reviews, journals and books recorded in electronic bibliographic databases; full-text journal articles; journal tables of content; and grey literature, e.g. conference proceedings, annual reports and poster abstracts. The former and reference lists of previous risk assessments, e.g. by

FAO/WHO 2011, ANSES 2013, and review articles were screened as cross-checking quality assurance measures to ensure that no publications were missed in the bibliographic database searches.

Data on urinary levels of total BPA in humans were also retrieved from official websites of national health surveys (e.g. NHANES (National Health and Nutrition Examination Survey), CHMS (Canadian Health Measures Survey), German Federal Environment Agency, Flemish human biomonitoring programme) and from as yet unpublished sources (e.g. European research programme, DEMOCOPHES (Demonstration of a study to Coordinate and Perform Human Biomonitoring on a European Scale). The methodological quality of these data are assessed and described in the main text.

4.2.6. The EFSA call for data

In July 2012, Member States, research institutions, academia, food business operators (e.g. food-packaging manufacturers and food industries) and other stakeholders were invited by EFSA to submit analytical data on (i) the occurrence of BPA in food and beverages intended for human consumption; (ii) BPA migration from food contact materials; and (iii) BPA occurrence in food contact materials. Details on the eligibility and inclusion of data received from the call for data are given in Appendix B.

4.2.7. Handling of left-censored data

Left-censored data, i.e. samples with concentrations below the LOD or LOQ were handled as recommended in "Principles and Methods for the Risk Assessment of Chemicals in Food" (WHO, 2009) and in the EFSA scientific report "Management of left-censored data in dietary exposure assessment of chemical substances" (EFSA, 2010) through the substitution method. The lower bound (LB) was obtained by assigning a value of zero to all the samples reported as less than the left-censoring limit, the middle bound (MB) by assigning half of the left-censoring limit and the upper bound (UB) by assigning the left-censored limit as the sample result.

Handling of left-censored biomonitoring data is extensively discussed in Section 4.6.2.

4.2.8. Calculation of exposure

4.2.8.1. Dietary exposure to BPA

Dietary exposure to BPA in infants aged less than six months has been assessed by means of a model diet based on a standard level of consumption combined with BPA concentration in human milk or infant formula. Average and high BPA concentration values have been used to assess average and high chronic dietary exposure. Dietary exposure in 12-month-old toddlers to the elderly has been estimated using individual consumption data from the EFSA Comprehensive European Food Consumption Database combined with available concentration data derived from the scientific literature or from the EFSA call for data. Two scenarios were considered: 1) Only foods specifically codified as canned in the dietary survey are assigned the corresponding occurrence level for BPA and 2) At FoodEx level 4, any food which has been codified as canned in at least one survey is always considered to be consumed as canned in all dietary surveys included in the Comprehensive Database. Chronic exposure was estimated by multiplying the average BPA concentration for different food groups and type of packaging (canned or non-canned) with their respective consumption amount per kilogram body weight separately for each individual in the database, calculating the sum of exposure for each survey day for the individual and then deriving the daily average for the survey period. Average and 95th percentile exposure was calculated for the total survey population separately for each survey and age class.

Data for migration into food simulants reported in the literature and from the EFSA call were indirectly used to estimate the concentration of BPA in the products consumed after being in contact with PC food contact materials (namely water coolers, tableware, kettles, filters) and non-stick-lined cookware. Estimates were made taking into consideration the relationship between testing conditions reported in the studies and real contact conditions of time and temperature in the BPA concentration. Further details on this are provided in Section 4.3.1.

4.2.8.2. Non-dietary exposure to BPA

For the calculation of exposure to BPA via non-food sources, occurrence data or - if available - data on BPA transfer into human body fluids or tissue were combined with data on the use of certain sources. An average and a high scenario were calculated for all sources. For the average scenario, an attempt was made to choose average values for all parameters, including parameters describing frequency of use. For the high scenario, the same average parameters were used for absorption rates and occurrence data, but in line with the methodology used to assess exposure from food, the frequency of use parameters were modified to account approximately for a 95th percentile of the population. If not mentioned otherwise, the arithmetic mean was used for each parameter, but in some cases only medians and percentiles were available. In order to follow a similar approach to that of exposure from food, behavioural parameters were derived considering both users and non-users in the general population. For calculations for specific population groups (e.g. users of pacifiers with PC shields), behavioural data were taken only from the group of users.

Non-dietary exposure estimates were given per kilogram body weight. For the different age groups, different default body weights were used. For infants the default body weight of 5 kg for one- to three-month-old infants was used (EFSA Scientific Committee, 2012). For toddlers the default body weight of 12 kg for 1–3 years old children was used (EFSA Scientific Committee, 2012). For children and adolescents default values of 30 kg for nine-year-old children and of 44 kg for 15-year-old adolescents were used (van Engelen and Prud'homme de Lodder, 2007). For adults, the default body weight of 70 kg was used (EFSA Scientific Committee, 2012).

4.2.8.3. Biomonitoring data

For biomonitoring, estimation of BPA exposure for the different age classes was based on urinary concentration of total BPA (obtained from European studies), the urinary output rate and body weight. Estimates of the average and high daily BPA exposure were calculated from the geometric means and 95th percentiles of the urinary BPA concentrations. Depending on whether body weight was available from the studies, either study-specific individual or mean values, or generic values from the literature, were used. Literature data were also used for the urinary output rate, except for cases in which study-specific individual urinary volumes from 24-hour urine sampling were available.

4.3. Occurrence data

4.3.1. Data on occurrence in and migration from food contact materials into food simulants

Values for BPA occurrence in different food contact materials and for BPA migration into food simulants reported in the scientific literature and obtained through the EFSA call for data were screened. From the scientific literature only studies focusing on samples collected in Europe were considered. The quality of data from both sources was assessed according to criteria defined in Appendix A. Details on the quality of data received through the EFSA call for data are given in Appendix B. The outcome of the assessment of the scientific literature is reported in Tables 63 to 70 in Appendix I.

4.3.1.1. Occurrence data in food contact materials

Germany submitted BPA occurrence data through the EFSA call for data for different kinds of food contact materials (plastic, paper and board, others, aluminium, glass). In all, 545 results were reported from 2001 to 2012, the large majority (98 %) originating from accredited laboratories. The packaging samples, classified according to EFSA's standard sample description system and taking into account the information provided in the data element "Packaging" and "Product comment", were: paper and board (39.1 %); plastic (38.2 %); plastic/plastic film and combined paper and film packaging (2.8 %); tinplate aluminium (2.2 %); glass (0.2 %); no information; and not packed (loose; open) (17.5 %). In the standard sample description system it was not always possible to give detailed information, so for glass it is most likely that the twist-off lid of a glass jar was analysed and in the case of tinplate aluminium the coating was most probably analysed.

The majority of the studies published in the scientific literature involved the determination of the residual level of the BPA monomer in PC plastics and in particular in baby bottles (Ehlert et al., 2008; Mercea, 2009; Alin and Hakkarainen, 2012). Values of residual BPA in PC containers, water coolers with PC reservoirs, bottles, baby bottles, trays, etc. reported in the literature ranged from 400 to 70 000 µg/kg. Values specific for PC baby bottles averaged 9 422 µg/kg with a maximum of 35 300 µg/kg. Average values for other PC bottles and water coolers with PC reservoirs were 10 224 and 18 763 µg/kg, respectively.

BPA content in cookware coatings was detected in 7 out of 26 samples, with values ranging from 0.5 to 18 µg/dm^2, with an average value of 3.2 µg/dm^2 (derived from the concentration in the coating of 10 224 µg/kg for an average coating weight of 313 mg/dm2) (Bradley et al., 2007).

BPA content in a small number of recycled paper and board food contact samples was reported (Bradley et al., 2008a; Pérez-Palacios et al., 2012). The following average values were found: paper cloth—25 400 µg/kg; paperboard box—7 390 µg/kg; paper bag—500 µg/kg; and kitchen paper—330 µg/kg (Pérez-Palacios et al., 2012). Lopez-Espinosa et al. (2007) investigated the BPA content in 40 paper and paperboard containers used for take-away food. BPA was detected in 47 % of the samples, and concentrations ranged from 0.05 to 1 817 µg/kg in paperboard products and from 0.08 to 188 µg/kg in paper products. All but one of the 40 samples tested contained recycled fibres.
Residual BPA was detected in metal closure coatings (epoxy phenolic basecoat plus organosol topcoat) in the range 2–16 µg/dm^2 (Oldring et al., 2013). The authors reported a ratio of surface area to food weight for metal closures ranging from 0.2 to 2.2 dm^2/kg. If a complete migration of residual BPA is assumed, an average migration value of 12.5 µg/kg would be obtained. These estimates were not used in the present exposure assessment because more adequate occurrence data in food were available.

4.3.1.2. Migration data from food contact materials

European Economic Area (EEA) countries and Switzerland submitted BPA migration data through the EFSA call for data from different kinds of materials: 988 results were reported from 2004 to 2012, the large majority (93 %) originating from accredited laboratories.

The packaging samples analysed and classified according to EFSA's standard sample description system were: PC 82.8 %; polypropylene 3.9 %; aluminium foil/aluminium sheet 2.4 %; packed (no additional information provided) 2.2 %; metal 2.1 %; plastic/plastic film 1.4 %; combined aluminium and film packaging 1 %; tinplate and varnished/partly varnished 1 %; polyamide 0.8 %; combined material 0.4 %; and polyethylene terephthalate (PET) (one sample). No information was sent for 1.8 % of the samples including the variables "no information" and "not packed (loose; open)".

Polycarbonate (PC) and other plastics used in baby bottles

BPA can migrate from PC into foods by diffusion of residual BPA present in the polymer after the manufacturing process as well as by hydrolysis of ester bonds of the polymer, a reaction that is catalysed by hydroxide when the polymer is in contact with aqueous food and simulants (Mountfort et al., 1997; Hoekstra and Simoneau, 2013). Some studies indicate that diffusion-controlled migration of the residual monomer makes a minor contribution to the release of BPA from polycarbonate articles, and that hydrolysis of the polycarbonate polymer chains at the interface with the aqueous media is the main release process (Biedermann-Brem et al., 2008; Biedermann-Brem and Grob, 2009; Mercea, 2009). In fact, BPA migration from PC plastics into aqueous media was found to be essentially independent of the residual concentration (Mercea, 2009), indicating that transfer mechanisms other than diffusion take place. The migration experiments with food simulants used the conditions foreseen in the applicable European legislation (Council Directive 82/711/EEC) at that time[21].

Numerous studies have investigated factors influencing BPA migration from PC plastics. These include the effect of temperature, time and repeated use (De Coensel et al., 2009; Kubwabo et al., 2009; Mercea, 2009). The effect of the pH of the water is important for the release of BPA under boiling conditions: heating evaporates carbon dioxide from (hard) tap water, which increases the pH up to around 9 and strongly accelerates the release of BPA – which is the reason why simulation with distilled water may severely underestimate the migration (Biedermann-Brem and Grob, 2009). The effect of PC ageing was investigated by Le et al., 2008, Kubwabo et al., 2009 and Mercea, 2009. Although temperature has a major impact on BPA migration no significant difference in migration was noted between heating in a water bath and by microwave (Ehlert et al., 2008). Hoekstra and Simoneau (2013) have reviewed the studies on the release of BPA from PC.

In the majority of the reported BPA migration studies PC plastics, particularly baby bottles were involved. Results from Simoneau et al. (2011) showed BPA < LOD (0.1 µg/kg) in 32 out of 40 PC baby bottles analysed in the European market when tested with 50 % ethanol for two hours at 70 °C after boiling for five minutes. The highest migration value was 1.83 µg/kg and most of the bottles did not release detectable levels of BPA in the second or third migration test carried out with this simulant. Samples of *PC baby bottles* (72) from 12 different brands collected in the Spanish market were tested for BPA migration into 50 % ethanol and 3 % acetic acid, for two hours at 70 °C followed by 24 hours at 40 °C. Results were below the LOD (5 µg/kg) in the third migration test in most cases. The highest value found in the third migration test was 18 µg/kg into 3 % acetic acid, migrating from one of the bottles tested (Santillana et al., 2011).

Further studies show evidence of increased BPA migration into water due to the effect of residual alkaline detergent remaining on the surface of the baby bottle after dishwashing (Biedermann-Brem et al., 2008; Maragou et al., 2008; Biedermann-Brem and Grob, 2009; Maia et al., 2009). Results highlighted the importance of good practices of rinsing and drying *PC baby bottles*.

Kubwabo et al. (2009) carried out a study on the migration from PC and other plastic baby bottles, PC reusable drinking bottles and baby bottle liners. Twenty-four baby bottles (polyethersulphone (PES), polypropylene (PP), PC), 10 baby bottle liners (high-density polyethylene (HDPE), low-density polyethylene (LDPE), vinyl acetate, "BPA-free"), five new re-usable PC bottles and five old bottles (six months to 10 years) were tested for BPA migration into water. A range of migration test conditions were investigated. After 10 days at 40 °C migration of BPA from *PC baby bottles* reached a concentration of 1.88 µg/kg into water and 2.39 µg/kg into 50 % ethanol.

Significant differences between BPA migration from new and used PC drinking bottles of 0.01 and 0.2 µg/kg, respectively, were found (Kubwabo et al., 2009). However, different results were reported by Le et al. (2008) that indicated that at room temperature the migration of BPA is independent of whether or not the PC bottle has been previously used. After seven days of contact at room temperature, the migration values from new (1.0 µg/kg) and used (one to nine years) PC bottles (0.7 µg/kg) were not significantly different.

Migration of BPA from 31 *PC baby bottles* into aqueous food simulants was studied under realistic repetitive use (effect of cleaning in a dishwasher or with a brush, sterilisation with boiling water and the temperature). Brushing did not seem to have an impact, whereas temperature was found to be the crucial factor, in line with the findings of other studies. All samples released BPA in the concentration range of 2.4–14.3 µg/kg when filled with boiled water and left at ambient temperature for 45 minutes. Normal repeated use was simulated over 12 cycles, and migration values showed a decrease of BPA release in the sterilisation water and in the food simulant (Maragou et al., 2008).

A survey on potential migrants, including BPA, from non-PC baby bottles was performed by Simoneau et al. (2012). BPA was not detected in baby bottles made of PP, PES or silicone but was detected in some samples of two models of polyamide baby bottles of one single brand found in Switzerland and the Netherlands. Levels ranged from 1 to 329 µg/kg, with an average value of all data (including non-detects) of 25 µg/kg in the third migration test. In the first migration test a high

migration value of 1 005 µg/kg was found for one bottle. A follow-up investigation indicated an incidental illegal presence of BPA.This indicates a sporadic finding. The follow-up given by local authorities and industry professional associations established that the incident was limited and under control (email from PlasticsEurope and World Association of the Manufacturers of Bottles and Teats to the European Commission from 30 May 2013, provided to EFSA on 31 May 2013).

Potential exposure was calculated based on a hypothetical consumption frequency of six times per day for three months (90 days) from bottles found to contain initial detectable BPA. Data showed that migration decreased by 80 % from the first to the third migration. A linear decrease was assumed, which meant falling below the LOD (0.1 µg/kg) between the third and the sixth use (i.e. day 1). The simulation was based on the experimental value from migration into 50 % ethanol as simulant It led to an average estimate of 0.45 µg/kg food and the 95th percentile was 1.24 µg/kg (MB).

Coatings, caps, closures and other

Migration values from cooking ware coatings were found to be lower than 6 µg/kg after the third reuse with olive oil at 175 °C for 30 minutes and with a tendency to decline in sequential contact periods (Bradley et al., 2007).

The migration of BPA into food simulants from 11 common food-packaging materials was assessed by Fasano et al. (2012). The packages comprised cans intended for tuna (both packed in brine or oil) and caps for marmalade jars, all coated with epoxy resins, as well as several plastic packages/materials such as HDPE yogurt packaging, polystyrene (PS) dish, teat, bread bag, LDPE film, PC baby bottle, aseptic plastic laminated paperboard carton and two plastic wine tops.

The results for BPA migration from food-packaging materials retrieved from the literature are summarised in Table 2.

Table 2: BPA migration into food simulants

Food contact material	Average migration (µg/L)			Max.	Non-detects/n	Reference
	LB	MB	UB			
Can epoxy	1.26	1.26	1.27	16.00	8/23	Viñas et al., 2010; Cooper et al., 2011; Fasano et al., 2012
Can polyester	0.00	0.03	0.05	0.05	4/4	Cooper et al., 2011
Cookware coating	0.60	0.68	0.76	5.80	21/26	Bradley et al., 2007 [(a)]
Copolyester bottle	0.00	0.04	0.09	0.09	10/10	Cooper et al., 2011; Simoneau et al., 2012
HDPE cup	0.00	0.02	0.03	0.03	3/3	Fasano et al., 2012
LDPE film	0.09	0.10	0.11	0.19	3/6	Fasano et al., 2012
PA baby bottle [(b)]	25	25	25	329	8/28	Simoneau et al., 2012
PC baby bottle	0.70	0.91	1.20	14.3	461/588	Biedermann-Brem et al., 2008; Cao and Corriveau, 2008a [(a)]; Cao et al., 2008; Ehlert et al., 2008; Maragou et al., 2008 [(a)]; De Coensel et al., 2009 [(a)]; Kubwabo et al., 2009; Santillana et al., 2011 [(a)]; Simoneau et al., 2011 [(a),(b)]; Fasano et al., 2012 [(a)]
PC bottle	0.92	0.92	0.92	7.67	4/44	Cao and Corriveau, 2008a [(a)]; Cao et al., 2008; Le et al., 2008 [(a)] Kubwabo et al., 2009 [(a)]; Cooper et al., 2011 [(a)]

Food contact material	Average migration (µg/L)			Max.	Non-detects/n	Reference
	LB	MB	UB			
PC container	2.64	2.64	2.64	2.64	0/10	Guart et al., 2011 (a)
PC tableware	0.95	0.95	0.95	1.27	0/4	Oca et al., 2013 (a)
PE/board	0.00	0.02	0.03	0.03	3/3	Fasano et al., 2012
PS cup	0.00	0.02	0.03	0.03	3/3	Fasano et al., 2012
Silicone teat	0.00	0.02	0.03	0.03	3/3	Fasano et al., 2012
PP baby bottle	0.00	0.05	0.10	0.10	149/149	Simoneau et al., 2012
PES baby bottle	0.00	0.05	0.10	0.10	30/30	Simoneau et al., 2012
Silicone baby bottle	0.00	0.05	0.10	0.10	5/5	Simoneau et al., 2012

LB, average (lower bound) BPA concentration (assigning the value 0 when LOD or LOQ is reported); Max., maximum value reported (assigning LOD or LOQ when LOD or LOQ is reported); MB, average (middle bound) BPA concentration (assigning the value for LOD/2 or LOQ/2 when LOD or LOQ is reported); n, total number of samples; UB, average (upper bound) BPA concentration (assigning the value for LOD or LOQ when LOD or LOQ is reported); HDPE, high-density polyethylene; LDPE, low-density polyethylene; PA, polyamide, PC, polycarbonate; PE, polyethylene; PS, polystyrene; PP, polypropylene; PES, polyethersulphone.
(a): Studies used to retrieve data to estimate exposure in Section 4.5.2.
(b): Migration values in PA bottles refer to a contamination during production.

The values for migration of BPA from food packaging materials into food simulants retrieved from the literature and from the call for data were not used in the exposure assessment of the general population. Instead, occurrence values in foods, presented in the following section, were used for the general population. However, selected data on migration into simulants from published studies were used to assess the exposure of specific groups of consumers: those consuming water from water coolers with PC reservoirs and users of PC tableware, PC water kettles, PC filters and cookware. Those studies from which data were retrieved are marked in Table 2.

Water coolers

Consumers might be loyal to the type of water they consume, and will either consume bottled water or tap water (either as such or filtered). *Water from water coolers* with PC reservoirs would mainly be consumed away from home (usually at working places), and also in this case consumers might be loyal consumers.

To determine a BPA concentration for the estimation of exposure from water coolers with PC reservoirs, data were retrieved from published literature and were combined with data provided to EFSA by PlasticsEurope (email from PlasticsEurope to EFSA on 29 November 2012).

The data from the literature were from migration experiments conducted at moderate temperature (typically 20–40 °C) from all PC products into water for all migration times. Concentration data in 10 samples of water stored in water coolers with PC reservoirs were available from the literature in Spain (Guart et al., 2011). BPA concentrations ranged from 1.6 µg/kg to 4.44 µg/kg. The average BPA concentration was 2.64 µg/kg.

Data from PlasticsEurope (email from PlasticsEurope on 29 November 2012) on migration of BPA from 41 samples of water coolers with PC reservoirs (both new and used), collected for different periods of use at temperatures from 5 to 36 °C were also provided through the EFSA call for data. These data were also subjected to the quality screening protocol applied to all data. The contact conditions (temperature and time) used in the study were considered to reflect the most common, variable real use contact conditions. BPA concentrations ranged from 0.001 µg/kg to 4.05 µg/kg. Average BPA concentration was 0.50 µg/kg.

When all data for water coolers with PC reservoirs were pooled (from the literature and the call), the average BPA concentration of 0.81 µg/L was derived (see Table 3) and this value was used to estimate the exposure of this specific group of consumers.

The concentration values in water stored in water coolers with PC reservoirs in China (Chen et al. 2011) and in most samples in Canada (Cao et al., 2008) were in the same range as in the European samples. However, the water in two PC carboys in Canada had BPA concentrations of 6.5 µg/kg and 8.8 µg/kg. The authors suggest that the carboys had been exposed to high temperatures for extended periods of time during storage or transport.

Several earlier opinions have not considered a specific BPA value for water stored in water coolers with PC reservoirs (EFSA, 2006a; FAO/WHO, 2011). In the ANSES report (2013) water from water coolers with PC reservoirs was found to have an average concentration of 1 µg/L and a 95th percentile of 4 µg/L.

Water kettles, tableware, water filters

Migration data into water from PC products, tested at temperatures in the range of 70 to 100 °C for 24 hours, and data obtained from the scientific literature were considered to derive a migration value associated with the use of *PC kettles*. A PC kettle is typically used to warm/boil water to prepare hot beverages such as tea and coffee, foods such as soups and other dehydrated products such as infant formula. The average migration value for the 24-hour contact time derived from the literature (2.55 µg/L) was divided by 24 to reflect the migration occurring during a cycle of one hour of contact during which the water is boiled and allowed to cool and fresh water may be added to the water remaining in the kettle and a new boiling cycle started. This is considered typical behaviour of a user of such kettles. An average value of 0.11 µg/L was derived (see Table 3). However, these assumptions may not apply to situations where the same water is repeatedly heated in the kettle, as it would underestimate the migration value.

For *PC tableware*, migration data from the literature for all PC products, into water, 3 % acetic acid and 50 % ethanol, obtained under testing conditions of two hours at 70 °C, were considered. These data were combined with data from the EFSA call for data obtained under the same testing conditions. The average values ranged from 0.18 µg/L (LB) to 1.31 µg/L (UB). The average values from the two-hour contact time were divided by eight to reflect a single use of approximately 15 minutes use (5 minutes of heating in a microwave + 10 minutes of additional contact during consumption). Average migration values of 0.02 µg/L (LB), 0.09 µg/L (MB) and 0.16 µg/L (UB) were derived from experiments using any simulants (see Table 3).

PC filters are most likely used for shorter periods of contact time, compared with water coolers with PC reservoirs. The migration was estimated considering the same data as for water coolers with PC reservoirs but only for periods of time up to 24 hours. It is reasonable to assume that this condition of contact (one hour at room temperature) also covers the potential migration for longer periods of contact at the refrigerator temperature. An average value of 0.96 µg/L was derived from the data and divided by 24 to simulate a maximum one hour of contact time for this application, assuming a constant BPA transfer rate. An average value of 0.04 µg/L was used to estimate exposure.

For cooking ware coatings, an average value of 0.29 µg/kg (MB) was derived to be used in estimating exposure (see Table 3), taking into consideration the decrease in migration observed after the third reuse with olive oil at 175 °C for 30 minutes (Bradley et al., 2007) and extrapolating it over a set of 100 uses.

Table 3: Estimated migration values for specific PC food contact materials used in the exposure assessment

Food contact material	Average BPA migration (µg/L)			Max.	Non-detects/n
	LB	MB [(a)]	UB		
Water cooler with PC reservoirs	0.81	0.81	0.81	4.10	4/100
PC tableware	0.02	0.09	0.16	0.63	217/232
PC kettle	0.11	0.11	0.11	0.32	0/6
PC filter	0.04	0.04	0.04	0.17	2/17
Cookware	0.20	0.29	0.39	7.60	21/26

LB, average (lower bound) BPA concentration (assigning the value 0 when LOD or LOQ is reported); Max., maximum value reported (assigning LOD or LOQ when LOD or LOQ is reported); MB, average (middle bound) BPA concentration (assigning the value for LOD/2 or LOQ/2 when LOD or LOQ is reported); n, total number of samples both from literature and the EFSA call for data; UB, average (upper bound) BPA concentration (assigning the value for LOD or LOQ when LOD or LOQ is reported(a): MB values were used for exposure estimate.

4.3.2. Occurrence data in food

Data on the occurrence of BPA in food were retrieved from both scientific journals and provided through the EFSA call for data.

Governmental institutions, academia, food manufacturers and one association (Fédération romande des consommateurs (FRC) submitted in total 2 076 results for BPA occurrence in food and beverages to EFSA. These data were obtained from samples collected in the EEA countries (EU, plus Iceland, Liechtenstein, Norway and Switzerland).

The majority of data were provided by France from a total diet study (EAT2). Roughly 20 000 samples prepared as consumed were combined to pools of 15 foods of similar type, resulting in 1 464 samples analysed for BPA. They referred mainly to non-canned products, in particular "Drinking water" (396 samples)", "Meat and meat products" (172 samples" and "Milk and dairy products" (139 samples). France reported BPA results for only 36 samples of canned foods or beverages. Most of the data (95 %) originated from accredited laboratories and 5 % of results were submitted from non-accredited laboratories. Some data were obtained by methods not complying with the quality criteria for analytical methods (see Appendix A) and therefore the number of data considered was 1 943. A comprehensive description of data from the EFSA call for data can be found in Appendix B.

One hundred and twenty-three scientific papers reported occurrence data in food and beverages and were eligible according to the criteria listed in Section 4.2 (publication period, language, geographical distribution). These papers are listed in Tables 63 and 64 of Appendix I. The analytical methods reported in the papers were scrutinised according to the quality criteria established in Appendix A. The outcome of this process is also documented in Tables 62 and 63. Concentration data were extracted from only those papers (n = 72) that matched the eligibility criteria and were found to be produced by sufficiently suitable analytical methods. In total, 573 data for occurrence in food and beverages were retrieved from the scientific literature.

A specific, automated process was applied to check and remove double entries of datasets, from the call and from the literature. This was ensured by comparing 38 fields for each dataset. Data from the literature and from the call for data did not show major differences in BPA concentrations and so have been merged to provide one BPA concentration for each food category.

A total of 2 516 analytical results on BPA in food and beverages from the two sources were then inserted in a database. All samples included in the final dataset were considered sufficiently robust and were treated equally; no weighting was used based on the accuracy of the analytical results.

Most of the information included in the combined dataset referred to foods and beverages sampled in 2008 and 2012 (Figure 2). Analytical results from a small number of food and beverages sampled in 2004 and 2005 (n = 11) and received through the call for data were also included in the database, as these results would have been published anyway after 2006 and therefore are in line with the restriction used for the literature search, where this year was used as a threshold.

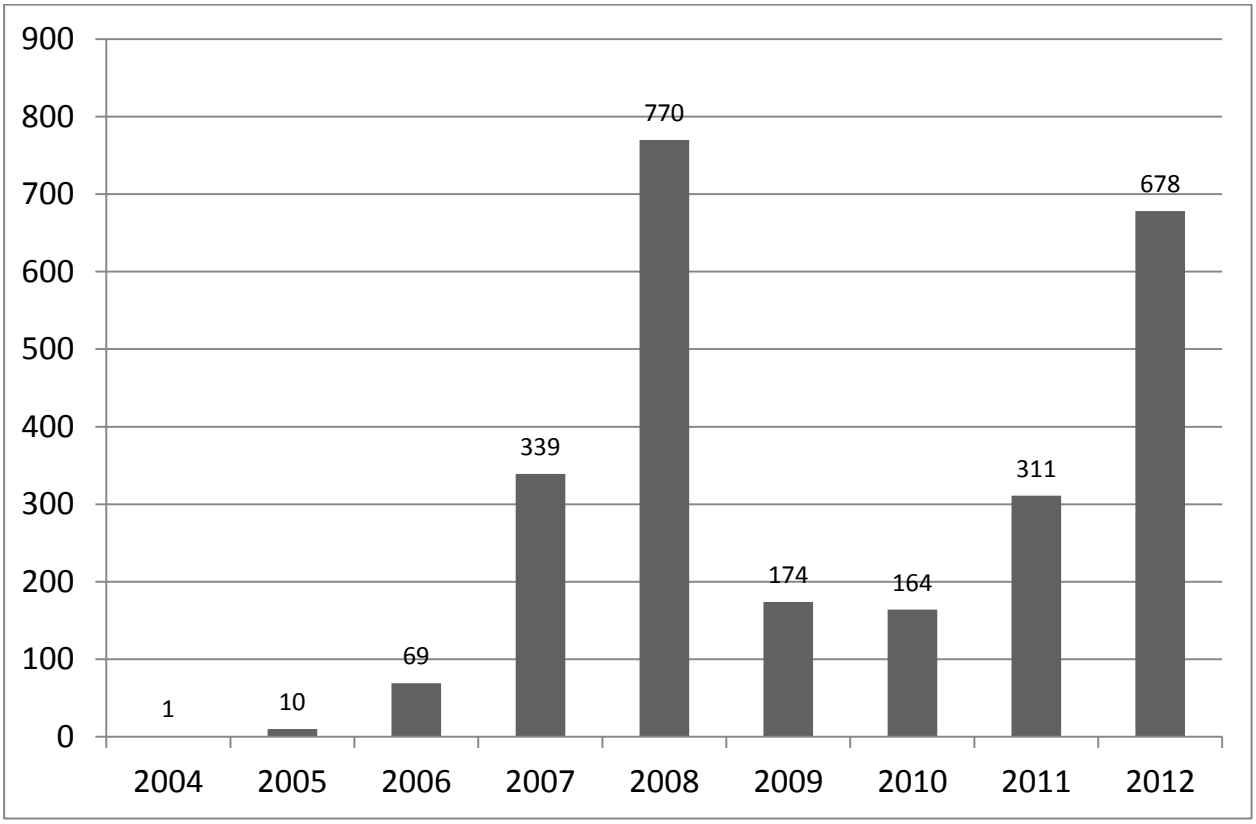


Figure 2: Total number of BPA samples from the scientific literature and the EFSA call for data per sampling year

France provided by far the majority of the data on non-canned foods and beverages. The distribution of canned samples by country was more homogeneous, with Germany and Portugal being the main contributors (Figure 3).

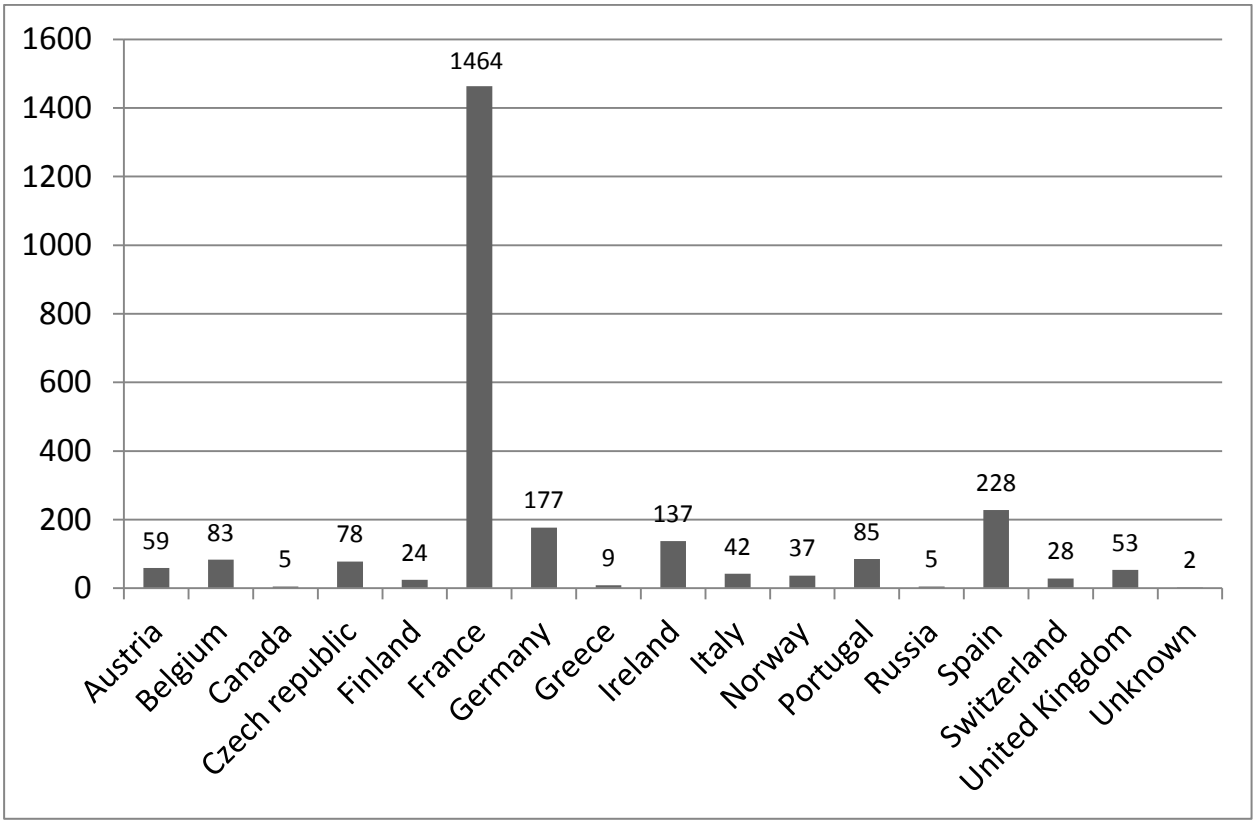


Figure 3: Total number of BPA samples from the scientific literature and the EFSA call for data per sampling country

A specific inclusion criterion for data on occurrence in food reported in the scientific literature is that only foods purchased in the European region (EU and non-EU) would be included in the exposure assessment. The reason for this is that data on BPA occurrence in food are collected in order to assess dietary exposure to BPA in Europe. Data from a market basket survey recently conducted in Sweden (Gyllenhammar et al., 2012) were not considered in the exposure assessment, as analytical determinations were performed on composite samples of non-canned and some canned products. These values could therefore not be assigned to either canned or non-canned products, and the proportion of canned/non-canned products in each category could not be considered representative of other European countries. They have, however, been used for the comparison of BPA levels between the market baskets and the occurrence data used in this opinion. The same applies to 99 pooled samples, including canned and not canned foods, from the French total diet study. Furthermore, non-European data are summarised in relation to the descriptions of the food categories (Appendix C, Food categories). These data have been used for comparison with European data as a check on the BPA concentration levels.

Most of the information on the occurrence of BPA in food and beverages was available at the level of individual samples, both from the literature and from the EFSA call for data. In the case of aggregated results, average results have been weighted for the number of samples in order to calculate the overall average for the food category. When only a median value was available for aggregated results, it was considered as a proxy for the average.

Where available, the information on the type of packaging (not packaged, canned, glass jar with metal lid, etc.) was reported and codified. When this information was not available, but assumptions could be made that the food was most probably non-canned (e.g. pizza, coffee), it was assigned to the non-canned food category. Otherwise, the information was not used in the calculation.

Analytical data were grouped according to the type of packaging and food category, with the use of EFSA's food classification and description system, FoodEx. The assumption is that a large portion of the variability observed in BPA concentration between samples of the same food category is related to the packaging. Thus, in the study by Grumetto et al. (2008) on peeled tomatoes, no BPA could be detected in products packaged in glass, whereas BPA could be detected in more than half of canned products. Analytical data were grouped by food category, as it was observed that the BPA concentration in food with the same type of packaging could vary according to the type of food, i.e. lower BPA concentrations were observed in canned beverages than in solid foods (Geens et al., 2012a). The present opinion presents BPA concentration results for more specific food categories than the earlier EFSA opinion on BPA (EFSA, 2006a), and the FAO/WHO opinion (2011). In particular, a BPA concentration value was estimated for all food categories. This approach differs from some earlier opinions in which, for instance, non-canned foods were not considered.

Despite the limited number of samples, especially for some of the food categories, consistent differences in BPA concentration between canned and non-canned food were observed in the large majority of food categories, with higher BPA concentrations in the canned food. However, noteworthy differences in BPA levels can also be observed within the canned and the non-canned food categories, as illustrated in Table 4 (see column "All—Average BPA"). Seven out of 17 canned food categories present have an average (MB) BPA concentration above 30 µg/kg ("Grain and grain-based products", "Legumes, nuts and oilseeds", "Meat and meat products", "Fish and other seafood", "Herbs, spices and condiments", "Composite food" and "Snacks, desserts, and other foods"). Four of the canned food categories have average BPA concentrations (MB) between 2.7 and 23.5 µg/kg ("Vegetables and vegetable products", "Fruit and fruit products", "Fruit and vegetable juices" and "Milk and dairy products"), while the remaining six categories have average BPA concentrations (MB) below 1.2 µg/kg. These differences are probably related to the heating after packaging (the main migration occurs during this heating process). Beverages are seldom heated, acidic product merely pasteurized, whereas other foods are sterilized. Still other cans are not coated with epoxies.

Among the 19 non-canned food categories, the highest levels of BPA were found in the categories "Meat and meat products" and "Fish and other seafood" with average BPA concentrations (MB) of 9.4 and 7.4 µg/kg, respectively (Table 4, column "All—average BPA"). The relatively high levels of BPA in food of animal origin are mainly based on data from France owing to the very large number of samples of non-canned products received from this country. The CEF Panel considers that the French results for BPA in food of animal origin (unconjugated BPA) are corroborated by the positive results for a limited number of samples from Ireland (in "Pork (grilled)", "Chicken (oven roasted)" and "Offal, kidney (dry fried") and Spain (in "Mussels"). These results are similar to those reported by ANSES in their most recent study of BPA concentrations in food, in which the Agency measured both total and unconjugated BPA (the former being measured after enzymatic hydrolysis of the sample). ANSES reported average concentrations of unconjugated BPA in fish and meat ranging between 10 and 15 µg/kg, the levels of total and unconjugated BPA in foods of animal origin being virtually the same (ANSES, 2013). The correspondence between the EFSA data and those reported by ANSES probably reflects the high preponderance of French data on non-canned food in the EFSA database.

Any BPA to which food production animals are exposed is likely to be present in their tissues as glucuronated BPA, as a result of metabolism primarily to glucuronated (conjugated) BPA (see the section on Toxicokinetics, Part II of this opinion – Toxicological assessment and risk characterisation, of this opinion). Measurement of unconjugated BPA in food of animal origin (in particular meat and fish) might indicate that deconjugation may have occurred owing to the action of glucuronidases during processing of the sample. Another potential source of unconjugated BPA in meat products is its migration from any food contact materials or from articles used in the processing of the product. The fact that elevated levels of unconjugated BPA were observed in meat and fish, but not to the same extent in eggs or milk, gives more support to the possibility that BPA is due to contamination. ANSES also considered that the detection of unconjugated BPA in the samples could be due to contamination (ANSES, 2013). With the exception of the data submitted by France through the EFSA call for data, none of the methods, published in the scientific literature or obtained through the EFSA call, described

deconjugation steps, and so it was assumed that the BPA concentrations reported were for unconjugated BPA only. Therefore, the data on total BPA reported by France were merged with the other data from the EFSA call for data.

For the remaining 17 non-canned food categories, the average BPA concentrations (MB) were all equal to or below 1.2 µg/kg, with the exception of "Composite foods", which includes fish- and meat-based products and had a BPA average equal to 2.4 µg/kg.

When comparing European with non-European concentration data, average BPA levels of concentration resulted mostly in the same range as the samples from Europe. However, there were single non-European foods that were reported to have higher BPA concentrations than those found in Europe. For instance some canned beans and peas from the United States of America (USA) had a concentration four times above the highest European value, and a sample of canned mango from Singapore had a value 10 times higher. It seems, however, that these very high values may be outliers and not representative of non-European BPA concentrations. Data presented at the national meeting of the American Chemical Society in April 2013 indicated that BPA concentrations in foods that are produced and canned in Japan have dropped considerably since 2000. In comparison with imported canned food from other countries, the decrease has been of the order of a factor of 10–20. Concentration values for Japanese canned food are in the range of some tens of micrograms per kilogram (Kawamura et al, 2014).

Table 4: Summary of average BPA concentrations (μg/kg) from the literature and the EFSA call for data

Food category (FoodEx level 1) and type of packaging (canned or non-canned)	Literature				Call for data				All					
	n [a]	MB [b]	% <LOD/LOQ [e]	Maximum	n [a]	MB [b]	% <LOD/LOQ [e]	Maximum	n [a]	LB [d]	MB [b]	UB [c]	% <LOD/LOQ [e]	Maximum
Canned														
Grains and grain-based products	1	67.4	0	67.4	18	34.9	0	47.5	19	36.6	36.6	36.6	0	67.4
Vegetables and vegetable products	50	26.0	40	116	73	21.7	18	100	123	22.9	23.5	24.0	27	116
Legumes, nuts and oilseeds	2	86	0	103	18	28.8	33	137	20	32.6	34.6	36.6	30	137
Fruit and fruit products	7	15.9	0	24.4	14	12.2	21	107	21	13.1	13.4	13.7	14	107
Meat and meat products	31	14.7	39	51.1	16	64.2	38	203	47	27.7	31.5	35.4	45	203
Fish and other seafood	107	39.5	20	169	67	33.0	33	198	174	34.7	37.0	39.2	27	198
Milk and dairy products	19	2.6	63	15.2	3	19.8	0	35.9	22	4.4	4.9	5.5	55	35.9
Sugar and confectionery	1	0.2	0	0.2	–	–	–	–	1	0.2	0.2	0.2	0	0.2
Fruit and vegetable juices	5	2.7	0	4.7	–	–	–	–	5	2.7	2.7	2.7	0	4.7
Non–alcoholic beverages	54	0.5	26	8.1	11	0.5	27	1.5	65	0.5	0.5	0.5	26	8.1
Alcoholic beverages [f]	18	0.9	17	4.7	49	0.8	35	4.5	67	0.7	0.8	0.8	30	4.7
Drinking water (bottled and tap)	1	0	100	0	10	0–0	100	0	11	0.0	0.0	0.0	100	0
Herbs, spices and condiments	–	–	–	–	2	41.4	0	82.1	2	41.4	41.4	41.4	0	82.1
Food for infants and small children [f]	10	0.3	70	2.2	–	–	–	–	10	0.3	0.3	0.3	70	2.2
Products for special nutritional use [f]	14	1.2	36	4.8	–	–	–	–	14	1.2	1.2	1.2	36	4.8
Composite food	6	25.9	17	73.1	25	39.6	20	110	31	34.6	37.0	39.3	19	110
Snacks, desserts and other foods	1	52.0	0	52.0	–	–	–	–	1	52.0	52.0	52.0	0	52.0
Non-canned														
Grains and grain-based products	1	0.9	0	0.9	95	1.0	43	11.9	96	0.8	1.0	1.1	43	11.9
Vegetables and vegetable products	4	0.4	0	1.0	201	1.2	34	5.3	205	1.2	1.2	1.3	33	5.3
Starchy roots and tubers	–	–	–	–	45	0.7	16	2.6	45	0.6	0.7	0.7	16	2.6
Legumes, nuts and tubers	–	–	–	–	5	0.2	60	0.5	5	0.1	0.2	0.3	60	0.5

Food category (FoodEx level 1) and type of packaging (canned or non-canned)	Literature				Call for data				All					
	n [a]	MB [b]	% <LOD/LOQ [e]	Maximum	n [a]	MB [b]	% <LOD/LOQ [e]	Maximum	n [a]	LB [d]	MB [b]	UB [c]	% <LOD/LOQ [e]	Maximum
Fruit and fruit products	3	0.5	0	1.3	85	0.3	73	2.1	88	0.2	0.3	0.4	71	2.1
Meat and meat products	1	0.9	0	0.9	191	9.5	5	395	192	9.4	9.4	9.5	5	395
Fish and other seafood	8	1.9	75	11.2	68	8.1	2	97.9	76	7.4	7.4	7.4	11	97.9
Milk and dairy products	1	2.6	100	–	151	0.3	52	6.1	152	0.2	0.3	0.4	52	6.1
Eggs and egg products	–	–	–	–	15	0.9	20	4.5	15	0.8	0.9	0.9	20	4.5
Sugar and confectionery	1	0.3	0	0.3	19	0.5	42	2.6	20	0.5	0.5	0.6	40	2.6
Animal and vegetable fats and oils	–	–	–	–	26	0.5	46	1.4	26	0.3	0.5	0.7	46	1.4
Fruit and vegetable juices	2	0.01	100	–	14	0.8	71	6.0	16	0.4	0.7	0.9	75	6.0
Non-alcoholic beverages	1	0.01	100	–	72	0.2	64	1.7	73	0.1	0.2	0.2	64	1.7
Alcoholic beverages	59	0.5	22	2.1	35	0.5	71	1.6	94	0.4	0.5	0.6	40	2.1
Drinking water (bottled and tap)	159	0.2	90	4.4	460	0.2	84	4.5	619	0.2	0.2	0.2	84	4.5
Herbs, spices and condiments	2	0.3	0	0.3	17	1.3	71	2.5	19	0.2	1.2	2.2	63	2.5
Food for infants and small children	1	0.9	100	–	–	–	–	–	1	0.0	0.9	1.7	100	–
Composite food	3	0.3	0	0.4	107	2.4	13	25.8	110	2.3	2.4	2.4	13	25.8
Snacks, desserts and other foods	–	–	–	–	31	0.4	68	0.4	31	0.1	0.4	0.7	68	0.4

(a): n, number of samples.
(b): MB, average (middle bound) BPA concentration (assigning the value for LOD/2 or LOQ/2 when LOD or LOQ is reported).
(c): UB, average (upper bound) BPA concentration (assigning the value for LOD or LOQ when LOD or LOQ is reported).
(d): LB, average (lower bound) BPA concentration (assigning the value 0 when LOD or LOQ is reported).
(e): % < LOD/LOQ: percentage of samples below limit of detection/limit of quantification. No significant difference between LB and UB BPA mean concentration owing to the relatively low LODs or LOQs.
(f): Food categories at FoodEx level 1 have been used.

4.3.3. Occurrence, migration and transfer data from non-dietary sources

Occurrence, migration and transfer data for BPA from non-food sources were retrieved from scientific journals and risk assessment reports (FAO/WHO, 2011; ANSES, 2013); an overview of the literature concerning non-food sources considered is given in Appendix D. The quality of each study was assessed on the basis of the criteria in Section 4.2 and Appendix A. All available information was collected, with a focus on environmental matrices sampled in Europe or consumer articles sold in Europe. The term "non-food sources" summarises all sources that contribute to exposure via pathways other than the food pathway (food pathway: food itself, migration from food contact materials, migration from the lining of water supply pipes).

Environmental media can be inhaled (airborne dust, vapours) or ingested (water, dust) directly, so that occurrence can be directly linked to exposure. Drinking water is not considered as an environmental medium, since it is classified as food (see Table 4, Section 4.5.2), but untreated surface water may be ingested occasionally during, for example, swimming in a lake. Consumer products and articles are included as non-food sources in the present assessment only if they are potentially in close contact with the consumer (e.g. dermal exposure, mouthing, hand-to-mouth contact possible) and if migration and/or transfer rates have been reported. This is the case for children's toys, for example (KEMI, 2012), and indicatively for thermal paper. Consequently, for consumer products, in addition to data on occurrence, data for migration into saliva and transfer to skin are also summarised in this section.

The pathway of exposure via medical devices and medical materials is currently under review by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) of the Directorate General Health and Consumers (DG SANCO). Only dental materials are medical treatments that are considered to be applied on a regular basis for a large proportion of the population and therefore occurrence data on dental materials are summarised below.

The known sources of exposure that presumably are the most relevant for the consumers by magnitude of exposure and prevalence of sources are discussed below.

4.3.3.1. Environmental sources (air, dust and surface water)

Outdoor air

Data for outdoor air in Europe are available from only two studies, one in Greece and one in France. In Greece the presence of BPA was determined in outdoor air in the city of Thessaloniki (Salapasidou et al., 2011). From January to February 2007, ambient PM10 (particulate matter < 10 µm) was sampled from an urban traffic site and an industrial site. BPA in the particulate phase was collected using a low-flow air sampler over 24 hours and analysed by gas chromatography (GC)-MS. BPA concentrations measured in the particulate phase ranged between 0.06 and 47.3 ng/m^3. At the urban traffic site, the BPA concentrations in the particulate phase ranged from 0.06 to 18.6 ng/m^3 (average 6.78 ng/m^3); at the industrial site the BPA concentrations ranged from LOD to 47.3 ng/m^3 (average 13.2 ng/m^3. The air concentrations as presented above do not discriminate between BPA vapour and BPA associated with the airborne particulate phase. It was estimated that 99 % of the BPA is present in the airborne particulate phase and only a small fraction is present in the gaseous phase of the air.

The results from a French study show that BPA was detected in outdoor air in the gaseous phase and particulate phase in an urban setting in Paris and in the forest in Fontainebleau at concentrations varying from 1 to a few ng/m^3 (ANSES, 2013).

Further data for outdoor air are available from the USA. Wilson et al. (2007) collected outdoor air samples in children's homes and daycare centres in two states in the USA (North Carolina and Ohio). Outdoor air concentrations (75th percentiles) ranged between 1.0 and 1.5 ng/m^3 in North Carolina and between 0.7 and 0.9 ng/m^3 in Ohio. The 50th percentile values were below the method detection limit (not fully specified, around 0.9 ng/m^3). These levels were confirmed by Rudel et al. (2010), who measured BPA in outdoor air in Richmond and Bolinas (California, USA). Median levels were around

0.5 ng/m^3, the highest level was below 2 ng/m^3. For Osaka, Japan, Matsumoto et al. (2005) measured BPA in urban ambient outdoor air during a six-month period. Samples were collected using a high-volume air sampler situated on a roof top and analysed with GC-MS. BPA concentrations ranged from 0.02 to 1.92 ng/m^3, with an average of 0.51 ng/m^3. The highest and lowest average concentrations were reported for February and October, respectively. Fu and Kawamura (2010) reported that the concentrations of BPA in outdoor air ranged over four orders of magnitude in the world (0.001–17.4 ng/m^3, aerosol sampling) with a declining trend from the continents to remote sites. The highest concentrations were measured in the rural areas (mainly in Asia; no data for Europe were reported).

The two US studies show that the concentration levels in indoor air are comparable to or even higher than those in outdoor air, suggesting that the indoor air in the house contributes more than the outside air to exposure to BPA through inhalation in the general population. Furthermore, in Europe most of the population spends around 90 % of its time indoors (EuroStat, 2004). For these reasons, no distinction was made between time spent indoors and outdoors, but for the calculation only indoor air levels were used.

Indoor air

Volatilisation and/or abrasion of very small particles from epoxy-based floorings, adhesives, paints, electronic equipment and printed circuit boards are a source of contamination of indoor air and dust (Loganathan and Kannan, 2011).

As BPA has a comparatively low vapour pressure, from indoor air it is deposited onto surfaces or dust. As a result of the low vapour pressure, concentrations of BPA in air can be expected to be low and it will be present mainly in the particulate phase, adsorbed to dust. European data are available only from one recent report by ANSES (2013). BPA levels were measured in indoor air of 30 French homes with an average of 1.0 ng/m^3 (median: 0.6 ng/m^3) in the particulate phase of the air. The highest level was 5.3 ng/m^3.

US data are in the same range. Wilson et al. (2007) measured indoor air concentrations in 257 US homes with an LOD around 0.9 ng/m^3 (LOD deduced by Beronius and Hanberg (2011)). Concentrations in indoor air from homes and daycare centres ranged from < LOD to 193 and 8.99 ng/m^3, respectively, with a median and 95th percentile for homes of 1.82 and 11.1 ng/m^3, respectively. A second study from the USA (Rudel et al., 2010) determined the BPA in indoor air of 50 non-smoking Californian households. BPA was found in only five samples with concentrations of 0.5 to 20 ng/m^3; the median for all samples was given as 0.5 ng/m^3 (which was also the LOD).

For the exposure calculation, the average level of 1 ng/m^3 reported by ANSES (2013) was used, as this is the only study available for indoor air in Europe.

Dust

Ingestion of house dust was reported to be an exposure pathway for BPA in young children owing to the use of BPA in a variety of indoor applications and consumer products and because of children's more frequent hand-to-mouth contact and larger intake of dust than adults (Jones-Otazo et al., 2005; Calafat et al., 2008). BPA was observed in dust from homes, laboratories (Loganathan and Kannan, 2011) and offices (Geens et al., 2009a). Data for Europe are available from three studies conducted in Germany (Völkel et al., 2008), Belgium (Geens et al., 2009a) and France (ANSES, 2013). They are in the same order of magnitude as data from private homes in the USA (Loganathan and Kannan, 2011; Rudel et al., 2003).

Völkel et al. (2008) measured BPA in dust from 12 homes in Germany to investigate potential sources of contamination of urine samples in a biomonitoring study. Samples were collected by residents in homes using regular vacuum cleaners. BPA concentrations in dust ranged from 117 to 1 486 µg/kg with a median of 553 µg/kg.

Geens et al. (2009a) measured concentrations of BPA in indoor dust from 18 homes and two offices in Belgium. Samples were collected using a vacuum cleaner. BPA concentrations measured in dust from homes ranged from 535 to 9 729 µg/kg with a median of 1 460 µg/kg. The concentrations of BPA in dust from the two offices were 4 685 and 8 380 µg/kg (but included in the median). The reason for the higher concentrations of BPA in offices was not explained by the authors.

ANSES (2013) measured settled dust in 25 houses in France. The average, median and maximum concentrations of BPA were 5 800, 4 700 and 20 000 µg/kg, respectively.

As no raw data were available from the cited studies, it was not possible to evaluate all data together. Instead, for the exposure calculation, the median dust concentration of 1 460 µg/kg was taken from Geens et al. (2009a), which is the study that provides the median of the medians reported by the recent studies available for Europe.

Surface water

In a recent study, the concentrations of BPA in North American and European aquatic environments were critically reviewed and statistically characterised (Klecka et al., 2007). A total of 100 papers or reports, published between 1991 and 2007, were identified that contained environmental monitoring data for BPA in European and North American surface water and sediment. Median BPA concentrations in freshwater in Europe were lower than those for North America (0.01 and 0.08 µg/L, respectively), although the 95th percentile concentrations were similar (0.35 and 0.47 µg/L, respectively).

Deblonde et al. (2011) reported concentrations of BPA in wastewater treatment plants ranging from 0.088 to 11.8 µg/L in the influent and from 0.006 to 4.09 µg/L in the effluent. This is in agreement with the levels reported by Klecka et al. (2007).

Data on BPA from surface water were not included in the exposure assessment, as this source contributes very little to the overall dermal exposure, as confirmed by ANSES (2013).

4.3.3.2. Paper products

BPA is present in thermal papers that are used as cash receipts, airline tickets, bus tickets and papers for laboratory use (Liao and Kannan, 2011a). BPA is loosely bound to the paper surface. It has been reported that in Europe, thermal paper containing BPA amounts to 72 % (ANSES, 2013) or 80 % (Lassen et al., 2011) of total thermal paper. According to the European Thermal Paper Association, BPA is still used in thermal paper and, in 2012, 80 % of thermal paper was used for point-of-sales grades, which are mainly used for supermarkets and shop tickets and not for tickets for transport (bus/boarding passes) and tickets for lotteries (email from European Thermal Paper Association to EFSA, 17 June 2013). In Switzerland 11 samples out of 13 investigated thermal papers contained BPA (Biedermann et al., 2010). Reported values ranged from 8 to 17 g/kg, with an average of 13.3 g/kg. In Sweden, receipt and receipt-like papers contained on average 14 and 16 g/kg, respectively (Östberg and Noaksson, 2010). The highest levels in this study were found in car park tickets and bus tickets with an average concentration of 32 and 23 g/kg, respectively. In Belgium 73 % of collected thermal paper samples had BPA concentrations between 9 and 21 g/kg, the remaining 27 % were < 0.1 g/kg (Geens et al., 2012b). Similar values have been reported for the USA. 94 % of all thermal receipt papers contained BPA, and the range was from below the LOQ of 1 µg/kg up to 13.9 g/kg (Liao and Kannan, 2011a).

Receipts and bus tickets are commonly stored in wallets in close contact with paper currency. BPA has been shown to be transferred from thermal paper to paper currencies at levels ranging from 0.001 to 82.7 mg/kg for currencies worldwide (Liao and Kannan, 2011b). These levels are considerably lower (by a factor of approximately 1 000) than levels of BPA in thermal paper, and the CEF Panel considered that this source could be ignored in the exposure. Levels in other paper products are, for example, 3.2 to 46.1 mg/kg dry matter for recycled toilet paper (Gehring et al., 2004), with BPA

originating from the waste paper used in the recycling process. In this case, BPA is included in the bulk of the paper and not readily available from the surface.

BPA may also be present in some cigarette filters (Jackson and Darnell, 1985). However, no analytical data are available for BPA in cigarette filters.

Consequently, consumers are predominantly exposed to BPA in thermal papers by handling cash receipts, tickets, etc. Biedermann et al. (2010) determined the amount of BPA transferred to the fingers of one volunteer by touching thermal paper. Different scenarios were tested with regard to the moisture and grease content of the finger. BPA transfer increased with wetness and greasiness. For what the authors called "standard skin" (slightly greasy skin) five different thermal papers were touched for 30 seconds. The average amount transferred by one handling was found to be 1.1 µg BPA per finger. In another study, migration from paper receipts from Denmark was investigated (Lassen et al., 2011). Eight fingers touched five different receipts for 10 seconds. Migration to dry fingers on average was 11 µg, i.e. 1.4 µg/finger, which is similar to the value derived by Biedermann et al. (2010). In order to create a conservative average value, the latter was used in this assessment. This does not consider crumpling paper before trashing it, which results in contact with most of the hand when the printed surface happens to be outside.

4.3.3.3. Children's toys and articles intended to be mouthed

Information on the potential exposure to BPA from toys in children is rather limited. A recent study (Viñas et al., 2012) investigated migration of BPA into artificial saliva from articles purchased in Spanish supermarkets. Migration from two toys and three pacifiers tested by one minute's immersion without stirring in 100 mL of artificial saliva was in the range of 0.2 to 0.3 µg/L, while the migration from a teether was 5.9 µg/L. The contact time of one minute used by Viñas et al. (2012) was considered too short to account for real migration, and therefore the data from this study are not used.

In another migration study, toys and pacifiers from the Swedish market were put into contact with artificial saliva at 24 °C for 24 hours (KEMI, 2012) by submersing the toys in the smallest volume of artificial saliva needed to completely cover the toys, which was between 100 and 700 mL (pers. comm., KEMI, 2013). Migration of < 0.1 µg/L (LOQ) up to 2.1 µg/L was reported with 8 of 14 toys/pacifiers below LOQ. The maximum levels of 2.1 µg/L were reported for a rattle (0.63 µg BPA migration per product) and a pacifier (0.21 µg BPA migration per product). The average values in this study were 0.14 µg/product for rattles and 0.11 µg/product for pacifiers. The authors of the study state that it had been difficult to find children's products made of PC. In order to find 14 products that contained BPA they had to buy 80 products altogether.

Migration from pacifiers into artificial saliva was also determined by Lassen et al. (2011). BPA was detected in six out of eight migration experiments (LOD: 0.1 µg/kg saliva). The maximal amount detected was 1.36 µg migration after 7.75 hours at 37 °C. Average amounts were from 0.28 to 0.36 µg/product (LB to UB), and the average MB was 0.32 µg/product.

Exposure was calculated from rattles as a surrogate for any PC toy that can be mouthed (general population—children) and pacifiers with PC shields (specific population groups). Migration data for rattles from KEMI (2012) were used in the exposure calculation: the average migration (MB) was 0.14 µg/product. For pacifiers the average MB found by Lassen et al. (2011) was used (0.32 µg/product).

4.3.3.4. Cosmetics

In Europe, BPA is not permitted as an ingredient in cosmetics (Appendix B of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic

products: List of substances prohibited in cosmetic products[22]). However, if BPA was present in the packaging (e.g. PC packaging), it could migrate into the cosmetic products.

European data on BPA in cosmetics are very scarce. A recent study (Cacho et al., 2013) reports levels of < LOQ to 88 µg/kg for different cosmetics (shower gel, hair gel, face lotion, make-up remover and mouthwash) bought in Spain. Furthermore, worldwide data are scarce. Another recent study reports BPA concentrations, banded in the crude range of 1–100 mg/kg in a number of personal care products bought in the USA such as bar soap, body lotion, shampoo, conditioner, shaving cream, face lotion, facial cleanser, body wash and nail polish (Dodson et al., 2012). No reasoning was given by the authors as to why BPA was present in these products.

As shown by Cacho et al. (2013), BPA can be present in trace amounts in cosmetics. The source could be migration from cosmetic packaging or alternatively BPA may be present as an impurity in the cosmetic ingredients. The European cosmetics legislation allows impurities to be present in "small quantity" (Cosmetics Directive Article 17) as long as it is "safe for human health" (Article 3). Even if these data are by no means representative for the EU, nor representative for the wide range of cosmetics that are on the market, it can be concluded that cosmetics could contain trace amounts of BPA as an impurity. The most important contribution to exposure will be from body lotion, because of the large body surface that is treated and because this leave-on product is nearly entirely taken up by the skin (Lorenz et al., 2011). Rinse-off products such as shampoos and hair gel that are removed after washing contribute comparatively low amounts to exposure. Therefore, to account for a realistic worst case, exposure to body lotion was chosen for an exemplary assessment. As no body lotion was analysed by Cacho et al. (2013), the concentration of 31 µg/kg found in facial lotion was selected as a proxy for body lotion since its matrix, ingredients and use (leave-on) are most similar to body lotion.

4.3.3.5. Medical devices

Medical devices are a particular product category in which BPA is found. Examples of these products are implants, catheters, and dental devices. BPA-containing medical devices may have direct and/or indirect contact with the patients (e.g. autotransfusion apparatus, filters, bypasses, tubing, pumps, instruments, surgical equipment, blood pathway circuits and respiratory tubing circuits). The pathway of exposure via medical devices is currently under review by SCENIHR of DG SANCO. In the present assessment, where the risk of BPA for the general public is assessed, the exposure to these medical devices will not be included, as they are used only in specific sub-populations. Dental materials are used in the general population, so the occurrence of BPA in dental materials is considered here.

4.3.3.6. Dental materials

Dental sealants and composite filling materials containing BPA are used in dentistry, especially in children (Fleisch et al., 2010). The most commonly used BPA-derived material is BPA glycidyl methacrylate (bis-GMA). BPA dimethacrylate (bis-DMA), BADGE and BPA ethoxylate dimethacrylate (bis-EMA) are also used. Only bis-DMA, which has an ester linkage, can be hydrolysed to release BPA. The ether linkage in bis-GMA is stable (Schmalz et al., 1999). The resins are polymerised *in situ* during placement of dental sealants and unpolymerised material may be released into saliva directly after treatment. The release of BPA over time as a result of hydrolysis of the resin (Pulgar et al., 2000) was reported. However, other studies describe BPA exposure after dental sealant placement as an acute event (Fleisch et al., 2010; Kang et al., 2011). Variability between brands and analytical method sensitivity and uncertainty make it difficult to draw conclusions regarding exposure from this source (Beronius and Hanberg, 2011). Polydorou et al. (2009a) demonstrated that bleaching did not increase the release of BPA from composite materials.

[22] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ L 342, 22.12.2009, p. 59 209.

Van Landuyt et al. (2011) reviewed the release of substances from dental materials into water-based solutions, and the highest individual value for BPA was 67 nmol/mm^2 surface area of material. According to Van Landuyt, the value corresponds to a worst-case release of 132 µmol after 24 hours on one full crown restoration of a molar.

Zimmerman-Downs et al. (2010) studied the effect of dental sealants on the BPA concentration in saliva in 30 volunteers (with no history with dental sealants or composite material treatment). One group of 15 volunteers received one occlusal sealant, the other group received four sealants. One hour before treatment, the mean baseline value was around 1 µg/L saliva. In the high-dose group, the mean peak value was 6 µg/L (measured 1 hour after treatment) whereas in the low-dose group this mean peak value was around 2 µg/L. Sasaki et al. (2005) measured BPA levels in saliva in 21 volunteers after restoration with composite resins (from nine different companies). BPA levels in saliva ranged from several tens to 100 µg/L but sufficient gargling could remove it from the oral cavity. Both studies indicate that BPA levels in saliva return to baseline (1 µg/L saliva) after 24 hours.

A few studies have also investigated systemic absorption of BPA after placement of dental sealants. Measured levels in blood up to five days after sealant placement could not detect any BPA (Fung et al., 2000; Zimmerman-Downs et al., 2010). Median urinary levels of BPA increased from 2.4 µg/L (pretreatment) to 12.9 µg/L one hour after treatment with one type of sealant but treatment with another brand did not result in the same increase in urinary concentrations (Joskow et al., 2006). Urinary concentrations of BPA had decreased significantly after 24 hours but were not completely back to baseline within this time.

Kang et al. (2011) reported BPA levels in saliva and urine samples collected from 22 South Korean volunteers who received a lingual bonded retainer on their mandibular dentition. Samples were collected immediately before placement and 30 min, one day, one week, and one month after placement. The only significantly high level of BPA was observed in the saliva collected just after placement of the lingual bonded retainer (average 5 µg/L; maximum value 21 µg/L). One day after placement, the level decreased to the background level again (average value: 0.5 µg/L saliva). No statistically significant increase in BPA in the urine samples at any time point was observed.

As the baseline level is very low (the level before treatment is the same as about 24 hours after treatment), it is probable that this saliva concentration represents exposure to BPA from other sources rather than dental material.

Another exposure assessment of BPA concluded that exposure from dental materials does not contribute significantly to the exposure (von Goetz et al., 2010). This is also concluded in a report recently published by the Swedish National Board of Health and Welfare (2012) addressing bisphenol A in dental materials. This report summarises research on *in vitro* and *in vivo* studies related to BPA from dental materials and concludes that there is a possibility of low-dose exposure to BPA from dental materials, either as a contaminant (very low amounts) or from degradation of bis-DMA. Furthermore, as only bis-DMA leaches BPA it is unlikely that the general population is chronically exposed to BPA from dental sealants. Therefore, exposure to dental materials was not included in the present exposure calculation.

Based on the assessment of occurrence, migration and transfer data presented above, the data presented in Table 5 have been selected for use in the exposure calculation for non-food (see Section 4.5.3).

Table 5: Overview of BPA concentrations and sources considered for the present exposure assessment

Source	Pathway	Type of study (direct/ migration/ transfer)	BPA concentration	Unit	Reference	Reasoning
Air	Inhalation	Direct	1.0	ng/m^3	ANSES, 2013	Single data source for indoor air in Europe
Dust	Inhalation/ Ingestion	Direct	1 460	µg/kg dust	Geens et al., 2009a	Middle median from three European studies
Thermal paper	Dermal	Transfer to finger	1.4	µg/finger	Lassen et al., 2011	Most extensive study available
Toys (rattle)	Ingestion	Migration into saliva	0.14	µg/product	KEMI, 2012	Most reliable study conditions
Pacifiers with PC shields	Ingestion	Migration into saliva	0.32	µg/product	Lassen et al., 2011	Most reliable study conditions
Cosmetics	Dermal	Direct	31	µg/kg	Cacho et al., 2013	Single data source for cosmetics in Europe, value for face lotion used

4.4. Food consumption

Data from the EFSA Comprehensive European Food Consumption Database (hereafter called the Comprehensive Database) were used to assess dietary exposure to BPA in all age groups, excluding infants aged zero to six months. The Comprehensive Database was built in 2010 from existing national information on food consumption at a detailed level. Competent organisations in the European Union Member States provided EFSA with data from the most recent national dietary survey in their country at the level of consumption by the individual consumer. Survey results for children were mainly obtained through the EFSA Article 36 project "Individual food consumption data and exposure assessment studies for children" through the EXPOCHI consortium (EFSA, 2011). Results from a total of 32 different dietary surveys carried out in 22 different Member States covering more than 67 000 individuals are included in the Comprehensive Database version 1 as published (EFSA, 2011; Merten et al., 2011).

There are two surveys available for infants, nine surveys available for toddlers, 17 surveys available for children 3-10 years, 12 surveys available for adolescents, 15 surveys available for adults, seven surveys available for the elderly and six surveys available for the very elderly. Only surveys covering more than one day, and thus appropriate for calculating chronic exposure, were selected. For each survey, food consumption data are coded according to the FoodEx classification system.

4.5. Exposure estimation

4.5.1. General assumptions for exposure calculation

For each source of exposure (dietary; non-dietary oral, inhalation and dermal) and in each age group (infants (0–1 year), toddlers (1–3 years), children (3–10 years), adolescents (10–18 years), women (18–45 years), men (18–45 years), other adults (45–65 years), elderly and very elderly (over 65 years) (EFSA, 2011), a scenario for average exposure and a scenario for high exposure was developed. Average exposures from the different sources have been added together by route to assess average exposure. High exposures from the different sources have been added together by route to assess high exposure. In order to quantify the relative impact of each source, the assumptions made in the

exposure assessments aimed to obtain a similar degree of conservativeness among the different sources.

In the case of infants, owing to their very monotonous dietary pattern, loyalty was considered. Thus, high exposure was assessed considering that some infants might be systematically exposed to products containing a higher concentration of BPA, e.g. an infant formula containing a high concentration of BPA or a baby bottle releasing more BPA than other bottles. In all other age classes, an average BPA concentration was considered and high chronic exposure was assessed considering higher levels of consumption of products containing BPA, as explained in detail in Section 4.5.2.4 (see "Assessment of dietary exposure based on the EFSA Comprehensive Database").

As far as possible, exposure to total BPA from dietary and other sources has been calculated. Where possible, exposure to conjugated and unconjugated BPA has been assessed separately, i.e. through human milk.

Thus, for non-food sources too an attempt was made to choose average values for all parameters, including parameters describing frequency of use. For the high scenario, the same average parameters were used for occurrence data, and, in line with the methodology used to assess exposure from food, the frequency of use parameters were modified to account for exposure of approximately the 95th percentile of the population. For calculating exposure levels for the general population behavioural parameters were derived considering both users and non-users. For calculations for specific population groups (e.g. users of pacifiers with PC shields, s. Table 24), behavioural data were taken only from the group of users (see Table18). Loyalty was assumed in the case of cosmetics.

Biomonitoring studies have been used to assess how much total BPA is excreted in urine (backward modelling), allowing the estimation of exposure from all sources to total BPA. These estimates have been compared with the total internal exposure value calculated by forward modelling, as a check of plausibility. In addition, biomonitoring studies might be able to identify the existence of unrecognised source of exposure.

4.5.2. Exposure estimation from dietary sources

Dietary exposure to BPA in infants aged less than six months was assessed by means of a model diet based on a standard level of consumption combined with BPA concentration in human milk or infant formula. Average and high BPA concentration values were used to assess average and high chronic dietary exposure.

4.5.2.1. Dietary exposure from colostrum and human milk

Initial human milk (colostrum), which is produced from the first day to approximately five days after delivery, differs from mature human milk. The assessment of exposure to BPA in the first few days of life has therefore been considered separately.

The quantity of initial human milk consumed by infants on their very first day of life is very small; it was estimated to be 44 ± 71 g (mean ± SD (standard deviation)) by Neville et al. (1988) and as low as 15 ± 11 g by Santoro et al. (2010). The quantity of initial human milk consumed increases steadily each day and reaches around 500 g/day on the fifth day of life (Neville et al., 1988). Taking an average consumption of 250 g over the first five days, and assuming an average body weight for a newborn infant of 3.25 kg, an average consumption rate of 75 g/kg bw per day (rounded by 5-g steps) is obtained. For infants aged five days to three months the average level of consumption of 150 g/kg bw per day considered by the US Environmental Protection Agency (EPA, 2011) to derive exposure factors in the first month of life was used here. As human milk consumption per kilogram of body weight decreases steadily from month 1 to month 3, the level of consumption observed at month 1 allows a conservative assessment of exposure for this age class up to three months old. For infants aged up to three months and breastfed with mature human milk, a level of consumption of 150 g/kg bw per day, and for breastfed infants aged four to six months, the level of consumption

established in the EFSA opinion on default assumptions (132 g/kg bw per day) (EFSA Scientific Committee, 2012) was considered.

Based on data from the scientific literature described in Section 4.6.4, average exposure for infants aged one to five days was assessed assuming that initial human milk would contain 3.0 µg of total BPA/L whereas high exposure was assessed assuming that initial human milk would contain 5.8 µg of total BPA/L. The CEF Panel noted that only very few data from Europe were available and therefore decided to take into account data from Japan, reporting the above BPA concentrations. The CEF Panel noted, however, that these data had significant limitations, including the use of ELISA methodology and the fact that the samples dated back to 2000. The non-specificity of the ELISA method may tend to overestimate the BPA concentration in colostrum which, however, would be conservative for the exposure assessment of breastfed newborn infants. These limitations were addressed in the uncertainty analysis. Results are presented in Table 6.

Table 6: Exposure to total BPA from initial human milk

	Consumption of initial human milk (g/kg bw per day)	Average exposure (ng/kg bw per day) [(a)]	High exposure (ng/kg bw per day) [(b)]
Infants, day 1–5	75	225	435

(a): Based on an average BPA concentration in initial human milk of 3.0 µg/L assuming a milk density of 1 kg/L.
(b): Based on a high BPA concentration in initial human milk of 5.8 µg/L assuming a milk density of 1 kg/L.

Average exposure of breastfed infants from six days of age to six months was assessed considering that mature milk would contain 1.1 µg of total BPA/L, whereas high exposure was assessed considering that mature milk would contain 4 µg of total BPA/L. Results are presented in Table 7.

Table 7: Exposure to total BPA from mature human milk

	Consumption of mature human milk (g/kg bw per day)	Average exposure[(a)] (ng/kg bw per day)	High exposure [(b)] (ng/kg bw per day)
Infants, 0–3 months	150	165	600
Infants, 4–6 months	132	145	528

(a): Based on an average BPA concentration in mature human milk of 1.1 µg/L assuming a milk density of 1 kg/L.
(b): Based on a high BPA concentration in mature human milk of 4.0 µg/L assuming a milk density of 1 kg/L.

4.5.2.2. Dietary exposure from infant formula

The highest level of consumption per kilogram of body weight is observed during the first months of life of formula-fed infants. The level of consumption of infant formula considered is the one that would provide a water consumption in infants of 150 g/kg bw per day. This is based on the scenario of a 5-kg infant consuming 0.75 L of water per day for the reconstitution of infant formula, as suggested by WHO (2003). This is consistent with the approach used in the recent CEF Panel's opinion on the criteria to be used for safety evaluation of recycling processes (EFSA CEF Panel, 2011a).

Infant formula may be purchased as powder or ready-to-use (liquid). According to the European Dietetic Food Industry Association (email to EFSA dated 27 June 2013), canned liquid infant formula is not offered in cans in Europe and therefore exposure is not considered here. For powdered infant formula, the factor that is generally considered to calculate the quantity of reconstituted infant formula based on the quantity of powder (1/7) was used (EFSA, 2010). Thus the total weight of infant formula consumed is 150 g × 8/7.

A specific exposure assessment was performed for infants fed with such formulas, based on the average and high BPA concentration observed in European samples.

In Table 22 and 23, reporting exposure to BPA for the general population, only powdered infant formula (canned and not canned) and liquid infant formula (not canned) have been considered. A unique value, without distinction between these three types of formula, has been used based on the following considerations:

For powdered infant formula—canned, based on 10 sets of European analytical data, an average concentration of 0.3 μg/kg and a high concentration of 2.2 μg/kg were considered (see Section 4.3.2, "Occurrence in food", and Appendix C). Dietary exposure would amount to 6 ng/kg bw per day in an infant fed about 21 g/kg bw per day of infant formula powder (equivalent to 150 g/kg bw per day of ready-to-drink liquid infant formula) containing an average concentration of 0.3 μg/kg. As infant formula powder is diluted in water, the baseline BPA contamination of drinking water reported in Table 3 was also considered MB 0.2 μg/kg). Overall, exposure to BPA from the consumption of 150 mL/kg bw per day of reconstituted formula would be 36 ng/kg bw per day at the average ($150 \times 0.2 + 150 \times 0.3 \times 1/7$) with more estimated BPA deriving from the water than from the powder. High exposure would be 77 ng/kg bw per day ($150 \times 0.2 + 150 \times 2.2 \times 1/7$).

For powdered infant formula—not canned, only one analytical dataset was available for Europe (under the limit of detection, MB 0.9 μg/kg) whereas no data were available in Europe for liquid infant formula—not canned. Exposure from the consumption of 150 mL/kg bw per day of either reconstituted formula or of liquid infant formula—not canned would mainly derive from the background contamination of water and, based on an MB value of 0.2 μg/kg, would be in the range of 30 ng/kg bw per day.

The CEF Panel noted that for these three types of formula, BPA concentration values in formulas and water were low and rather uncertain. Overall, no significant difference in exposure is expected between canned infant formula powder and non-canned infant formula (either liquid or powder).

Rough estimates of 30 ng/kg bw per day for average exposure and of 80 ng/kg bw per day for high exposure were therefore considered for these three types of products.

4.5.2.3. Dietary exposure from water coolers with PC reservoirs, PC water filters and old waterpipes repaired with epoxy resins

Water dispensers (also known as water coolers with PC reservoirs) and water filters can be used at household level (e.g. fridge water dispensers), at work places and in schools. The water coolers with PC reservoirs hold a large bottle (approximately 10 L) on top, which is often made from PC and is exchanged for a new bottle when empty. When referring to PC coolers in this opinion the actual bottle is meant. Regular consumers of water from these reservoirs are exposed to an additional source of exposure compared with the general population. The same is true for households living in buildings where old water pipes have been repaired with epoxy resins that release BPA into tap water.

Additional chronic exposure to BPA in these specific population groups was assessed considering total water consumption in each age class, as reported in Table 24. Data on the consumption of drinking water was derived from the EFSA Comprehensive Database for all age classes, from toddlers to the very elderly, at individual level. The median of average consumption and the highest observed 95th percentile are reported and were used to assess average and high exposure.

For PC water dispensers, only average exposure was assessed, as it is unlikely that high consumption of water would derive exclusively from PC dispensers. For PC water filters and water pipes, average and high exposure was assessed considering the average and high consumption as described above.

The use of PC water dispensers and PC filters was not considered for infants, as it was considered unlikely that infant formula would be reconstituted with water from such water dispensers.

For PC water dispensers and PC filters, migration values of 0.81 µg/L and 0.04 µg/L, respectively, were considered (see Table 3 in Section 4.3.1, "Estimated migration values for specific PC food contact materials used in the exposure assessment"). For water pipes, the average and high exposure was assessed based on average BPA concentration in cold water in those buildings where water pipes had been repaired with a two-component technique leading to high release of BPA (see Section 4.3.2, "Occurrence in food", and Appendix B) of 0.1 µg/L. Results are presented in Table 8.

Table 8: Exposure to BPA from drinking water in specific population groups based on chronic [(a)] water consumption as reported in the EFSA Comprehensive Database

	Median of mean water consumption (g/kg bw per day)	Highest 95th percentile of water consumption (g/kg bw per day)	Average exposure ng/kg bw per day [(b)]			High exposure ng/kg bw per day [(c)]	
			Water coolers	Water pipes	PC filters	Water pipes	PC filters
Toddlers	26.6	95.6	22	2.7	1.1	10	3.8
Children (3-10 years)	19.2	68.8	16	1.9	0.8	7	2.8
Adolescents	10.9	39.4	9	1.1	0.4	4	1.6
Women (18–45 years)	9.8	39.2	8	1.0	0.4	4	1.6
Men (18–45 years)	7.7	33.8	6	0.8	0.3	3	1.4
Other adults (45–65 years)	8.5	32.3	7	0.9	0.3	3	1.3
Elderly and very elderly	10.5	28.6	9	1.1	0.4	3	1.1

(a): In order to assess chronic water consumption, only surveys with at least two survey days were considered.
(b): Considering median water consumption and the following concentration of BPA (µg/kg): water coolers 0.81; water pipes 0.1; PC filters 0.04.
(c): Considering high water consumption and the following concentration of BPA (µg/kg): water pipes 0.1; PC filters 0.04.

4.5.2.4. Dietary exposure from PC kettles, PC tableware, cookware and old PC baby bottles

BPA may migrate into food and beverages through contact with PC food contact materials such as tableware used to heat foods and beverages in microwave ovens, tableware used when the food or beverage is eaten (mugs, beakers, plates, bowls) and water kettles used to boil water for preparing hot drinks such as coffee, tea or rehydrated soups. As migration increases with temperature, time of contact and surface of contact, it is likely to be highest when hot beverages are prepared with water heated in a PC kettle or consumed in PC mugs or cups. The case of infant formula reconstituted with water heated in a PC water kettle and of infants fed with formula from an old PC baby bottle bought before the EU ban must also be considered. PC tableware and PC kettles are used by only a fraction of the population, but in this fraction of the population that uses them regularly it needs to be assessed as an additional source of exposure to BPA.

The migration value chosen to represent average potential migration from PC kettles into water was 0.11 µg/kg. This value is an estimate of BPA concentration in water that would be warmed twice in a kettle and left in it for a total of about 50 minutes (see Table 3 in Section 4.3.1.2, "Estimated migration values for specific PC food contact materials used in the exposure assessment"). The migration value was added to the background level of BPA in water, resulting in combined value of BPA concentration of 0.31 µg/kg. It was considered that water heated in a kettle could be used to prepare hot beverages such as coffee (espresso excluded) or tea. Individual consumption data from the Comprehensive Database have been used to estimate the exposure to BPA from kettles. Average and high (95th percentile) exposure have been assessed for each survey and in each age class for exposure to BPA from PC kettles. Summary data are presented in Table 9. As expected, the highest estimated exposure from PC kettles was observed in adults and the elderly owing to their higher consumption of coffee and tea.

Table 9: Exposure to BPA in specific population groups using PC kettles, based on chronic consumption of beverages that could be prepared with hot water, as reported in the EFSA Comprehensive Database

Population group	Median of average consumption of beverages (g/kg bw per day)	Highest 95th percentile of beverages consumption (g/kg bw per day)	Average exposure ng/kg bw per day [(a)]	High exposure ng/kg bw per day [(b)]
Infants, formula-fed [(c)]	150 (+ powder contribution)		53	94
Toddlers	0.4	19.3	0.11	5.98
Children (3-10 years)	0.4	16.0	0.13	4.96
Adolescents	1.0	15.4	0.32	4.77
Women (18–45 years)	3.3	25.8	1.02	8.01
Men (18–45 years)	1.9	23.6	0.59	7.31
Other adults (45–65 years)	2.0	29.4	0.63	9.12
Elderly and very elderly	2.5	27.4	0.77	8.48

(a): Considering median beverage consumption and the following concentration of BPA: 0.31 µg/kg.
(b): Considering high beverage consumption and the following concentration of BPA: 0.31 µg/kg.
(c): Considering the consumption of 150 mL/kg bw per day of water with a BPA concentration 0.31 µg/kg, plus the contribution from powder formula.

For infants fed with infant formula reconstituted from powder, dietary exposure related to the use of PC kettles to warm the water was assessed considering a water consumption of 150 mL/kg bw per day.

For breastfed infants, the additional exposure from the consumption of herbal tea prepared with water heated in a PC kettle was estimated considering the consumption of one small baby bottle (100 mL) per day for a 5-kg infant.

Chronic dietary exposure to BPA from tableware and from cookware was also estimated for age classes from toddlers to the elderly with the use of individual consumption data from the EFSA Comprehensive Database. In this case, all occasions on which food was consumed and beverages that may be consumed hot were assumed to contain a BPA concentration level equal to 0.09 and 0.29 µg/kg, respectively. These values are the estimated migration during 15 minutes of contact between the food and the tableware (see Table 3 in Section 4.3.1.2, "BPA migration into food simulants"). All food and beverages, with the exception of "alcoholic beverages", "drinking water", "fruit and fruit products" and "fruit and vegetable juices", at the first level of the FoodEx system, were assumed to be consumed hot. Average and high (95th percentile) exposure have been assessed for each survey and in each age class for the exposure to BPA from tableware. Results are presented in Table 10. The highest estimated exposure from PC tableware was observed for toddlers owing to their higher consumption of beverages per kilogram of body weight. This age class is also the one in which regular use of PC tableware is most likely to occur, as "unbreakable" plastic mugs and beakers are often used for toddlers.

Table 10: Exposure to BPA in specific population groups using PC tableware or cookware containing BPA, based on chronic consumption of food that could be consumed warm, as reported in the EFSA Comprehensive Database

Population group	Median of average consumption of food (g/kg bw per day)	Highest 95th percentile of food consumption (g/kg bw per day)	Average exposure ng/kg bw per day [a]		High exposure ng/kg bw per day [b]	
			Tableware	Cookware	Tableware	Cookware
Toddlers	64.6	156.9	6	19	14	46
Children (3-10 years)	46.7	96.6	4	14	9	28
Adolescents	26	54.9	2	8	5	16
Women (18–45 years)	22.4	52.2	2	6	5	15
Men (18–45 years)	22.7	49.2	2	7	4	14
Other adults (45–65 years)	21.8	51	2	6	5	15
Elderly and very elderly	20.8	49	2	6	4	14

(a): Considering median food consumption and the following concentration of BPA (µg/kg): 0.09 in tableware and 0.29 in cookware.
(b): Considering high food consumption and the following concentration of BPA (µg/kg): 0.09 in tableware and 0.29 in cookware.

The case of infants fed with formula in old PC baby bottles that would have been bought before the EU ban was also considered by combining the consumption level of 150 mL/kg bw per day with an average migration of 0.91 µg/L and a high migration of 2.8 µg//L (see Table 2 in Section 4.3.1.2, "BPA migration into food simulants").

In the 2006 EFSA opinion, a single value of 5 µg/kg was considered for migration from tableware. The consumption of food in contact with tableware was extremely conservative, in particular for toddlers: 3 kg for a 60-kg adult (50 g/kg bw per day) and 2 kg for a 11-kg toddler (182 g/kg bw per day). Estimated exposure from this source was therefore one order of magnitude higher compared with

the present assessment, which derives estimates of 250 ng/kg bw per day in adults and 900 ng/kg bw per day in toddlers.

4.5.2.5. Assessment of dietary exposure based on the EFSA Comprehensive Database

Dietary exposure from 12-month-old toddlers to the elderly has been estimated using individual consumption data from the EFSA Comprehensive Database combined with available concentration data derived from the scientific literature or from the EFSA call for data. In order to consider separately women of childbearing age, in the present assessment the adult age group has been broken down into three subgroups, comprising women from 18 to 45 years old, men from 18 to 45 years old and other adults from 45 to 65 years old. The subgroups of the elderly and very elderly were merged. As food consumption data for infants aged 6 to 12 months in the Comprehensive Database were very limited and consequently not used in the present assessment, dietary exposure in toddlers (12–36 months) was used as an estimate for the dietary exposure in infants aged 6 to 12 months. The CEF Panel noted that the consumption pattern in these two age groups is likely to be different, but the approach taken was likely to provide a conservative dietary exposure estimate for this age group.

The average BPA concentration in each food category was assessed by merging data from different sources or scientific publications (see Section 4.3.2). Chronic exposure was estimated by multiplying the average BPA concentration for each FoodEx level 1 food group (see Appendix E for details) and type of packaging (canned or non-canned) with their respective consumption amount per kilogram of body weight separately for each individual in the database, calculating the sum of exposure for each survey day for the individual and then deriving the daily average for the survey period. Average and 95th percentile exposure was calculated for the total survey population separately for each survey and age class. Details of the surveys are given in Table 11.

Only a limited number of dietary surveys included in the Comprehensive Database included information on the type of packaging (canned or non-canned, in particular). The number and percentages of food codes specific for canned products per country and per survey are presented in Table 12.

Two scenarios were therefore considered:

Scenario 1. Only foods specifically codified as canned in the dietary survey are assigned the corresponding occurrence level for BPA.

Scenario 2. At FoodEx level 4, any food which has been codified as canned in at least one survey is always considered to be consumed as canned in all dietary surveys included in the Comprehensive Database. A list of all these products is reported in Appendix J. The corresponding average occurrence of BPA in canned products is consequently always assigned to these foods. In order to avoid an artificial overestimate of exposure to BPA, exceptions have been made for products that are consumed in large quantities in many EU countries and would generally not be consumed as canned. For these foods, only those effectively codified as canned in the original survey have been assigned the BPA occurrence in canned food. The exceptions were as follows: apples, beef, cow's milk (all types), cream (all types), crème fraiche (all types), croissants, mandarins, oranges, potatoes—fried, potatoes and potato products, poultry, rice and sour cream (all types).

4.5.2.6. Presentation of results

Table 13 presents the minimum, median and maximum values for the average and 95th percentile in each age class, for LB, MB and UB, under scenario 1. Table 14 presents the same results under scenario 2. The highest levels of exposure were estimated for toddlers and children 3-10 years, up to 857 and 813 ng/kg bw per day, respectively, for the 95th percentile under the MB scenario. Overall, among the population older than six months, infants and toddlers presented the highest estimated average (375 ng/kg bw per day) and high (857 ng/kg bw per day) dietary exposure. The CEF Panel

considered that this was mainly due to their higher consumption of foods and beverages per kilogram of body weight.

Owing to a very low percentage of left-censored samples, mainly among canned foods, the techniques used to model data under the LOD or LOQ had a very small impact on the average concentration in the different food categories and, consequently, on the exposure. On average, exposure estimates calculated by the MB technique were 4–30 % (scenario 1) and 4–12 % (scenario 2), respectively, higher than those calculated by the LB method. Compared with the UB estimates, the MB estimates were 4–19 % (scenario 1) and 2–8 % (scenario 2) lower.

Table 11 reports for each survey age group the average and 95th percentile for each scenario, and it is sorted according to the ratio between the 95th percentile exposure in scenario 2 and scenario 1. This ratio is lowest in countries where many food codes were available for canned products and/or where canned products are largely consumed. It is the case for UK men and women from 18 to 45 years old where the ratio is 1.9 and 2.2 at the average and 1.7 and 2.1 at the 95th percentile, respectively. The highest difference was noted in Belgian toddlers, with a ratio equal to 5.0 and 6.8 for the average and the 95th percentile, respectively.

Table 15 presents the number of dietary surveys according to the percentage of average dietary exposure to BPA per type of packaging (canned vs. not canned) and scenario. Under scenario 1, the percentage contribution to BPA from non-canned foods was predominant (but less than 50 %) in the most of the dietary survey. Under this scenario, only for one survey (related to males from 18 to 45 years old) canned foods contributed between 50 % and 75 % of average BPA exposure. Under scenario 2, canned products dominated in all surveys, with the percentage contribution to BPA from non-canned foods mainly ranging between 10 % and 25 %. Canned foods contributed up to more than 90 %; this is the result of one dietary survey among toddlers: "Fish and other seafood".

The number of dietary surveys according to the percentage of average dietary exposure to BPA per type of packaging (canned vs. non-canned), FoodEx level 1 food category and scenario is reported in Appendix E for all age groups. Under scenario 1, non-canned "Meat and meat products" turned out to be a major contributor to BPA average exposure in the large majority of countries and age classes. "Vegetables and vegetable products" was the only canned food category that contributed up to 25–50 % in some of the population groups. "Meat and meat products" was also the major contributor among the non-canned food categories under scenario 2 but never exceeded 10–25 % of the exposure. On the other hand, the canned versions for "Vegetables and vegetable products", "Meat and meat products" and "Composite food" were the major sources of average BPA exposure.

Under scenario 2, dietary exposure in women of childbearing age was slightly higher (132 and 388 ng/kg bw per day for average and high exposure, respectively) than that of men of the same age (126 and 335 ng/kg bw per day for average and high exposure, respectively). This may be due to women consuming different food items, as reported in the individual surveys.

Table 11: Dietary exposure by country survey and age group and scenarios under the middle bound assumption (sorted according to the ratio between the 95th percentile (P95) exposure in scenario 2 and scenario 1)

Country	Survey	Age group	Number of subjects	Middle bound					
				Scenario 1 (ng/kg bw per day)		Scenario 2 (ng/kg bw per day)		Scenario 2/ Scenario 1	
				Mean	P95	Mean	P95	Mean	P95
United Kingdom	NDNS	Men (18–45 years)	459	59	109	112	182	1.9	1.7
United Kingdom	NDNS	Women (18–45 years)	587	49	91	107	191	2.2	2.1
Denmark	Danish_Dietary_Survey	Adolescents	479	64	117	137	248	2.1	2.1
United Kingdom	NDNS	Adults (45–65 years)	678	51	94	120	201	2.3	2.1
Czech Republic	SISP04	Men (18–45 years)	446	55	97	120	220	2.2	2.3
Denmark	Danish_Dietary_Survey	Men (18–45 years)	781	51	80	109	182	2.1	2.3
Ireland	NSIFCS	Adults (45–65 years)	358	48	85	124	203	2.6	2.4
Italy	INRAN_SCAI_2005_06	Children (3-10 years)	193	120	206	267	502	2.2	2.4
Ireland	NSIFCS	Men (18–45 years)	282	55	90	126	218	2.3	2.4
Czech Republic	SISP04	Adults (45–65 years)	801	41	75	102	186	2.5	2.5
Spain	AESAN	Women (18–45 years)	160	56	126	161	313	2.8	2.5
Spain	AESAN	Men (18–45 years)	141	57	100	142	249	2.5	2.5
Italy	INRAN_SCAI_2005_06	Adolescents	247	70	121	169	302	2.4	2.5
Italy	INRAN_SCAI_2005_06	Men (18–45 years)	575	50	83	125	209	2.5	2.5
Hungary	National_Repr_Surv	Men (18–45 years)	244	46	85	123	217	2.7	2.5
Czech Republic	SISP04	Adolescents	298	59	109	152	277	2.6	2.6
Czech Republic	SISP04	Children (3-10 years)	389	78	142	198	363	2.5	2.6
Denmark	Danish_Dietary_Survey	Elderly and very elderly	329	47	74	111	190	2.4	2.6
Denmark	Danish_Dietary_Survey	Adults (45–65 years)	1 117	47	76	115	201	2.4	2.7
Denmark	Danish_Dietary_Survey	Women (18–45 years)	924	49	79	119	211	2.4	2.7
Denmark	Danish_Dietary_Survey	Children (3-10 years)	490	102	165	253	446	2.5	2.7
Spain	AESAN_FIAB	Men (18–45 years)	367	54	92	148	249	2.7	2.7
Ireland	NSIFCS	Women (18–45 years)	318	47	82	123	223	2.6	2.7
Italy	INRAN_SCAI_2005_06	Adults (45–65 years)	1 055	47	78	124	219	2.7	2.8

Country	Survey	Age group	Number of subjects	Middle bound					
				Scenario 1 (ng/kg bw per day)		Scenario 2 (ng/kg bw per day)		Scenario 2/ Scenario 1	
				Mean	P95	Mean	P95	Mean	P95
Italy	INRAN_SCAI_2005_06	Women (18–45 years)	683	52	87	138	242	2.7	2.8
Spain	AESAN_FIAB	Adolescents	86	63	101	156	293	2.5	2.9
Czech Republic	SISP04	Women (18–45 years)	419	38	67	97	195	2.6	2.9
Germany	National_Nutrition_Survey_II	Adolescents	1 011	41	87	121	252	2.9	2.9
Germany	National_Nutrition_Survey_II	Men (18–45 years)	2 517	46	91	127	264	2.8	2.9
Italy	INRAN_SCAI_2005_06	Elderly and very elderly	518	44	70	116	206	2.6	2.9
Hungary	National_Repr_Surv	Adults (45–65 years)	503	38	67	113	199	3.0	3.0
Finland	DIPP	Toddlers	497	111	228	316	688	2.8	3.0
Hungary	National_Repr_Surv	Elderly and very elderly	286	35	60	107	183	3.1	3.1
Finland	FINDIET_2007	Men (18–45 years)	333	37	59	101	184	2.7	3.1
Sweden	Riksmaten_1997_98	Women (18–45 years)	354	42	73	137	228	3.3	3.1
Spain	AESAN_FIAB	Adults (45–65 years)	207	52	90	163	283	3.1	3.1
Sweden	Riksmaten_1997_98	Men (18–45 years)	352	41	67	127	209	3.1	3.1
Finland	DIPP	Children (3-10 years)	933	87	140	248	440	2.9	3.1
Spain	enKid	Adolescents	209	62	111	190	350	3.0	3.2
Sweden	NFA	Children (3-10 years)	1 473	79	147	263	476	3.3	3.2
Hungary	National_Repr_Surv	Women (18–45 years)	327	41	69	120	224	2.9	3.3
Spain	AESAN_FIAB	Women (18–45 years)	407	61	99	182	329	3.0	3.3
Bulgaria	NUTRICHILD	Toddlers	428	137	253	431	846	3.1	3.3
Sweden	Riksmaten_1997_98	Adults (45–65 years)	504	43	71	141	238	3.3	3.4
Finland	FINDIET_2007	Adults (45–65 years)	821	33	57	103	194	3.2	3.4
Spain	NUT_INK05	Adolescents	651	61	103	201	352	3.3	3.4
Germany	National_Nutrition_Survey_II	Women (18–45 years)	3 285	38	73	124	251	3.2	3.4
Cyprus	Childhealth	Adolescents	303	41	77	142	269	3.5	3.5
Sweden	NFA	Adolescents	1 018	50	88	163	309	3.2	3.5
Finland	FINDIET_2007	Elderly and very elderly	463	29	51	97	179	3.3	3.5
Germany	National_Nutrition_Survey_II	Elderly and very elderly	2 496	38	70	125	247	3.3	3.5

Country	Survey	Age group	Number of subjects	Middle bound					
				Scenario 1 (ng/kg bw per day)		Scenario 2 (ng/kg bw per day)		Scenario 2/ Scenario 1	
				Mean	P95	Mean	P95	Mean	P95
France	INCA2	Men (18–45 years)	517	37	60	121	211	3.3	3.5
Bulgaria	NUTRICHILD	Children (3-10 years)	433	127	223	409	790	3.2	3.6
Germany	National_Nutrition_Survey_II	Adults (45–65 years)	4 617	40	75	127	268	3.2	3.6
Netherlands	DNFCS_2003	Women (18–45 years)	398	41	80	142	286	3.5	3.6
Finland	FINDIET_2007	Women (18–45 years)	421	33	56	109	205	3.2	3.6
Spain	enKid	Children (3-10 years)	156	96	179	298	668	3.1	3.7
Spain	NUT_INK05	Children (3-10 years)	399	92	148	312	556	3.4	3.8
Netherlands	DNFCS_2003	Men (18–45 years)	352	49	89	175	335	3.6	3.8
Spain	AESAN	Adults (45–65 years)	109	50	86	158	331	3.2	3.9
Netherlands	VCP_kids	Children (3-10 years)	957	79	160	290	635	3.7	4.0
Greece	Regional_Crete	Children (3-10 years)	839	96	165	345	674	3.6	4.1
France	INCA2	Adolescents	973	43	73	156	307	3.7	4.2
France	INCA2	Adults (45–65 years)	947	36	55	138	230	3.8	4.2
Belgium	Diet_National_2004	Men (18–45 years)	365	40	69	158	290	4.0	4.2
France	INCA2	Women (18–45 years)	812	35	55	132	235	3.8	4.3
Latvia	EFSA_TEST	Men (18–45 years)	376	42	76	172	333	4.1	4.4
Germany	DONALD_2006_2008	Children (3-10 years)	660	57	86	215	381	3.8	4.4
Germany	DONALD_2006_2008	Toddlers	261	72	108	235	487	3.3	4.5
France	INCA2	Elderly and very elderly	348	34	51	137	231	4.0	4.6
France	INCA2	Children (3-10 years)	482	75	117	314	550	4.2	4.7
Netherlands	VCP_kids	Toddlers	322	97	178	375	857	3.9	4.8
Latvia	EFSA_TEST	Children (3-10 years)	189	60	112	264	544	4.4	4.9
Latvia	EFSA_TEST	Adolescents	470	44	78	187	381	4.3	4.9
Latvia	EFSA_TEST	Adults (45–65 years)	547	34	63	161	309	4.7	4.9
Belgium	Diet_National_2004	Adolescents	584	37	65	161	345	4.3	5.3
Latvia	EFSA_TEST	Women (18–45 years)	383	33	61	153	328	4.6	5.4
Belgium	Diet_National_2004	Adults (45–65 years)	554	36	61	168	341	4.6	5.6

Country	Survey	Age group	Number of subjects	Middle bound					
				Scenario 1 (ng/kg bw per day)		Scenario 2 (ng/kg bw per day)		Scenario 2/ Scenario 1	
				Mean	P95	Mean	P95	Mean	P95
Finland	STRIP	Children (3-10 years)	250	70	108	362	620	5.2	5.8
Belgium	Regional_Flanders	Children (3-10 years)	625	81	131	415	813	5.1	6.2
Belgium	Diet_National_2004	Elderly and very elderly	1 230	35	59	183	375	5.2	6.3
Belgium	Diet_National_2004	Women (18–45 years)	385	34	57	170	388	5.0	6.8
Belgium	Regional_Flanders	Toddlers	36	104		551		5.3	
Italy	INRAN_SCAI_2005_06	Toddlers	36	145		312		2.1	
Spain	enKid	Toddlers	17	116		390		3.4	

Table 12: Presence of canned food codes in Comprehensive Database per country and survey

Country	Survey	Number of national food codes			Number of FoodEx codes		
		Canned	All	Percentage	Canned	All	Percentage
Germany	National_Nutrition_Survey_II	1 694	22 387	8	168	817	21
United Kingdom	NDNS	210	3 228	7	87	678	13
Netherlands	VCP_kids	43	1 194	4	39	429	9
Sweden	Riksmaten_1997_98	57	1 055	5	44	487	9
Denmark	Danish_Dietary_Survey	22	315	7	21	233	9
Spain	AESAN	39	709	6	32	366	9
Sweden	NFA	67	1 529	4	46	528	9
Netherlands	DNFCS_2003	177	3 485	5	47	554	8
Spain	AESAN_FIAB	36	572	6	32	381	8
Spain	NUT_INK05	24	602	4	21	293	7
Ireland	NSIFCS	61	1 681	4	38	536	7
Czech Republic	SISP04	28	502	6	19	313	6
Cyprus	Childhealth	10	244	4	9	179	5
Italy	INRAN_SCAI_2005_06	15	1 085	1	13	462	3
Finland	STRIP	10	917	1	9	331	3
Bulgaria	NUTRICHILD	12	511	2	8	308	3
Spain	enKid	6	385	2	6	248	2
Hungary	National_Repr_Surv	10	536	2	8	357	2
Greece	Regional_Crete	6	376	2	5	257	2
Finland	FINDIET_2007	5	1 042	0	5	400	1
Finland	DIPP	5	925	1	5	413	1
Latvia	EFSA_TEST	5	1 300	0	5	488	1
France	INCA2	1	1 251	0	1	570	0
Belgium	Diet_National_2004	0	2 229	0	0	750	0
Belgium	Regional_Flanders	0	940	0	0	360	0
Germany	DONALD_2006_2008	0	3 769	0	0	680	0

Table 13: Dietary exposure estimates for scenario 1

Age class	Number of surveys	Average			95th percentile		
		Minimum	Median	Maximum	Minimum	Median	Maximum
Lower bound (ng/kg bw per day)							
Toddlers	7 (4)	55	92	131	94	178	241
Children (3-10 years)	15	51	73	118	78	135	207
Adolescents	12	34	51	67	60	89	112
Women (18–45 years)	15	31	38	58	51	69	119
Men (18–45 years)	15	34	45	55	56	81	103
Other adults (45–65 years)	14	30	39	50	52	71	88
Elderly and very elderly	6	27	33	43	47	57	68
Middle bound (ng/kg bw per day)							
Toddlers	7 (4)	72	111	145	108	203	253
Children (3-10 years)	15	57	81	127	86	147	223
Adolescents	12	37	55	70	65	95	121
Women (18–45 years)	15	33	41	61	55	73	126
Men 18–45 years)	15	37	49	59	59	85	109
Other adults (45–65 years)	14	33	42	52	55	75	94
Elderly and very elderly	6	29	35	47	51	60	74
Upper bound (ng/kg bw per day)							
Toddlers	7 (4)	88	126	159	135	223	267
Children (3-10 years)	15	63	90	135	94	157	235
Adolescents	12	41	59	74	70	100	127
Women (18–45 years)	15	35	44	64	58	78	132
Men (18–45 years)	15	39	53	64	63	90	115
Other adults (45–65 years)	14	35	45	55	58	79	100
Elderly and very elderly	6	31	38	50	54	64	78

Table 14: Dietary exposure estimates for scenario 2

Age class	Number of surveys	Average			95th percentile		
		Minimum	Median	Maximum	Minimum	Median	Maximum
Lower bound (ng/kg bw per day)							
Toddlers	7 (4)	212	356	516	445	721	817
Children (3-10 years)	15	184	275	393	337	525	766
Adolescents	12	114	150	190	237	288	357
Women (18–45 years)	15	91	125	172	179	225	363
Men (18–45 years)	15	94	118	164	170	204	314
Other adults (45–65 years)	14	95	118	158	172	213	321
Elderly and very elderly	6	90	110	172	169	194	352
Middle bound (ng/kg bw per day)							
Toddlers	7 (4)	235	375	551	487	767	857
Children (3-10 years)	15	198	290	415	363	550	813
Adolescents	12	121	159	201	248	304	381
Women (18–45 years)	15	97	132	182	191	235	388
Men (18–45 years)	15	101	126	175	182	218	335
Other adults (45–65 years)	14	102	126	168	186	224	341
Elderly and very elderly	6	97	116	183	179	206	375
Upper bound (ng/kg bw per day)							
Toddlers	7 (4)	257	395	587	504	812	886
Children (3-10 years)	15	212	306	440	392	584	868
Adolescents	12	128	168	212	259	320	403
Women (18–45 years)	15	104	139	192	200	244	413
Men (18–45 years)	15	108	134	186	193	230	360
Other adults (45–65 years)	14	109	133	179	198	235	364
Elderly and very elderly	6	103	122	195	192	216	396

Table 15: Percentage of average dietary exposure according to the type of packaging and scenario

Age group	Packaging type	Total number of surveys	Number of dietary surveys															
			Scenario 1 % average BPA contribution (middle bound)								Scenario 2 % average BPA contribution (middle bound)							
			< 1 %	1–5 %	5–10 %	10–25 %	25–50 %	5 –75 %	75–90 %	>90 %	< 1 %	1–5 %	5–10 %	10–25 %	25–50 %	50–75 %	75–90 %	>90 %
Toddlers	Canned	7	3	0	1	1	2	0	0	0	0	0	0	0	0	1	5	1
	Not canned		0	0	0	0	0	2	1	4	0	0	1	5	1	0	0	0
Children (3-10 years)	Canned	15	3	0	2	3	4	0	0	0	0	0	0	0	0	1	14	0
	Not canned		0	0	0	0	0	4	3	8	0	0	0	14	1	0	0	0
Adolescents	Canned	12	4	0	1	6	2	0	0	0	0	0	0	0	0	1	11	0
	Not canned		0	0	0	0	0	2	6	4	0	0	0	11	1	0	0	0
Women (18–45 years)	Canned	15	4	0	2	5	4	0	0	0	0	0	0	0	0	1	14	0
	Not canned		0	0	0	0	0	4	5	6	0	0	0	14	1	0	0	0
Men (18–45 years)	Canned	15	4	0	1	6	3	1	0	0	0	0	0	0	0	3	12	0
	Not canned		0	0	0	0	1	3	6	5	0	0	0	12	3	0	0	0
Other adults (45–65 years)	Canned	14	4	0	2	5	3	0	0	0	0	0	0	0	0	1	13	0
	Not canned		0	0	0	0	0	3	5	6	0	0	0	13	1	0	0	0
Elderly and very elderly	Canned	7	3	0	0	2	2	0	0	0	0	0	0	0	0	0	7	0
	Not canned		0	0	0	0	0	2	2	3	0	0	0	7	0	0	0	0

4.5.3. Exposure from non-dietary sources

For non-food sources in addition to oral exposure, also inhalation and dermal absorption have to be considered as routes of exposure. Inhalation is a relevant route for the sources outdoor and indoor air. Both ingestion and inhalation can occur for dust. Dermal exposure has to be considered for BPA present on the surface of consumer products, such as thermal paper, or in cosmetics. If source concentrations are high, dermal exposure may also be relevant for dust and air. As a first step, all possible non-food sources of exposure were assessed with regard to their concentrations, migration and transfer potential for BPA (see Section 4.3.3). For the quantitative assessment the most important source/route combinations have been selected that most probably will contribute to daily exposure. They are listed in Table 16 and the relevant population groups are given for each source/route combination. All the equations used to calculate exposure from the non-food sources are given in Appendix F.

Table 16: Overview of sources, population groups exposed and routes considered in the quantitative assessment

Exposure routes	Sources and population groups exposed				
	Air	**Dust**	**Thermal paper**	**Toys**	**Cosmetics**
Inhalation	All ages	All ages	n/a	n/a	n/a
Oral	n/a	All ages excluding newborn infants	All ages excluding infants [(a)]	Infants and toddlers [(a)]	n/a
Dermal	n/a	n/a	All ages excluding infants and toddlers	n/a	All ages

n/a, not relevant for this route for all age groups.
(a): Indirect contact.

The following sources have not been assessed quantitatively: surface water ingestion, dermal exposure from water (both surface and tap water, e.g. during bathing and showering), dermal exposure to toys, dust, solid consumer products in which BPA is incorporated into the matrix, cigarette filters (ingestion, inhalation), thermal paper mouthed by children and medical devices including dental materials, for the following reasons. Surface water ingestion while swimming can be regarded as minor on both an acute and a chronic level compared with other sources such as drinking water. In addition, dermal exposure through surface water is negligible compared with dermal exposure to, for example, thermal paper. Dermal exposure from toys can be considered negligible because very few toys are made from PC (KEMI, 2012). From the few toys made of PC, migration to sweat was reported to be very low (KEMI, 2012). Dermal exposure to dust and solid consumer products (e.g. toilet paper, CDs) other than thermal paper can be neglected, because, compared with other dermal sources such as thermal paper, exposure to BPA from these sources is extremely low (e.g. 3 g of dust contain the amount of BPA that is transferred by one handling of thermal paper to one finger). Cigarette filters are suspected to be a source of exposure (Braun et al., 2011), but no evidence could be found that BPA is actually used in cigarette filters. Children chewing paper receipts is assumed to occur only sporadically, so that no chronic exposure results. Medical devices are dealt with by SCENIHR in a separate opinion and do not represent a chronic exposure pathway for the whole population. Dental materials that are commonly used in dental surgery both for children and adults, as dental fillers (adults) or as fissure sealants (children) were not found to be a source of chronic exposure either (see Section 4.3.3).

An average and a high scenario were calculated for all sources. For the average scenario, an attempt was made to choose average values for all parameters, including parameters describing frequency of use. For the high scenario, the same average parameters were used for absorption rates and occurrence data, but, in

line with the methodology used to assess exposure from food, the frequency of use parameters were modified to account approximately for a 95th percentile of the population. If not mentioned otherwise, the arithmetic mean was used for each parameter, but in some cases only medians and percentiles were available. In order to follow a similar approach to that of exposure from food, behavioural parameters were derived considering both users and non-users in the general population. The estimates for average and high exposure are included in Table 22 and 23.

For calculations for specific population groups (e.g. users of pacifiers with PC shields), behavioural data were taken only from the group of users (see Table 18).

Exposure estimates were given per kilogram body weight. For the different age groups, different default body weights were used. For infants, the default body weight of 5 kg for one- to three-month-old infants was used (EFSA Scientific Committee, 2012). For toddlers, the default body weight of 12 kg for one- to three-year-old children was used (EFSA Scientific Committee, 2012). For children and adolescents, default values of 30 kg for nine-year-old children and 44 kg for 15-year-old adolescents were used (van Engelen and Prud'homme de Lodder, 2007). For adults, the default body weight of 70 kg was used (EFSA Scientific Committee, 2012).

4.5.3.1. Ingestion

The non-food sources evaluated for ingestion include dust, toys and other articles intended to be mouthed (infants, toddlers) and transfer from hands to food after touching of thermal paper by the parent. For the calculation of external exposure only the most significant sources, ingestion of dust and mouthing of toys, were used. For ingestion, an absorption fraction of 1 was used.

Dust

For the average and the high scenario, the average BPA concentrations (C_{dust}) derived in Section 4.3.3 were multiplied with average dust ingestion rates (q_{dust}) according to the Exposure Factors Handbook (EPA, 2011) for the average and according to Oomen et al. (2008) for the high exposure (see Table 17), respectively, and divided by age-specific body weights (bw) as described above. Newborn infants (0–5 days) were assumed not to be exposed to dust via ingestion but only to fine dust in air (included in the calculation for air). Dust ingestion rates are commonly derived from soil ingestion rates as a proxy and thus are considered quite uncertain (Trudel et al., 2008).

The following equation was used to derive the exposure estimates:

$$E_{dust} = \frac{C_{dust} \times q_{dust}}{bw}$$

Table 17: Values for dust ingestion (mg/day) according to Exposure Factors Handbook (EPA, 2011) (average scenario) and according to Oomen et al., 2008 (high scenario) and estimates for exposure from dust (ng/kg bw per day)

Age group	Average scenario		High scenario	
	q_{dust}	E_{dust}	q_{dust}	E_{dust}
Infants	30	8.8	50	14.6
Toddlers	60	7.3	100	12.2
Children	60	2.9	100	4.9
Adolescents	60	2.0	100	3.3
Adults	30	0.6	50	1.0

The derived exposure values range from 0.6 ng/kg bw per day in adults to 8.8 ng/kg bw per day in infants for the average scenario. The CEF Panel considered that these are likely to be overestimated, because in the original studies soil and dust ingestion rates could not be determined separately, and so conservative assumptions have been made when deriving the dust ingestion rates. In the high scenario the exposure ranged from 1.0 ng/kg bw per day (adults) to 14.6 ng/kg bw per day (infants). It should be noted, that the high scenario is not intended to reflect situations in houses with high BPA concentrations in dust but addresses only variation owing to behavioural aspects.

Toys (rattles) and pacifiers with PC shields

Data for migration of BPA into saliva from rattles and pacifiers with PC shields was used for this assessment (see Section 4.3.3). The amount of substance migrating from pacifiers was adjusted to 24 hours by linear extrapolation from the incubation time of 7.75 hours. For rattles no extrapolation was needed, as the incubation time was 24 hours. The resulting amount of substance that leached over 24 hours from a product ($q_{product}$) was used in the equation below: 141.2 ng for rattles and 987.1 ng for pacifiers. Then, the migration over 24 hours for the average scenario was corrected by average or high daily sucking times, yielding a fraction of the day that the rattle or pacifier is sucked (f_{time}).

Sucking times of toys, including pacifiers, were determined for 42 Dutch children by Groot et al., 1998. Their findings have been used to develop Dutch reference values reported in Bremmer and van Veen (2002), which attempt to calculate exposure for the P75. These are the only data available for Europe and thus should be preferred. However, since Bremmer and van Veen report only P75 sucking times, and Groot et al. (1998) only observed sucking during the day, their data could not be used for assessing average sucking times and sucking times for pacifiers. Therefore, data on a larger study conducted on 385 US children aged 0–36 months (Juberg et al., 2001) were also considered. For the average exposure from plastic toys, sucking times for all participants (users and non-users) as reported by Juberg et al. (2001) were used. For the high exposure, P75 daily sucking times reported by Bremmer and van Veen (2002) (see Table 18) have been used. To calculate exposure from pacifiers with PC shields for toddlers (specific user group), the P75 for the user group was directly taken from Juberg et al. (2001).

In the migration experiments the toys were completely submersed. Therefore, in order to account for realistic exposure situations, it was further assumed that for toys (rattles) only 50 % of the toy surface is sucked ($f_{surface}$: 0.5). For pacifiers only the shield and ring are made of PC. Therefore, the available surface was assumed to be 25 % ($f_{surface}$: 0.25; only one side and only parts of the shield that are near to the mouth—approach according to Lassen et al., 2011). The following equation was used to assess exposure to toys and pacifiers with PC shields:

$$E_{toy} = \frac{q_{product} \times f_{time} \times f_{surface}}{bw}$$

Table 18: Values for factors dealing with sucking times, f_{time}, and estimates for exposure from toys and pacifiers with PC shields

Age group	Average scenario			High scenario		
	f_{time} (per day)	Reference	E_{toy} (ng/kg bw per day)	f_{time} (per day)	Reference	E_{toy} (ng/kg bw per day)
Infants (toys)	0.012	Juberg et al., 2001	0.2	0.04	Bremmer and van Veen, 2002	0.6
Toddlers (toys)	0.0014	Juberg et al., 2001	0.01	0.0021	Bremmer and van Veen, 2002	0.01
Infants (pacifier)	0.15	Juberg et al., 2001	7.6	0.20	Bremmer and van Veen, 2002	9.8
Infants (pacifier)	0.32	Juberg et al., 2001	6.6	1.49	Juberg et al., 2001	10.0

Using this approach, exposure values of 0.2 and 0.01 ng/kg bw per day for the average and 0.6 and 0.01 ng/kg bw per day for the high scenario for infants' and toddlers' exposure to rattles (as a proxy for PC mouthing toys) were derived.

For pacifiers with PC shields, owing to longer sucking times higher exposure was calculated with 7.6 and 6.6 ng/kg bw per day for the average scenario infants and toddlers, and 9.8 and 10.0 ng/kg bw per day for the high exposure scenario. It must, however, be mentioned that only 10–20 % of the shields of pacifiers may be made of PC, so that this exposure value is valid only for a specific consumer group (Lassen et al., 2011).

Thermal paper: transfer to food

After touching thermal paper, e.g. during shopping, BPA on the fingers can be transferred to food and consequently be ingested, either by the person him- or herself or a child. This may happen, e.g. if a parent shops, gets a thermal paper receipt, and directly afterwards eats a fruit or gives a piece of fruit to a toddler or child. In Biedermann et al. (2010) the transfer of BPA from contaminated hands back to dry paper was investigated and no BPA was detected (< LOD). However, as the same study revealed that transfer to wet and greasy fingers was much higher than that to dry fingers, transfer to more lipophilic and/or wet surfaces, such as to food, cannot be compared with dry paper.

No experimental data are available for transfer to food after touching thermal paper. In order to investigate this pathway, a transfer of 1 % from skin (f_{trans}) to food was hypothesised. It was assumed that a fraction of 1 is available for transfer (f_{avail}).These fractions were combined with the assumption that two, two and four transfer events ($q_{handling}$) for toddlers, children and adults (adults: e.g. one shopping, one canteen meal or bus ticket), respectively, occur per week (2/7, 2/7 and 4/7 per day) and that three fingers (n_{finger}) have touched the thermal paper. For the transferred amount of BPA from thermal paper to finger (a_{finger}) the mean value given by Lassen et al. (2011) was used, which is 1.4 µg/finger. The following equation was used to calculate exposure:

$$E_{tp\text{-}\,food} = \frac{a_{finger} \times n_{finger} \times f_{avail} \times f_{trans} \times q_{handling}}{bw}$$

This calculation yields exposures of 0.7 (toddlers), 0.3 (children), and 0.3 ng/kg bw per day (adults). Since there are no data available on the frequency of such unfavourable events, or on transfer rates, this exposure estimate was not included in the calculation of exposure for the general public and specific consumer groups. It might, however, serve as a benchmark value.

4.5.3.2. Inhalation

BPA concentrations in outdoor and indoor air are low, with indoor air levels being slightly higher (see Section 4.3.3). For the calculation of an average value, therefore, the assumption was made that people spend 24 hours indoors, therefore including outdoor exposure. Average and high intake rates of air (q_{air}) are taken from the Exposure Factors Handbook (EPA, 2011, long-term inhalation rates, see Table 19). In the calculations it is assumed that airborne particulate matter will fully contribute to the inhalation exposure to BPA. The following equation was used for the assessment:

$$E_{air} = \frac{C_{air} \times q_{air}}{bw}$$

Table 19: Values for air intake rates q_{air} from the Exposure Factors Handbook (EPA, 2011) and estimates for exposure from inhalation

Age group	Average exposure		High exposure	
	q_{air} (m^3/day)	E_{air} (ng/kg bw per day)	q_{air} (m^3/day)	E_{air} (ng/kg bw per day)
Infants	3.6	0.7	7.1	1.4
Toddlers	8.9	0.7	13.7	1.1
Children	12.0	0.4	16.6	0.6
Adolescents	16.3	0.4	24.6	0.6
Adults	16.0	0.2	21.4	0.3

The average exposure values range from 0.2 (adults) to 0.7 ng/kg bw per day (toddlers). High exposure levels range from 0.3 (adults) to 1.4 ng/kg bw per day (infants).

4.5.3.3. Dermal

Thermal paper

In this exposure assessment it was assumed that children (3 - 10 years), adolescents and adults come into contact with thermal paper from shopping/canteen receipts, credit card receipts, bus tickets or parking tickets. The CEF Panel assumed that infants and toddlers (i.e. children < 3 years old) do not regularly shop or ride buses with their own tickets, thus do not regularly come into contact with thermal paper from these sources. Therefore, an exposure assessment for these age groups is not needed. The number of handling events, $q_{handling}$, for adolescents and adults for the high exposure was taken from a usage study by Lassen et al. (2011) (4.6 handlings per day). Handling events for the average exposure were assumed to be one per day for adolescents and adults, deduced from the credit card receipts handled by Danish consumers over the age of 12 years (259 per year) from Lassen et al. (2011). Children were assumed to come into contact

with thermal paper 0.5 times a day in the average exposure and maximally twice a day on a regular basis (assessment of chronic exposure).

The paper is handled mainly by three fingers (n_{finger}) of one (average exposure) or two hands (high exposure). Each finger has a BPA load available for absorption (a_{finger}) of 1.4 µg/handling (Lassen et al., 2011). Thermal paper is covered with BPA only on one side. However, it is assumed that all fingers that touch the thermal paper come into contact with the BPA-containing side. The following equation was used for the assessment:

$$E_{tp\text{-}dermal} = \frac{a_{finger} \times n_{finger} \times q_{handling}}{bw}$$

The estimates of exposure from dermal contact with thermal paper are summarised in Table 20.

Table 20: Values for $q_{handling}$ and estimates for exposure from dermal contact with thermal paper

Age group	Average exposure		High exposure	
	$q_{handling}$ (1/day)	$E_{tp\text{-}dermal}$ (ng/kg bw per day)	$q_{handling}$ (1/day)	$E_{tp\text{-}dermal}$ (ng/kg bw per day)
Children	0.5	68.8	2.0	550
Adolescents	1.0	93.8	4.6	863
Adults	1.0	58.9	4.6	542

From these average assumptions, exposures of 68.8, 93.8 and 58.9 ng/kg bw per day were derived for children, adolescents and adults, respectively. For the high exposure, exposure ranges from 542 (adults) to 863 ng/kg bw per day (adolescents).

Cosmetics

Exposure to cosmetics in the form of body lotion is possible for all age groups. Medians and 95th percentiles for the amounts of body lotion used by adults ($q_{cosmetics}$) were taken from Hall et al. (2007). For infants, toddlers, children and adolescents no data were available for such use of cosmetics. For these age groups the amount used was estimated from the amount used by adults by adjusting them using an appropriate body surface ratio (see Table 21). Mean body surfaces for adults of 1.85 m^2 were taken from Tikuisis et al. (2001) and for the other age groups from van Engelen and Prud'homme de Lodder (2007) (see Table 21). The retention factor, f_{ret}, for leave-on cosmetics is 1. A retention factor characterises a cosmetic regarding the fraction of the substance remaining on the skin (e.g. for rinse-off cosmetics it is 0.1).

The exposure was calculated with the following equation:

$$E_{cosmetics} = \frac{C_{cosmetics} \times q_{cosmetics} \times f_{ret}}{bw}$$

Table 21: Body surfaces, derived parameter values for $q_{cosmetics}$ and estimates for dermal exposure from cosmetics

Age group	Body surface (m^2)	Average exposure		High exposure	
		$q_{cosmetics}$ (g/day)	$E_{cosmetics}$ (ng/kg bw per day)	$q_{cosmetics}$ (g/day)	$E_{cosmetics}$ (ng/kg bw per day)
Infants	0.31	0.77	4.8	1.51	9.4
Toddlers	0.44	1.09	2.8	2.14	5.5
Children	0.84	2.09	2.2	4.09	4.2
Adolescents	1.4	3.48	2.5	6.81	4.8
Adults	1.85	4.60	2.0	9.00	4.0

Average exposure ranges from 2.0 (adults) to 4.8 ng/kg bw per day (infants). High exposure ranges from 4.0 (adults) to 9.4 ng/kg bw per day (infants).

4.5.3.4. Overall external exposures from various routes

External exposure to BPA was estimated by forward exposure modelling. This involved the assessment of chronic exposure (absorbed dose) to BPA through different sources (diet, thermal paper, air, dust, toys, cosmetics) and routes of exposure (oral, inhalation and dermal) in the EU population. Analytical/experimental BPA concentrations were combined with food consumption (including human milk) to estimate dietary exposure and concentration data in and from non-food sources with behaviour patterns to estimate non-dietary exposure. For the oral route, an overall external exposure estimate was derived by adding up the average estimates from different sources. For dermal exposures, direct addition is not appropriate, as absorption depends on the source. For high external exposure, the same procedure was followed. Table 22 and 23 list the average and high external exposure to BPA from all sources in the general population that are to be used in the risk assessment.

Exposure to BPA from further sources was assessed in specific population groups or in consumers with specific consumption patterns. The aim was to identify possible additional sources of exposure to BPA that could lead to levels of exposure significantly higher than those estimated for the general population. Average and high exposures from these further sources are presented in Table 24. In a few cases, exposure from these further sources was higher, as was the case for infants fed using old PC baby bottles and infants living in buildings with old water pipes repaired with epoxy resins and fed with formula reconstituted with tap water. For the purpose of risk characterisation, the CEF Panel has carried out an assessment of aggregated oral and dermal exposure (the two main routes of exposure) to BPA using PBPK modelling (see Section 3.1.7.3. PBPK modelling of aggregated oral and dermal exposure in Part II – Toxicological assessment and risk characterisation of this opinion).
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).

Table 22: Average external exposure to BPA from all sources in the general population (ng/kg bw per day)

Source	Infants (0–6 months), breastfed			Infants (0–6 months), formula fed	Infants (6–12 months)	Toddlers (1–3 years)	Children (3–10 years)	Adolescents (10–18 years)	Women (18–45 years)	Men (18–45 years)	Other adults (45–65 years)	Elderly/ very elderly (65 years and over)
	1–5 days	6 days to 3 months	4–6 months									
Ingestion												
Dust (average)		8.8	8.8	8.8	8.8	7.3	2.9	2.0	0.6	0.6	0.6	0.6
Toys (average)		0.2	0.2	0.2	0.2	0.01						
Dietary exposure from food and beverages (average)	225	165	145	30	375	375	290	159	132	126	126	116
Sum of all ingestion sources (average)	225	174	154	39	384	382	293	161	133	127	127	117
Inhalation												
Air (average)	0.7	0.7	0.7	0.7	0.7	0.7	0.4	0.4	0.2	0.2	0.2	0.2
Dermal												
Thermal paper (average)							68.8	93.8	58.9	58.9	58.9	58.9
Cosmetics (average)		4.8	4.8	4.8	4.8	2.8	2.2	2.5	2.0	2.0	2.0	2.0

Table 23: High external exposure to BPA from all sources in the general population (ng/kg bw per day)

Source	Infants (0–6 months),breastfed			Infants (0–6 months), formula fed	Infants (6–12 months)	Toddlers (1–3 years)	Children (3–10 years)	Adolescents (10–18 years)	Women (18–45 years)	Men (18–45 years)	Other adults (45–65 years)	Elderly/ very elderly (65 years and over)
	1–5 days	6 days to 3 months	4–6 months									
Ingestion												
Dust (high)		14.6	14.6	14.6	14.6	12.2	4.9	3.3	1.0	1.0	1.0	1.0
Toys (high)		0.6	0.6	0.6	0.6	0.01						
Dietary exposure from food and beverages (high)	435	600	528	80	857	857	813	381	388	335	341	375
Sum of all ingestion sources (high)	435	615	543	95	872	869	818	384	389	336	342	376
Inhalation												
Air (high)	1.4	1.4	1.4	1.4	1.4	1.1	0.6	0.6	0.3	0.3	0.3	0.3
Dermal												
Thermal paper (high)							550	863	542	542	542	542
Cosmetics (high)		9.4	9.4	9.4	9.4	5.5	4.2	4.8	4.0	4.0	4.0	4.0

Table 24: Average and high exposure from further sources in specific population groups (ng/kg bw per day)

Source		Infants (0–6 months), breastfed			Infants (0–6 months), formula fed	Infants (6–12 months)	Toddlers (1–3 years)	Children (3–10 years)	Adolescents (10–18 years)	Women (18–45 years)	Men (18–45 years)	Adults (45–65 years)	Elderly/ very elderly (65 years and over)
		1–5 days	6 days to 3 months	4–6 months									
Residents of buildings with old water pipes repaired with epoxy resins	Average					2.7	2.7	1.9	1.1	1.0	0.8	0.9	1.1
	High					29	29	21	12	11	8	9	12
Users of PC tableware	Average					6	6	4	2	2	2	2	2
	High					14	14	9	5	5	4	5	4
Users of PC kettles	Average				53	0.11	0.11	0.13	0.32	1.02	0.59	0.63	0.77
	High				94	5.98	5.98	4.96	4.77	8.01	7.31	9.12	8.48
Consumers of water from PC filters	Average					1.1	1.1	0.8	0.4	0.4	0.3	0.3	0.4
	High					3.8	3.8	2.8	1.6	1.6	1.4	1.3	1.1
Consumers of water from water coolers with PC recipients	Average					22	22	16	9	8	6	7	9
Users of PC baby pacifiers	Average	8	8	8	8	8	7						
	High	10	10	10	10	10	10						
Infants fed with formula in old PC baby bottles	Average				143								
	High				426								
Infants consuming herbal tea prepared with water warmed in a PC kettle	Average	6	6	6									
	High	12	12	12									
Users of cookware	Average					19	19	14	8	6	7	6	6
Users of cookware	High					46	46	28	16	15	14	15	14

4.6. Biomonitoring and backward exposure calculation

4.6.1. General introduction

Biomonitoring denotes the determination of substance concentrations in human body fluids, excrement or tissues such as blood, urine, mother's milk, etc. Measurements in blood and urine are usually used as a measure of exposure, whereas measurements in mother's milk also serve as source concentrations for breastfed infants. A number of sensitive analytical methods have been developed to measure low concentrations including trace amounts of BPA in biological samples such as urine and blood (Dekant and Völkel, 2008; WHO, 2011b; Asimakopoulos et al., 2012), which are by far the most appropriate biological matrices for human biomonitoring (Angerer et al., 2007).

By using toxicokinetic considerations and parameters such as blood volume and/or daily urine excretion, biomonitoring measurements can be transformed into human exposure estimates. In contrast to source-to-dose modelling this "backward exposure calculation" integrates exposure from all sources and via all uptake routes (Angerer et al., 2007; Hengstler et al., 2011). Therefore, it is an appropriate tool to validate the external exposure estimates that were derived by forward exposure calculation. In the following subsections an overview of biomonitoring of BPA in different matrices will be given first and then a comparison of forward and backward exposure calculation will be presented.

For the translation of biomonitoring data into daily exposure estimates apart from the quantification of BPA-related biomarkers in relevant matrices, a detailed understanding of the potential analytical/methodological pitfalls (see Appendix A) and of the toxicokinetics of BPA is needed. As a non-persistent chemical with an elimination half-life of a few hours, BPA is rapidly removed from circulation via conjugation and subsequent renal excretion (Völkel et al., 2002; Doerge et al., 2010c). Toxicokinetic studies with oral (gelatine capsule) administration of stable isotope-labelled BPA in humans have shown that BPA is almost completely excreted in urine in the conjugated form and that the elimination process is essentially complete within 24 hours of exposure (Völkel et al., 2002, 2008). Despite still disputed (Vandenberg et al., 2010), these studies show that BPA is metabolized and excreted via the urinary pathway. Urine is therefore the matrix of choice for biomonitoring, and the urinary concentration of total (unconjugated plus conjugated) BPA is the biomarker of choice to estimate BPA exposure (Calafat et al., 2008). Information on the presence and concentration of unconjugated and total BPA in serum is useful, and will also be compiled in this section, in order to inform toxicological risk assessment. However, given the low exposure in the ng/kg bw range, the high first-pass metabolism in the liver after oral exposure, and the elimination characteristics of BPA, low serum concentrations of unconjugated and total BPA are to be expected. Also compiled in this section is information on unconjugated and total BPA in human milk to enable the estimation of BPA exposure in breastfed infants.

4.6.2. Biomonitoring studies on urinary levels

4.6.2.1. Methodological aspects

Data on urinary levels of total BPA in humans were retrieved from scientific journals, from official websites of national health surveys (e.g. NHANES, CHMS, German Federal Environment Agency, Flemish human biomonitoring programme), and from as yet unpublished sources (e.g. DEMOCOPHES). The quality criteria for urinary BPA data were assessed, and a literature quality table was developed for the methodical aspects and study aspects. The quality of each study was assessed on the basis of the criteria given in Appendix I.

As a general rule, only data published from 2006 onwards were considered. Since then, substantial methodological improvements have been achieved in terms of both sensitivity and specificity by using MS-based analytical techniques. Moreover, efforts have been improved/implemented to preserve sample integrity and to reduce external contamination; more recent data should therefore be of higher quality than older data. Furthermore, the more recent data will provide a more up-to-date indication of the current exposure to BPA.

A specific inclusion criterion for data on urinary BPA is that the biomonitoring studies have been performed in the European region. Only these data are included for estimating daily exposure to BPA for different age groups of the European populations. The data from NHANES and CHMS are also considered for comparative purposes to provide reference values on average and high concentrations of total BPA in urine.

To compare the distribution characteristics of the urinary concentration of total BPA between the different studies, box-percentile plots (Esty and Banfield, 2003) comprising the 5th, 12.5th, 25th, 37.5th, 50th, 62.5th, 75th, 87.5th and 95th percentiles are used. In contrast to the practice in the food area (see Section 4.3.2), the geometric mean (GM) rather than arithmetic mean (AM) was chosen as a measure of central tendency of the distribution for several reasons. Firstly, the urinary concentration of total BPA is approximately log-normally distributed (Figure 4), so that the GM rather than the AM is the most appropriate measure of central tendency. Secondly, since the GM of a log-normal distribution equals the median, the median can be used instead in cases when only the median is reported. Finally, biomonitoring studies on urinary BPA always report the GM and/or the median, whereas the AM is only rarely given. The GM and the 95th percentile of the volume-based total BPA concentrations are used to derive estimates of average and high daily BPA exposures. For comparative purposes, daily BPA exposures are also calculated from creatinine-based BPA concentrations.

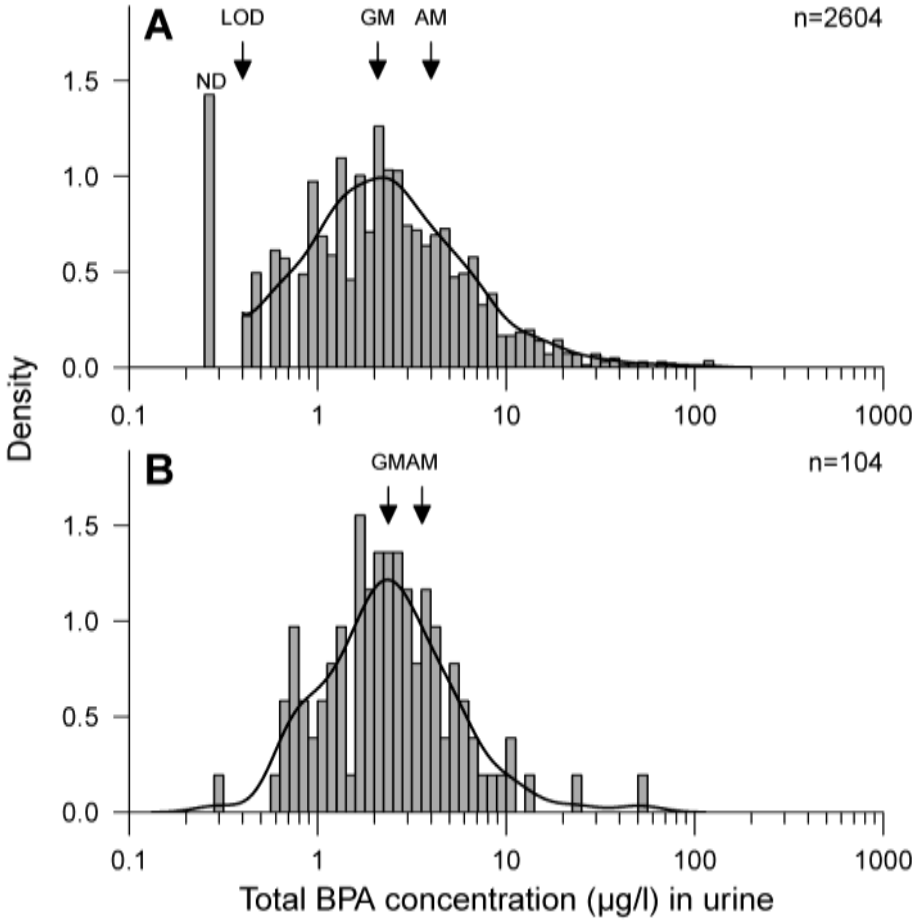


Figure 4: Log-normal distribution shape of urinary BPA concentration. Shown are the histogram and density plot of the total BPA concentration in urine for two example datasets. (A) NHANES 2005–2007 data for the total US population. (B) children of the Duisburg birth cohort study (Kasper-Sonnenberg et al., 2012). Arrows indicate the location of the geometric mean (GM), arithmetic mean (AM), and the limit of detection (LOD). The number of subjects (n) is also given. ND, fraction of non-detects.

Information about the specific distribution characteristics of urinary BPA concentration has consequences on how to handle left-censored data, i.e. observations below the limit of detection. Using an LB approach (i.e. setting all undetected observations to zero) would make the GM calculation unfeasible, whereas the UB approach (i.e. setting them to the LOD) would introduce a positive bias and, thereby, would overestimate the average concentration. Hornung and Reed (1990) showed that the substitution of non-detectable values by LOD/√2 is most appropriate for log-normally distributed data with moderate geometric standard deviations (GSD < 3) and low non-detection rates (<30 %). For larger GSD values, the MB approach (i.e. setting the nondetectable values to LOD/2) is recommended (Hornung and Reed, 1990).

The GSD, which is a unit-less multiplicative factor, is only very rarely reported in the biomonitoring studies on urinary BPA. However, for the freely available raw data of NHANES (NHANES, online), the GSD can be calculated. Using the volume-based urinary BPA concentrations of the survey periods from 2003 to 2010 and a grouping in four age classes (Figure 7), the average GSD can be calculated to be 2.9 ± 0.2 (mean ± SD, range 2.5–3.1, n = 16 GSD values). Consequently, also taking into account the low non-detection rates (2.4–12 %; Figure 7), the replacement of non-detectable values by LOD/√2 is recommended according to Hornung and Reed (1990), and this setting has also been chosen by NHANES (Lakind et al., 2012). Using a value of LOD/2 instead of LOD/√2 for imputation would lower the GMs in Figure 7 by only 2.5 ± 1.2 % (n = 16, range 0.7–4.7 %), which is a negligible effect. In conclusion, according to Hornung and Reed (1990) the impact of the imputation procedure is negligible as long as the non-detection rates do not exceed 15 %.

The above decision of using the GM leads to an estimate for the average daily BPA exposure that is lower than the AM-based estimate. The reason for this so-called AM–GM inequality is the log-normal distribution shape of the urinary BPA data. To convert GM-based estimates into AM-based estimates, which are then comparable to those derived from the forward exposure calculation, a multiplicative conversion factor of $k = \exp[0.5 \times LN(GSD)]$ is introduced. Using the GSD values of the NHANES data (see above), an average value for k of 1.7 ± 0.1 (n = 16, range 1.5–1.9) is available, which is well in line with the directly calculated average AM/GM ratio of 1.9 ± 0.4 (n = 16). Additional information on the AM/GM ratio is obtained from CHMS 2007–2009 with an average value of 1.9 ± 0.1 (n = 4) and from a few European studies with values of 1.5 from the Duisburg cohort study (Monika Kasper-Sonnenberg, Ruhr University Bochum, Germany, 2013, personal communication), and 1.8 from the German Environmental Survey for Children (GerES IV). A conversion factor of 1.8 is therefore used in this opinion to convert GM-based estimates into AM-based estimates.

For NHANES, descriptive statistics were calculated for specific age classes (see Section 4.5.1) by using the statistical computing environment R (R Core Team, 2012) in combination with the R survey package (Lumley, 2004, 2012), which was used, for example, by Lakind et al. (2012). The outcome of the statistical procedures was checked by comparing the predictions for the default NHANES age groups with published data (CDC, 2012). All graphical figures were generated using the R lattice package (Sarkar, 2008).

4.6.2.2. Urinary BPA concentrations (volume-based data)

Since 2006, a relatively large number of data on total BPA concentration in urine have become available in selected populations from various regions, including North and South America, Europe, Africa, Asia and Australia (see literature quality table in Appendix I). The studies comprise large-scaled, population-based cross-sectional studies and a spectrum of smaller scale studies on specific population groups, usually from a single location or region, as well as retrospective studies and prospective longitudinal studies. The following overview includes only studies performed in the European region. Data from the North American Surveys, NHANES and CHMS, are also used for comparative purposes.

As shown in Figure 5, European human biomonitoring (HBM) data on urinary total BPA are available from GerES IV (Becker et al., 2009; Kolossa-Gehring et al., 2012), the German Environmental

Specimen Bank (ESB) study (Koch et al., 2012; Kolossa-Gehring et al., 2012), the Duisburg birth cohort study (BCS) (Kasper-Sonnenberg et al., 2012), two Munich studies (Völkel et al., 2008, 2011), the Austrian HBM study (Hohenblum et al., 2012), the Flemish and Liege HBM studies (Milieu en Gezondheid, 2010; Pirard et al., 2012; Schoeters et al., 2012), the Generation R (Rotterdam) study (Ye et al., 2008a), the Norwegian mother and child birth cohort (MoBa) study (Ye et al., 2009a), the Spanish environment and childhood (INMA) project (Casas et al., 2011), the French Elfe pilot study (Vandentorren et al., 2011) and the Italian InCHIANTI study (Galloway et al., 2010). Findings from the European-wide pilot study DEMOCOPHES (Joas et al., 2012) are shown in Figure 6.

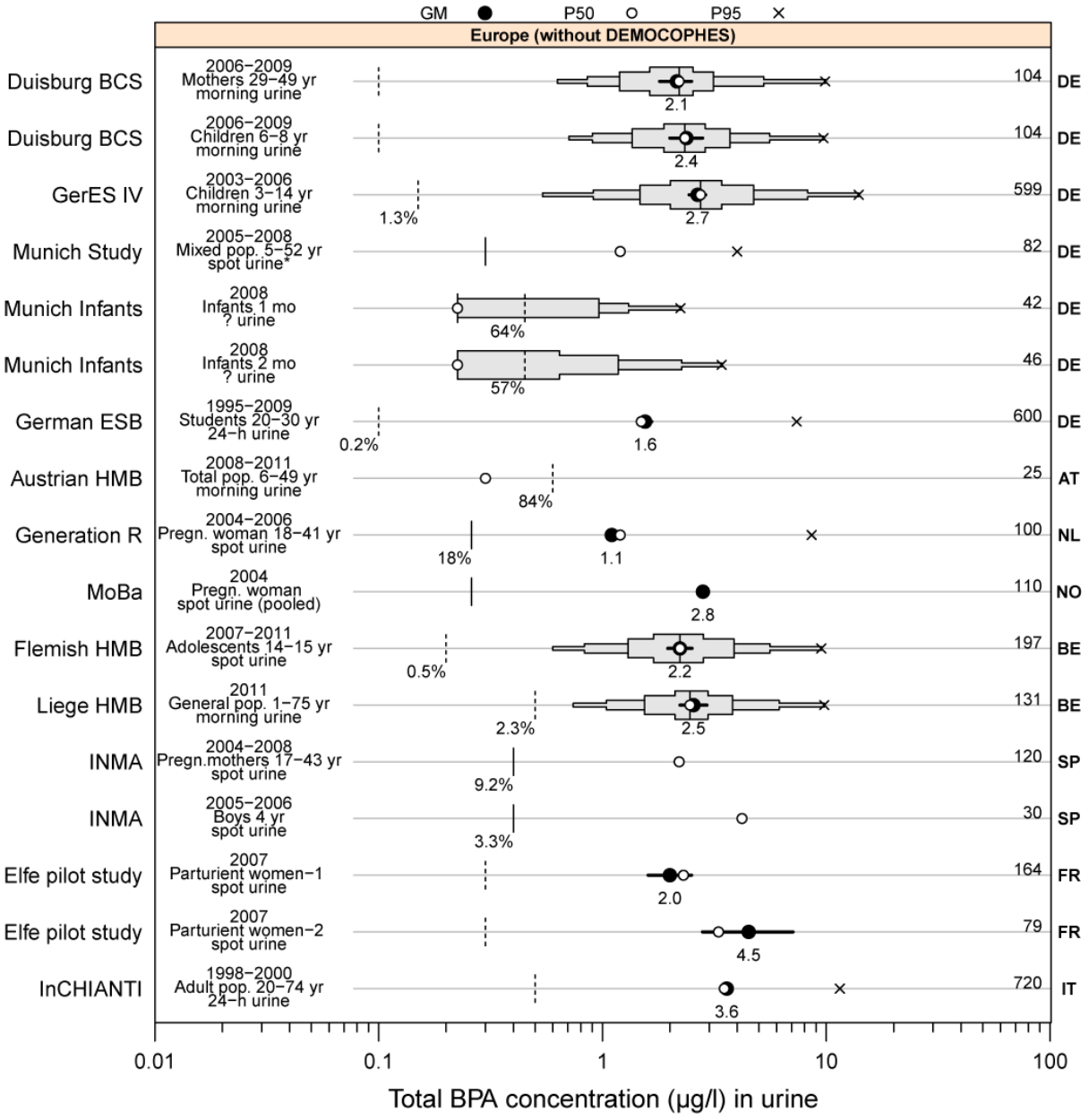


Figure 5: Urinary BPA concentrations of European studies (without DEMOCOPHES, see Figure 6). Shown are the concentrations of total urinary BPA from different European studies. Box-percentile plots (grey-shaded areas) show the distributional characteristics comprising the 5th, 12.5th, 25th, 37.5th, 50th, 62.5th, 75th, 87.5th, and 95th percentiles. Filled circles with associated values and error bars indicate the GMs and the 95 % confidence intervals. The 50th and 95th percentiles are shown by

open circles and crosses. The number of subjects is given on the right. Vertical solid and dashed lines indicate the LOD and the LOQ, respectively. The proportion of measured values below the LOD (or LOQ) is given as a percentage. Also given are the sampling periods and sampling populations, and the kind of urine sampling ("?" means that no information on the urine sampling was available).

The GerES IV is a representative study focusing on the chemical exposure of children (Becker et al., 2009; Kolossa-Gehring et al., 2012). Morning urine samples were collected from 3- to 14-year-old children in 2003–2006. The concentration of total BPA was measured by GC-MS/MS with a LOQ of 0.15 µg/L. BPA was detected in 98.7 % of the n = 599 samples with a GM of 2.7 µg/L and a 95th percentile of 14.0 µg/L (Becker et al., 2009) (Figure 5). The uncertainty in the GM as expressed by the 95th percentile confidence interval corresponded to a relative margin of error of 8–9 %. An analysis by age groups revealed a significantly higher BPA concentration (GM 3.55 µg/L) in the age category 3–5 years compared with the 6–8 years, 9–11 years and 12–14 years age categories (GM 2.22–2.72 µg/L).

By using historical samples from the German ESB, Koch et al. (2012) analysed retrospectively the extent of BPA body burden in the German population from 1995–2009 based on a total of 600 24-hour urine samples. According to the ESB concept, samples were taken annually from approximately 60 male and 60 female students (20–30 years old) in each of four university cities. Total and unconjugated BPA was determined by high-performance liquid chromatography (HPLC)-MS/MS with an LOQ of 0.1 µg/L. In the stored urine samples, total BPA was quantifiable in 99.8 % with a GM of 1.6 µg/L (relative margin of error 7 %) and a 95th percentile of 7.4 µg/L (Koch et al., 2012) (Figure 5). Unconjugated BPA was quantifiable in <15 % of the samples. Total BPA concentrations (GM) decreased over time from 1.9 µg/L in 1995 to 1.3 µg/L in 2009, but 24-hour urine volumes (mean) increased from 1.6 litres in 1995 to 2.1 litres in 2009. The derived daily exposures therefore remained rather constant at a GM of 39 ng/kg bw per day (95 % confidence interval (CI) 37–42 ng/kg bw per day) and a 95th percentile of 171 ng/kg bw per day.

Within the framework of the Duisburg BCS, 208 morning urine samples of 104 mother–child pairs (29–49 and 6–8 years old) were collected in 2006–2009 (Kasper-Sonnenberg et al., 2012). Total BPA was measured by liquid chromatography (LC)-MS/MS with an LOQ of 0.1 µg/L. Total BPA was quantifiable in all samples. The GM concentration was 2.1 µg/L (95 % CI 1.8–2.5 µg/L) in the mothers and 2.4 µg/L (95 % CI 2.0–2.8 µg/L) in the children (Figure 5); the relative margin of error was 14–19 %. The 95th percentile of total urinary BPA was 8.4 µg/L for the mothers and 9.7 µg/L for the children. The BPA concentrations between children and mothers showed a low but significant correlation ($r_{Spearman}$ = 0.22, P-value ≤ 0.05).

In the Munich infants study (Völkel et al., 2011), women who were participating in a birthing class in Munich were randomly selected, and 47 mother–infant pairs finally entered into the study. Urine was sampled from each infant at one month and two months of age in 2008. Total and unconjugated BPA was measured by HPLC-MS/MS with a LOQ of 0.45 µg/L. Unconjugated BPA was detectable in only 3.3 % of the samples. Total BPA was detected in 35.7 % of the first-month samples and in 43.5 % of the second-month samples (Figure 5). The 95th percentile of total urinary BPA for the first-month and second-month samples was 2.2 µg/L (n = 42) and 3.4 µg/L (n = 45), respectively. Note that these 95th percentile values are different from those reported in the study (9.6 and 5.1 µg/L) in which the subset of detectable values was used to derive the 95th percentile. The distributional shape of the total BPA concentration was quite unusual with a 95th percentile more than 10- to 15-fold higher than the median (Figure 5). A typical range for the 95th to 50th percentile ratio from other studies is 5–6.

The second Munich study (Völkel et al., 2008) analysed spot urine samples from different sources, comprising 62 (multiple) samples from 21 co-workers (19–52 years old) as well as single samples from 31 women (18–41 years old) and 30 children (5–6 years old). The samples were collected in 2005–2008. Total BPA was measured by HPLC-MS/MS with a LOQ of 0.3 µg/L. The median concentration and 95th percentile of this heterogeneous dataset was 1.2 and 4.0 µg/L, respectively (Figure 5).

The first population-based HBM study in Austria (Hohenblum et al., 2012) was performed in 2008–2011 and included 150 volunteers (6–49 years old) from 50 families from five different Austrian regions. Ten woman–child–man groups living in the same household were randomly selected per region. Twenty-five out of 100 collected first morning urine samples were analysed for total urinary BPA concentration. Questionnaire data were used to pre-select participants who might have a higher exposure (e.g. owing to occupation, frequent use of canned food/beverages, use of plastic bottles). Total BPA was quantified by HPLC-MS/MS with an LOQ of 0.6 µg/L. Total BPA was detected in 16 % of the samples; the maximum BPA concentration was 11 µg/L (Figure 5). The detection rate was remarkably low compared with the typical rates reported in other European studies.

The Flemish Environment and Health Survey 2007–2011 cycle 2 (FLEHS II) focused on obtaining reference values for a wide range of age-specific biomarkers of exposure in a representative sample of the Flemish population (Schoeters et al., 2012). BPA data from FLEHS II were provided by the Flemish Center of Expertise on Environment and Health, financed and steered by the Ministry of the Flemish Community. BPA was measured in spot urine samples of n = 197 adolescents (14–15 years old) by GC-MS with an LOQ of 0.2 µg/L (Milieu and Gezondheid, 2010). Total BPA was detected in 99.5 % of the samples. After adjusting for age, gender and urinary creatinine, a GM for the total BPA concentration of 2.2 µg/L (relative margin of error 12–13 %) was obtained (Figure 5). The 95th percentile was 9.5 µg/L.

The Liege HMB study analysed urinary levels of environmental contaminants of a general Belgian population (1–75 years old) living in Liege and surrounding areas (Pirard et al., 2012). Morning urine samples were collected in 131 subjects in 2011, and total urinary BPA was quantified by GC-MS/MS with a LOQ of 0.50 µg/L. Total BPA was quantifiable in 97.7 % with a GM of 2.6 µg/L and a 95th percentile of 9.8 µg/L (Figure 5). BPA levels in urine of people living in the same home and collected at the same time were fairly well correlated ($r_{\text{Pearson}} = 0.88$).

The Generation R study is a population-based birth cohort study in Rotterdam (Jaddoe et al., 2007). Multiple spot urine samples were collected from 9 778 pregnant women (18–41 years old) at 21–38 weeks of gestation. BPA was measured in a subset of urine samples collected from 100 women after 20 weeks of gestation in 2004–2006 (Ye et al., 2008a). BPA was quantified by GC-MS/MS with a LOD of 0.26 µg/L. Total BPA was detected in 82 % of the samples with a GM of 1.1 µg/L and a 95th percentile of 8.6 µg/L (Figure 5).

Within the framework of the Norwegian MoBa study, 110 urine spot samples were collected in 2004 from pregnant women at 17–18 weeks of gestation (Ye et al., 2009a). Urine samples from groups of 11 subjects each were combined to make 10 pooled samples. As in the Generation R study, BPA was quantified by GC-MS/MS with a LOD of 0.26 µg/L. The GM of the total BPA concentration in the 10 pooled samples was 2.8 µg/L (Figure 5).

The INMA (Infancia y Medio Ambiente) project is a population-based birth cohort study in Spain. 120 pregnant women (17–43 years old) were selected at random from four different regions, and 30 children (4-year-old boys) were selected from a fifth region (Casas et al., 2011). Spot urine samples were collected from the women during the third trimester of pregnancy in 2004–2008, and from the children in 2005–2006. Urinary BPA was quantified by HPLC-MS/MS with a LOD of 0.4 µg/L. In the pregnant women, total urinary BPA was detected in 90.8 % of the samples with a median concentration of 2.2 µg/L (Figure 5). The children had a median concentration of 4.2 µg/L; the detection rate was 96.7 %.

The French longitudinal study of children (Elfe: Etude Longitudinale Française depuis l'Enfance) is a national cohort study examining the effects of environmental exposure on children's health (Vandentorren et al., 2011). Prior to this study, a pilot survey was conducted in two regions for validation purposes, which included the collection of spot urine samples from parturient women having a natural delivery (n = 164) or a Caesarean/forceps delivery (n = 79) in hospital maternity units. Total and unconjugated BPA was quantified by GC-MS with an LOQ of 0.3 µg/L. Total BPA

was quantifiable in 96.9 % of all samples. The GM concentration was 2.0 µg/L (95 % CI 1.6–2.5 µg/L) in the natural delivery group and 4.5 µg/L (95 % CI: 2.8–7.1 µg/L) in the Caesarean/forceps delivery group (Figure 5). The higher values in women who had Caesarean sections (or forceps delivery) suggest a contamination from medical devices either from catheterisation or urine probes when biomonitoring at delivery (Vandentorren et al., 2011).

To estimate daily BPA excretion levels in a large European cohort, Galloway et al. (2010) selected participants from the InCHIANTI study, a representative population-based study conducted in Chianti. 24-hour urinary samples were collected from 720 participants (20–74 years old) in 1998–2000. During the three days before sample collection, the subjects consumed a diet free of meat and fish. Total BPA levels were measured by HPLC-MS/MS with a LOQ of 0.5 µg/L. The GM and 95th percentile of the total BPA concentration in urine was 3.6 µg/L (relative margin of error 5 %) and 11.5 µg/L (Figure 5), respectively.

DEMOCOPHES is a pilot study funded by the Directorate General Research in the 7th Framework Programme (FP7/2007–2013) and aiming to demonstrate the harmonisation of HBM in Europe (Joas et al., 2012). DEMOCOPHES is a cross-sectional study of the European population's exposure to various substances using human biomarker data collected in 17 European countries from a non-representative sampling of mother–child pairs in 2011–2012 (Joas et al., 2012). It is designed to cover an urban and a rural part of each country, involving mother–child pairs comprising an equal number of 6- to 11-year-old boys and girls and their mothers (Kolossa-Gehring et al., 2012). Urinary BPA was measured on a voluntary basis in only a few countries (Sweden, Luxembourg, Denmark, Spain, Slovenia, Belgium) using MS-based methods. Sweden recruited 100 mother–child pairs and reported GM BPA concentrations of 1.2 µg/L for the mothers and 1.5 µg/L for children (Marika Berglund, Karolinska Institutet, Sweden, 2013, personal communication) (Figure 6). In Luxembourg, 60 mother–child pairs were sampled, and the total BPA concentration was measured by LC-MS with LOQs of 1.0 and 2.0 µg/L (Arno C. Gutleb, Centre de Recherche Public – Gabriel Lippmann, Luxembourg, 2013, personal communication). The GM concentrations were 1.7 (mothers) and 1.8 µg/L (children). Denmark recruited 145 mother–child pairs from an urban area near Copenhagen and a rural area near Roskilde (Frederiksen et al., 2013). The study was additionally funded by the Danish Health and Medicines Authority, the Danish Environmental Protection Agency and the Danish Veterinary and Food Administration. The total BPA concentration was measured by LC-MS/MS, and the GM concentrations were 2.0 µg/L (mothers) and 1.9 µg/L (children). In Slovenia, 155 mother–child pairs were recruited, and the median BPA concentrations were of 0.7 µg/L for the mothers and 2.0 µg/L for the children (Milena Horvat, Jožef Stefan Institute, Slovenia, 2013, personal communication). In Belgium, 129 mother–child pairs were sampled in the urban region of Brussels and in a rural area in the west of the country. GM concentrations of BPA were 2.6 µg/L for the mothers and 2.4 µg/L for the children (Covaci et al., 2012). Additional data from Spain became available after the public consultation. These last data from the DEMOCOPHES project were included in order to complete the European dataset on urinary BPA concentration. BPA was measured in first morning urine samples of women aged 18–48 from Madrid and Añover de Tajo (Toledo province) and children aged 6–11 (one child per woman; in total 120 mothers and 120 children, half from each location; Argelia Castaño, CNSA, Institute of Health Carlos III, Spain, 2013, personal communication). Too diluted and too concentrated samples (3 out of 240) were discarded. The Spanish data on urinary BPA concentration are in the range of the other DEMOCOPHES data (Figure 6) but were not considered in the estimation of daily urinary excretion of BPA (because of their late arrival). Including these data would, however, have provided added confidence to the representativeness of these estimates for the European population.

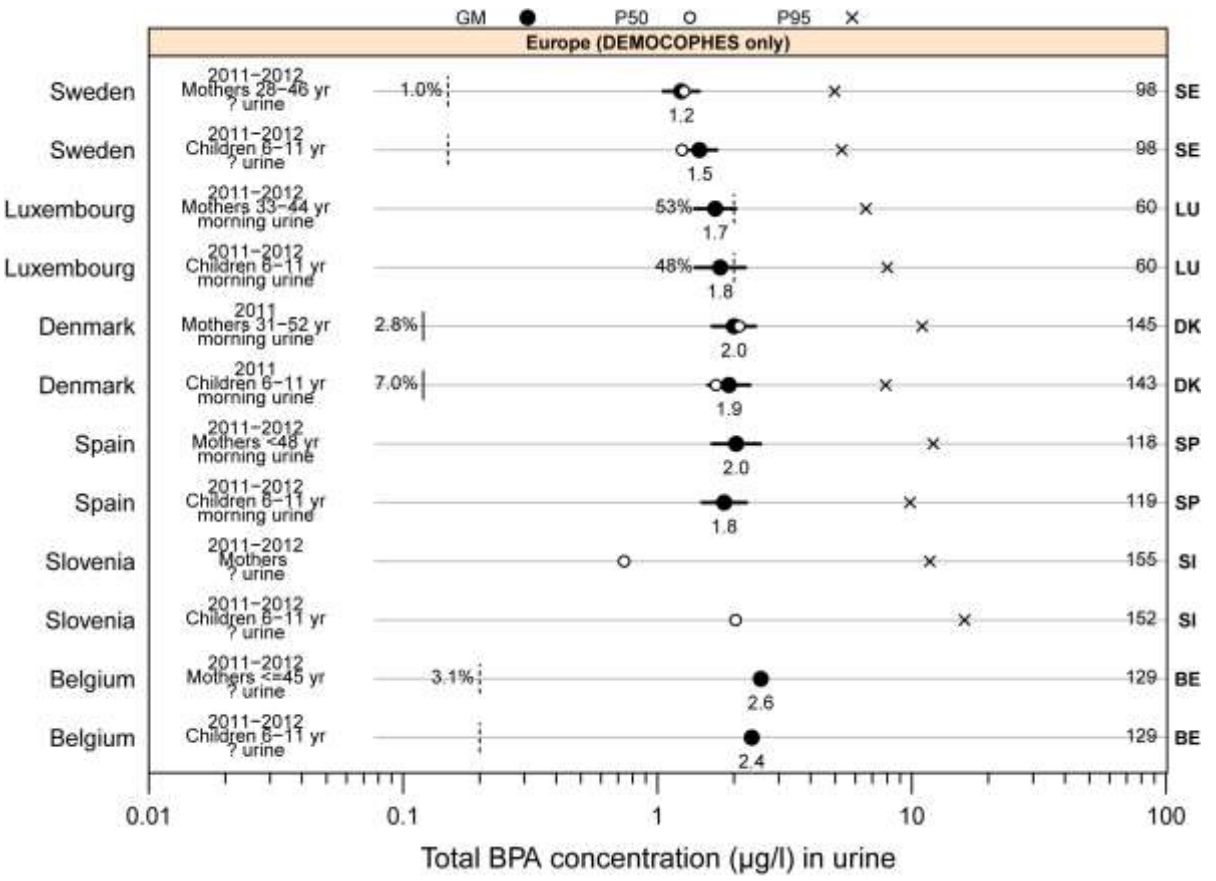


Figure 6: Urinary BPA concentrations in European mother–child studies from DEMOCOPHES. Shown are the concentrations of total urinary BPA in mothers and their 6- to 11-year-old children for individual European countries. Filled circles with associated numbers and error bars indicate the GMs and the 95 % confidence intervals. The 50th and 95th percentiles are shown by open circles and crosses. The number of subjects is given on the right. Vertical solid and dashed lines indicate the LOD and the LOQ, respectively. The proportion of measured values below the LOD (or LOQ) is given as a percentage. Also given are the sampling periods and the kind of urine sampling ("?" means that no information on the urine sampling was available). For references, see main text

Among the non-European data, the largest datasets on urinary BPA levels have been generated within the framework of NHANES and CHMS. Because of their large sample size and their cross-sectional, nationally representative, population-based character, these surveys are used here for comparative purposes to provide reference values on average and high concentrations of total BPA in urine.

Both North American surveys used spot urine samples and measured the concentration of total BPA. The surveys differed slightly in their analytical procedures (Lakind et al., 2012). For example, NHANES analysed the samples by HPLC-MS/MS with a LOD of 0.4 µg/L and a LOQ of 1.2 µg/L; measurements below the LOD were assigned a value of LOD/√2. CHMS used GC-MS/MS with a LOD of 0.2 µg/L and a LOQ of 0.82 µg/L; missing values (< LOD) were assigned a value of LOD/2. Both surveys performed reagent-blank checks, but only CHMS found results slightly above the LOD that were subtracted from the reported data.

In the NHANES surveys, covering the periods from 2003–2004 to 2009–2010, total BPA was detected among the different age classes in 88–98 % of the 6 to > 80 years old participants (n = 2 517–2 749 subjects in total) with a GM of 1.5–3.7 µg/L (relative margin of error 7–27 %) and a 95th percentile of 8.2–19.4 µg/L (CDC, 2012) (Figure 7). Additional data for the survey period 2011–2012 became available after the public consultation. These data continue to show a decreasing trend in the urinary

BPA concentration for the USA (Figure 7) but were not included in the estimation of daily urinary excretion of BPA (because of their late availability).

In the CHMS 2007–2009 cycle 1 survey, BPA was detected among the different age classes (Figure 7) in 88–94 % of the 6- to 79-year-old participants (n = 5 476 subjects in total) with GMs of 0.9–1.5 µg/L (relative margin of error 7–18 %) and 95th percentiles of 5.2–8.4 µg/L (Bushnik et al., 2010; Health Canada, 2010). These values are somewhat lower than the NHANES values. Recent data from the CHMS 2009–2011 cycle 2 survey do not differ from those found in the CHMS 2007–2009 cycle 1 survey period (Figure 7).

Given the survey differences in GMs and 95th percentiles of the urinary BPA levels between NHANES and CHMS, it can be speculated whether analytical differences such as CHMS-specific background subtraction could have led to a bias in the results. Lakind et al. (2012) examined this issue, as well as the differences in the survey methodologies (e.g. participant selection, urine sampling, fasting time), and concluded that the survey differences are unlikely to have substantial impacts on inter-survey comparisons of BPA exposures.

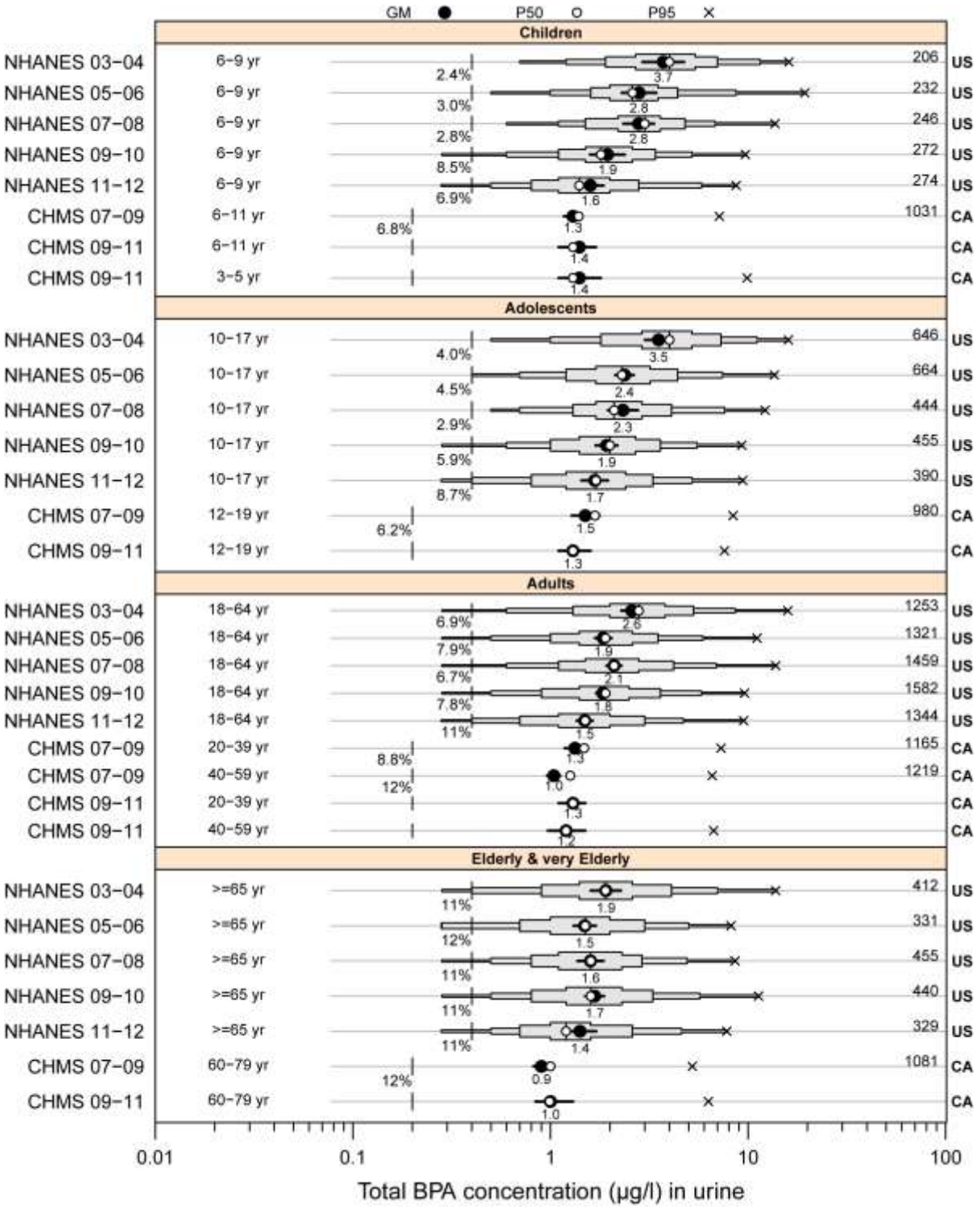


Figure 7: Urinary BPA concentrations of the large-sized North American surveys grouped by age classes and survey period. Shown are the concentrations of total urinary BPA from the US National Health and Nutrition Examination Survey (NHANES) and the Canadian Health Measures Survey (CHMS). Box-percentile plots (grey-shaded boxes) show the distributional characteristics comprising the 5th, 12.5th, 25th, 37.5th, 50th, 62.5th, 75th, 87.5th, and 95th percentiles. Filled circles with associated values and error bars indicate the GMs and the 95 % confidence intervals. The 50th and 95th percentiles are shown by open circles and crosses. The number of subjects is given on the right. Vertical lines indicate the LOD. The proportion of measured values below the LOD is given as percentages. Country codes are shown on the right

To conclude, a relatively large amount of information on urinary BPA concentration is available for the European region. Only a few of the larger-sized European studies, however, can be assumed to be representative such as the German Environmental Survey (GerES IV) for a population of children in Germany, the Flemish Environment and Health Survey (FLEHS II) for the 14–15 years old adolescents of the Flemish population, the INMA project for pregnant women in Spain, and the InCHIANTI study for the 20–74 year olds from the Chianti region. All age classes are covered except the 1–3 years old toddlers. The analytical sensitivity to detect and quantify BPA varied between the different studies with LODs of 0.05–0.4 µg/L and LOQs of 0.1–2.0 µg/L. The distributional characteristics of the total BPA concentrations in terms of shape and spread are generally quite homogeneous across the different studies. On a $\log_{10}$-transformed scale, the distributions appear symmetrical, and the similarity of the GM and the median (P50) indicate that the GM rather than the AM is the appropriate measure for the central tendency. For the European studies, the GM of the total BPA concentrations is in general localised in the range between 1.1–3.6 µg/L (Figure 5 and 6), which is in agreement with the results of the large-sized North-American surveys NHANES and CHMS (Figure 7). Exceptions from this general tendency are the Munich infants study and the Austrian HBM study with median values far below 0.6 µg/L, the Slovenian DEMOCOPHES study with a median value of 0.7 µg/L for the mothers, and the Elfe pilot study on parturient women having a Caesarean/forceps delivery (GM = 4.5 µg/L). An additional finding relevant for the estimation of high exposures is the 95th percentiles (P95), which, for studies with spot urine sampling, are 5–6-fold higher than the "corresponding" median values. The NHANES data covering the period from 2003–2012 show a decreasing trend in the urinary BPA concentration for the USA. For the European region, the German ESB study (Koch et al., 2012) observed a decrease in the urinary BPA concentrations between 1995 and 2009 which was accompanied by an increase in the 24-hour urine volumes so that the derived daily exposures remained rather constant over time. The remaining data for the European region do not allow to draw further conclusion about time trends in urinary BPA concentration.

4.6.2.3. Creatinine-based BPA concentrations in urine

Expressing urinary BPA concentration as creatinine-based data (µg BPA/g creatinine) rather than volume-based data (µg BPA/L urine) is an alternative that aims to correct for urinary dilution. Depending on which basis is chosen, assumptions on daily urinary output (volume) or daily creatinine excretion (mass) are required to estimate BPA exposure. Several factors contribute to the daily variability in creatinine output, as discussed in detail by Lakind and Naiman (2008) and in Appendix G. An important argument in favour of the use of creatinine-based concentrations instead of volume-based concentrations is the fact that the former is not dependent on drinking behaviour because the daily urinary excretion of creatinine depends primarily on the muscle mass of the individual (see Appendix G). Creatinine-based BPA concentrations in urine are available only for a few European studies comprising the Duisburg Duisburg BCS, the German ESB study, the Flemish and Liege HBM studies, the birth cohort study in Rotterdam (Generation R), and the Norwegian MoBa study. The descriptive statistics (GM, 50th percentile, 95th percentile) with associated information on gender, age and sampling are given in Table 25. The data for the North American surveys, NHANES and CHMS, are included for comparative purposes. For the European studies, with the exception of the MoBa study, the GMs of the creatinine-based total BPA concentrations are in the range between 1.7 and 2.5 µg/g creatinine which conforms with the results of NHANES and CHMS (GM 1.3–4.8 µg/g creatinine). The MoBa study on pregnant women is distinguished by a considerably higher value of 5.9 µg/g creatinine. The 95th to 50th percentile ratio for the studies with spot urine sampling is 4.4–5.2 (European studies) and 3.3–6.7 (NHANES and CHMS), respectively, which is similar to that found for the volume-based data. Remarkably, the 95th to 50th percentile ratio for the German ESB study is only 3.6, which indicates a reduced variability very likely due to the 24-hour urine sampling design.

Table 25: Descriptive statistics for creatinine-based BPA concentrations in urine. The table shows the geometric mean (GM), median (P50), and the 95th percentile (P95) of the creatinine-adjusted BPA concentration (µg/g creatinine) for the European studies and for the North American surveys NHANES and CHMS

Study	Gender	Age (years)	Sampling	BPA concentration (µg/g creatinine)		
				GM	P50	P95
German ESB	MF	20–30	24hU	1.8	1.7	6.2
Duisburg BCS	F	29–49	MU	2.3	2.1	10.0
Duisburg BCS	MF	6–8	MU	1.8	1.7	6.2
Generation R	Pregnant F	18–41	SU	1.7	1.6	8.3
MoBa	Pregnant F		SU	5.9	–	–
Flemish HMB	MF	14–16	SU	1.7	1.5	7.5
Liege HMB	MF	7–75	MU	2.5	2.3	13.7
NHANES03–05	MF	6–9	SU	4.8	4.7	15.7
NHANES05–06	MF	6–9	SU	3.4	3.0	22.5
NHANES07–09	MF	6–9	SU	3.6	3.3	20.8
NHANES09–10	MF	6–9	SU	2.7	2.6	9.9
CHMS07–09	MF	6–11	SU	2.0	1.9	9.8
NHANES03–05	MF	10–17	SU	2.9	2.9	12.2
NHANES05–06	MF	10–17	SU	1.9	1.7	11.9
NHANES07–09	MF	10–17	SU	2.0	1.8	7.0
NHANES09–10	MF	10–17	SU	1.7	1.6	7.2
CHMS07–09	MF	12–19	SU	1.3	1.3	6.4
NHANES03–05	MF	18–64	SU	2.4	2.4	9.8
NHANES05–06	MF	18–64	SU	1.8	1.6	8.7
NHANES07–09	MF	18–64	SU	2.0	1.9	9.1
NHANES09–10	MF	18–64	SU	1.9	1.8	7.7
CHMS07–09	MF	20–39	SU	1.5	1.5	6.8
CHMS07–09	MF	40–59	SU	1.3	1.3	7.5
NHANES03–05	MF	≥ 65	SU	2.3	2.3	12.1
NHANES05–06	MF	≥ 65	SU	1.8	1.6	8.8
NHANES07–09	MF	≥ 65	SU	2.2	2.1	9.3
NHANES09–10	MF	≥ 65	SU	1.9	1.8	8.4
CHMS07–09	MF	60–79	SU	1.3	1.3	7.6

M, male; F, female; 24hU, 24-hour urine; MU, morning urine; SU, spot urine.

4.6.2.4. Estimation of daily BPA exposure from volume-based urinary BPA concentration

Estimation of BPA exposure based on volume-based urinary BPA concentration is used in the present opinion as a plausibility check for the calculated exposure estimates for BPA uptake via food and non-food sources. Volume-based urinary BPA data are given preference over creatinine-based data because these are supported by a larger number of European studies. Based on measured urinary concentration of total BPA C_{BPA} (µg/L), the daily BPA exposure $\dot{m}_{BPA}$ (ng/kg bw per day) was calculated by

$$\dot{m}_{BPA} = \frac{C_{BPA} \times \dot{V}_{urine}}{W}$$

where $\dot{V}_{urine}$ (mL/day) is the urinary output rate and W (kg) is the body weight (Lakind and Naiman 2008; UBA, 2012). The CEF Panel noted that, because of the non-persistent nature and short elimination half-life of BPA, the C_{BPA} value of an individual spot urine sample cannot be used to arrive at a realistic estimate of daily BPA exposure. However, a set of spot urine samples can, when taken under certain conditions as detailed below, be used to obtain a reliable estimate of the average BPA exposure of the sampled population.

24-hour urine collections are preferable, as both C_{BPA} and $\dot{V}_{urine}$ are measured in 24-hour urine samples (in addition to the individual's body weight), allowing the calculation of 24-hour BPA excretion for each individual. The GM (or median) can directly be used as an estimate for the average exposure of the (sampling) population, whereas the 95th percentile might tend to overestimate the high exposure, as it includes not only the between-person variability but also the within-person between-day variation. Spot urine sampling provides information for C_{BPA} only, and only for a single urine sample per individual, whereas generic values are generally used for $\dot{V}_{urine}$ and W (see below). It may also permit estimation of the average BPA exposure of a population, provided that the sampling is at random in relation to meal ingestion and bladder-emptying times. However, the high exposure is likely to be overestimated because spot urine sampling includes more sources of variability (e.g. within-person, within-day variability) than 24-hour urine sampling. The collection of first morning urine is a non-random, single-sample sampling that is not representative of the daily variability and which bears the potential of introducing a bias and may result in an over- or underestimation of average exposure, although the sparse evidence available from the literature indicates comparability of the central tendency between first morning voids, spot urine samples and 24-hour urine samples (Christensen et al., 2012).

Depending on whether body weight is available from the studies, either study-specific individual or mean values, or generic values derived by linear interpolation from body weight vs. age relationships taken from the literature, were used. Literature data were also used for the urinary output rate, except for cases in which study-specific individual urinary volumes from 24-hour urine sampling were available. Lakind and Naiman (2008) provide detailed discussion on the range and variability of age-/gender-specific body weight and urinary output rate.

Table 26 shows the body weight and urinary output rate parameters that were used to translate urinary BPA concentration into daily exposure. Parameters are given only for European studies and the North American surveys. Generic values for body weight were taken from the German National Health Interview and Examination Survey 1998 (Bergmann and Mensink, 1999), the German Health Interview and Examination Survey for Children and Adolescents (Stolzenberg et al., 2007), the Italian National Food Consumption Survey, INRAN-SCAI 2005–06 (Leclercq et al., 2009), and from the reference values given by the International Commission on Radiological Protection (ICRP) (Valentin, 2002). For the urinary output rate, generic values were taken from Valentin (2002) and from Willock and Jewkes (2000). For comparative purposes, daily BPA exposures for the large-sized population-based surveys from North America (NHANES, CHMS) were also calculated, based on the survey-specific, individual body weights and on the generic urine volumes taken from ICRP reference tables (Valentin, 2002).

Estimates for the average and high levels of daily BPA exposure were calculated by using the GM, the median (50th percentile) and the 95th percentile of the urinary BPA concentration of spot urine samples, first morning urine samples, and 24-hour urine samples. Because of BPA's short elimination half-life, spot urinary concentrations primarily reflect the exposure that occurred within a relatively short period before urine collection (WHO, 2011a). Nevertheless, the single spot-sampling approach may adequately reflect the average BPA exposure of a population, provided the samples are collected from a large number of individuals and at random in relation to meal ingestion and bladder-emptying times.

The 95th percentile of urinary BPA concentration is used to obtain estimates for high BPA exposures. It is, however, noted that the 95th percentile has different interpretations depending on whether spot urine samples, first morning urine samples or 24-hour samples are used. For spot urine samples, the 95th percentile is related to the 95 % probability that a single, randomly collected sample from a randomly selected subject has a urinary BPA concentration not exceeding the 95th percentile. This is important as urinary BPA concentrations of repeated urine collections from individuals may vary up to two orders of magnitude (Teeguarden et al., 2011; Ye et al., 2011; Christensen et al., 2012). The variability of urinary BPA levels has been analysed from repeated/serial urine collections by using so-

called nested random-effects models (Braun et al., 2011; Ye et al., 2011), which can adequately reflect the hierarchical structure of the main sources of variability: (i) between persons; (ii) within person/between days; and (iii) within person/within day. The study by Ye et al. (2011) revealed that the total variance in spot urine collections could be subdivided into 70 % within-day variability, 21 % between-day variability and 9 % between-person variability. The substantial within-day variability is expected to be lacking in 24-hour urine samples, so that the 95th percentile should be closer to the average concentration (GM, median) than in spot urine samples and first morning urine samples (Aylward et al., 2012). However, the sparse evidence available for the European region (cf. German ESB study with other European studies for adults in Figure 5) and for the USA (Christensen et al., 2012) indicates that this effect is less pronounced.

Table 26: Body weight and urinary output rate parameters for the considered European and North American Studies. The table provides the parameters for body weight (W), urinary output rate ($\dot{V}_{urine}$) and the specific urinary output rate (spec. $\dot{V}_{urine}$), which were used to translate urinary BPA concentration into daily BPA exposure. Gender and age were taken into account when deriving generic parameter values from published parameter–age relationships by linear interpolation. Study-specific parameters are set in italic font. The references from which these parameters were taken are: [1] Koch et al. (2012); [2] Bergmann and Mensink (1999); [3] Valentin (2002); [4] Stolzenberg et al. (2007); [5] Willock and Jewkes (2000); [6] Ye et al. (2009a); [7] Leclercq et al. (2009); [8] Galloway et al. (2010); [9] CDC (2012); [10] Health Canada (2012); [11] Monika Kasper-Sonnenberg (Ruhr University Bochum, Germany, 2013, personal communication); [12] Elly Den Hond (Flemish Institute for Technological Research [VITO], Belgium, 2013, personal communication); [13] Arno C. Gutleb (Centre de Recherche Public – Gabriel Lippmann, Luxembourg, 2013, personal communication); [14] Frederiksen et al. (2013)

Study	Gender	Age (years)	Sampling	W (kg)	$\dot{V}_{urine}$ (mL/day)	spec. $\dot{V}_{urine}$ (mL/kg bw per day)	Reference
German ESB	MF	20–30	24hU	*72*	*1 790*	25	[1]
Duisburg BCS	F	29–49	MU	*71*	1 200	17	[11, 3]
Duisburg BCS	MF	6–8	MU	*24*	600	25	[11, 3]
DEMOCOPHES SE	F	28–46	?	70	1 200	17	[4, 3]
DEMOCOPHES SE	MF	6–11	?	27	600	22	[4, 3]
DEMOCOPHES LU	F	33–44	MU	*65*	1 200	17	[13, 3]
DEMOCOPHES LU	MF	6–11	MU	*29*	600	22	[13, 3]
DEMOCOPHES DK	F	31–52	MU	*67*	1 200	17	[14, 3]
DEMOCOPHES DK	MF	6–11	MU	*31*	600	22	[14, 3]
DEMOCOPHES SI	F	?	?	70	1 200	17	[4, 3]
DEMOCOPHES SI	MF	6–11	?	27	600	22	[4, 3]
DEMOCOPHES BE	F	≤45	?	70	1 200	17	[4, 3]
DEMOCOPHES BE	MF	6–11	?	27	600	22	[4, 3]
GerES IV	MF	3–5	MU	16	475	30	[4, 3]
GerES IV	MF	6–8	MU	24	580	25	[4, 3]
GerES IV	MF	9–11	MU	34	700	21	[4, 3]
GerES IV	MF	12–14	MU	49	1 000	20	[4, 3]
Munich Infants	MF	1/12	?	4	194	48	[3, 5]
Munich Infants	MF	2/12	?	5	237	48	[3, 5]
Generation R	Pregnant F	18–41	SU	74	2 000	27	[6]

Study	Gender	Age (years)	Sampling	W (kg)	$\dot{V}_{urine}$ (mL/day)	spec. $\dot{V}_{urine}$ (mL/kg bw per day)	Reference
MoBa	Pregnant F		SU	*74*	*2 000*	27	[6]
Flemish HMB	MF	14–16	SU	*57*	1 200	19	[12, 3]
Liege HMB	MF	7–11	MU	34	600	18	[2, 3]
Liege HMB	MF	12–19	MU	65	1 200	19	[2, 3]
Liege HMB	MF	20–39	MU	75	1 400	19	[2, 3]
Liege HMB	MF	40–59	MU	79	1 400	18	[2, 3]
Liege HMB	MF	60–75	MU	78	1 400	18	[2, 3]
INMA	Pregnant F	17–43	SU	74	2 000	27	[6]
INMA	MF	4	SU	18	475	26	[2, 3]
Elfe pilot study	Parturient F		SU	74	2 000	27	[6]
InCHIANTI	MF	20–40	24hU	70	*1 530*	22	[7, 8]
InCHIANTI	MF	41–65	24hU	70	*1 690*	24	[7, 8]
InCHIANTI	MF	66–74	24hU	70	*1 540*	22	[7, 8]
NHANES	MF	6–>65	SU	*29–83*	600–1 400	17–21	[9, 3]
CHMS	MF	6–79	SU	*33–80*	650–1 400	18–19	[10, 3]

M, male; F, female; 24hU, 24-hour urine; MU, morning urine; SU, spot urine, ?, not available.

The results for daily BPA exposure for the European studies and for the North American surveys (NHANES, CHMS) are shown in Figure 8. The data were grouped by the age classes defined in Section 4.5.1. Age-specific estimates were available for all age classes except the one- to three-year-old toddlers. As no data are available for this age group, an estimate was derived by extrapolation from 3- to 5-year-old children to be able to make a comparison with the forward exposure-modelling estimate. Section 4.5.1 defined the age classes "women (18–45 years)", "men (18–45 years)" and "other adults (45–65 years)", which could not be matched by the available biomonitoring data. As a surrogate, the age class "Adults (18–65 years)" and a subgroup "Women of childbearing age" (i.e. mothers and pregnant and parturient women) were used.

The GM and median values for average daily BPA exposure (as derived from volume-based BPA concentrations) are in good agreement among the European studies (Figure 8). Age classes with a relatively large coverage of European countries, such as children and adults, indicate a notable variability across the countries with the lowest exposures in Sweden (DEMOCOPHES SE) and Slovenia (DEMOCOPHES SI), and elevated exposures in Italy (InCHIANTI), Germany (GerES IV), and Spain (INMA). The CEF Panel noted that the urine collection periods cover a wide range from 1998–2000 (InCHIANTI) to 2011–2012 (DEMOCOPHES).

For the infants, only one study is available with an average BPA exposure of < 10 ng/kg bw per day for on- to two-month old infants (Munich infants study). For the children, there is a tendency to higher values in younger (3–5 years old) children (107 ng/kg bw per day) compared with older (5–10 years old) ones (49 ng/kg bw per day). In adolescents, adults and women of childbearing age, the estimated daily BPA exposure is 48 ng/kg bw per day, 39 ng/kg bw per day and 36 ng/kg bw per day, respectively. For the elderly, only sparse data are available from the Liege HBM study and the InCHIANTI study, with a daily BPA uptake of 56 ng/kg bw per day. Essentially no data are available for the very elderly (≥ 75 years old). In comparison with the North American surveys, the European data for the children, adolescents and adults appear to be more similar to the NHANES data than to the CHMS data. Table 27 summarises the age-specific daily BPA exposures, which are used as estimates of average BPA exposure.

To obtain estimates for high BPA exposure, the maximum of the reported 95th percentiles from the different studies were used. The estimates for high BPA exposure were 161 ng/kg bw per day for infants, 676 ng/kg bw per day for children three to five years old, 380 ng/kg bw per day for children 5–10 years old, 256 ng/kg bw per day for adolescents, 290 ng/kg bw per day for adults, 234 ng/kg bw per day for women of childbearing age and 203 ng/kg bw per day for the (very) elderly (see Table 28).

Table 27: Average daily BPA exposure as estimated from urinary BPA levels in different European studies. Estimates of average daily BPA exposure were calculated from the GMs of the volume-based urinary concentrations of total BPA. For each age class, the minimum, median and maximum was obtained from the data available in each age class. Studies with multiple subgroups per age class were merged by calculating the mean of the GMs and by summing up the sample sizes of the subgroups. The number of studies and the sample size range of participants is given for each age class. The age class "women cba" represents women of childbearing age (i.e. mothers and pregnant and parturient women)

Age class	Age (years)	No of studies	Sample size	Average daily exposure (ng/kg bw per day)		
				Minimum	Median	Maximum
Infants	0–1	1	88	n/a	<10	n/a
Toddlers	1–3	0	n/a	n/a	n/a	n/a
Children	3–5	2	30–137	105	107	109
Children	5–10	8	21–152	33	49	67
Adolescents	10–18	3	22–317	47	48	55
Adults	18–65	13	45–569	13	39	95
Woman cba	18–52	10	60–164	13	36	76
Elderly	65–75	2	23–452	40	56	73
Very Elderly	≥ 75	0	n/a	n/a	n/a	n/a

Table 28: High daily BPA exposure as estimated from urinary BPA levels in different European studies. Estimates of high daily BPA exposure were calculated from the 95th percentiles of the volume-based urinary concentrations of total BPA. For each age class, the minimum, median and maximum was obtained from the data available in each age class. Studies with multiple subgroups per age class were merged by calculating the mean of the 95th percentiles and by summing up the sample sizes of the subgroups. The number of studies and the sample size range of participants is given for each age class. The age class "women cba" represents women of childbearing age (i.e. mothers and pregnant and parturient women)

Age class	Age (years)	No of studies	Sample size	High daily exposure (ng/kg bw per day)		
				Minimum	Median	Maximum
Infants	0–1	1	88	n/a	161	n/a
Toddlers	1–3	0	n/a	n/a	n/a	n/a
Children	3–5	1	137	n/a	676	n/a
Children	5–10	6	60–152	118	204	380
Adolescents	10–18	2	197–317	200	228	256
Adults	18–65	8	60–569	85	184	290
Woman cba	18–52	6	60–155	85	182	234
Elderly	65–75	1	452	n/a	203	n/a
Very Elderly	≥ 75	0	n/a	n/a	n/a	n/a

n/a, not available.

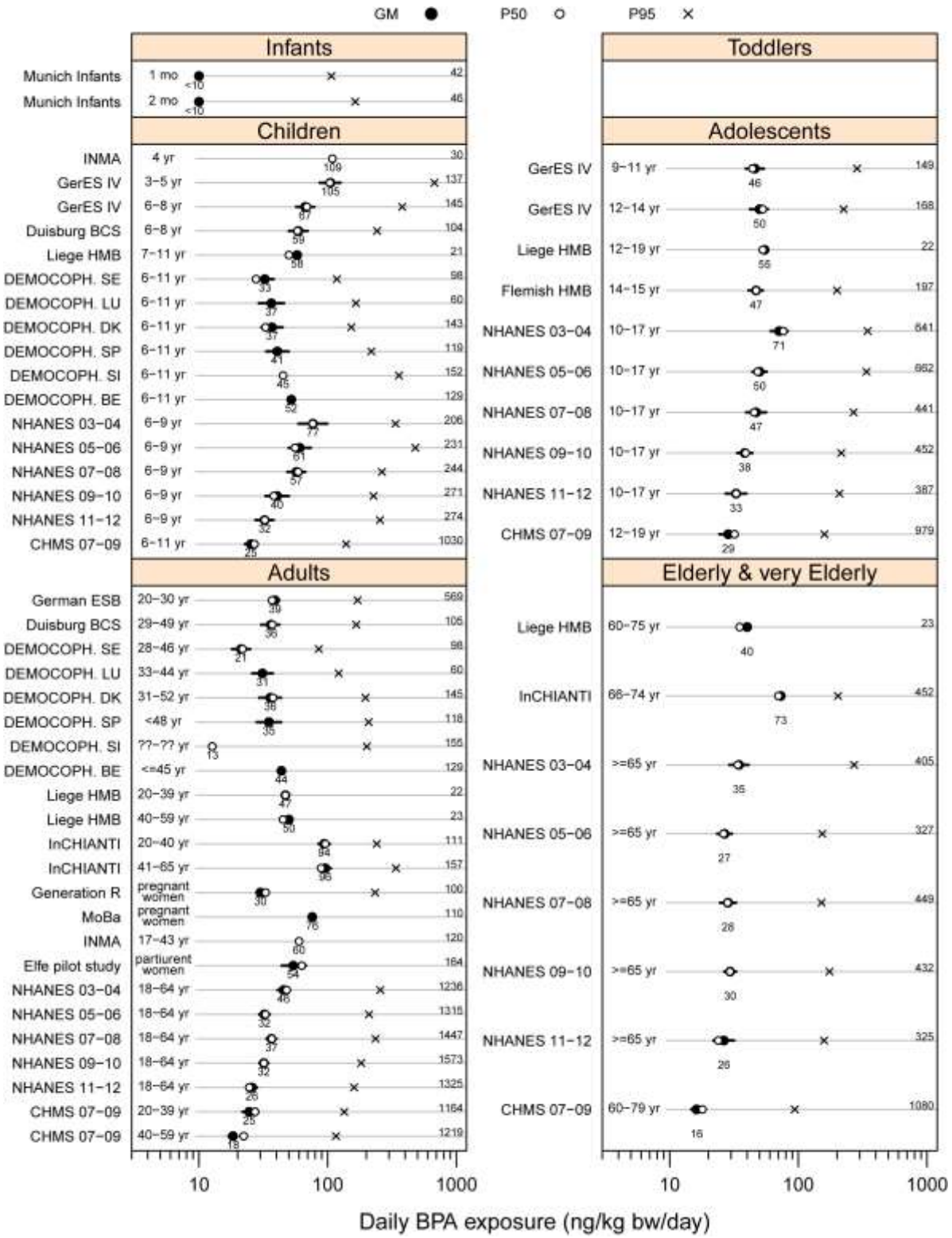


Figure 8: Daily BPA exposure as estimated from volume-based urinary BPA concentrations. The age-specific estimates for daily BPA exposure from the different studies are grouped by the age classes defined in Section 4.5.1. Filled circles with associated numbers and error bars indicate the GMs and the 95 % confidence intervals. The 50th and 95th percentiles are shown by open circles and crosses. The number (n) of subjects is given on the right. Age ranges and specific population groups (pregnant and parturient women) are indicated. The studies comprise the European studies, large-sized population-based surveys from North America (NHANES, CHMS).

4.6.2.5. Estimation of daily BPA exposure from creatinine-based urinary BPA concentration

The estimation of daily BPA exposure from creatinine-based urinary BPA concentrations leads to slightly different values than those obtained from volume-based urinary BPA concentrations (see Appendix G). For the few European studies providing information on creatinine-based BPA levels, there is a tendency for lower BPA exposures in children, adolescents and adults and a tendency for slightly higher exposures for the (very) elderly. These differences are (at least partly) explainable by daily urinary output rates that deviate from the generic values reported in literature. For the derivation of reference values for comparison with BPA uptake via food and non-food resources, the volume-based BPA exposures will be used because these are better supported by a larger number of European studies.

4.6.3. Biomonitoring studies on serum levels

4.6.3.1. Methodological aspects

Whether, and at which levels, serum BPA can be detected under normal, non-experimental exposure situations is one of the most controversial topics in the scientific literature on BPA (Dekant and Völkel, 2008; Vandenberg et al., 2010; Hengstler et al., 2011; Teeguarden et al., 2012; vom Saal et al., 2012; Vandenberg et al., 2013). In order to set the background for the assessment of HBM studies on serum BPA levels, the principal findings from the available toxicokinetic studies in humans and non-human primates, and from a controlled dietary exposure study, are briefly summarised in the following paragraphs.

In several toxicokinetic studies in humans (Völkel et al., 2002) and rhesus monkeys (Doerge et al., 2010c; Taylor et al., 2011; Patterson et al., 2013), stable isotope-labelled BPA (deuterated) was administered to avoid any interference by possible contamination of samples with free BPA from environmental sources and medical devices. The administration of oral or intravenous doses of 64–400 µg BPA/kg bw resulted in a transient increase in the serum concentrations of conjugated and total BPA up to 34–190 µg/L within the first hour (Figure 9), which was then followed by an approximately linear decrease (on a log-transformed scale) during the next hours. Unconjugated BPA was not detectable in the study by Völkel et al. (2002), because of the relatively high LOD, but was quantifiable in the three other studies. In these studies, unconjugated BPA contributes 0.2–2.8 % (oral administration) and 8–29 % (intravenous injection) to the total BPA concentration during the first four hours after dosing. In monkeys, after oral administration, the maximum levels of unconjugated BPA in serum did not exceed 1 and 4 µg/L at doses of 100 and 400 µg/kg bw, respectively (Doerge et al., 2010c; Taylor et al., 2011; Patterson et al., 2013). After intravenous injection of 100 µg/kg bw, however, much higher maximum levels of 34–39 µg/L were observed (Doerge et al., 2010c; Patterson et al., 2013). The oral dosing studies used different administration procedures and vehicles which (apart from different doses, species, and analytical sensitivities) might have contributed to differences in the peak level and shape of the serum concentration profiles (see Part II - Toxicology assessment and risk characterisation, Section 3.1.2.1). Nevertheless, the CEF Panel considered these studies sufficiently reliable and relevant to enable back-and-forth calculations between serum levels and oral exposures for the general population in humans (see below).

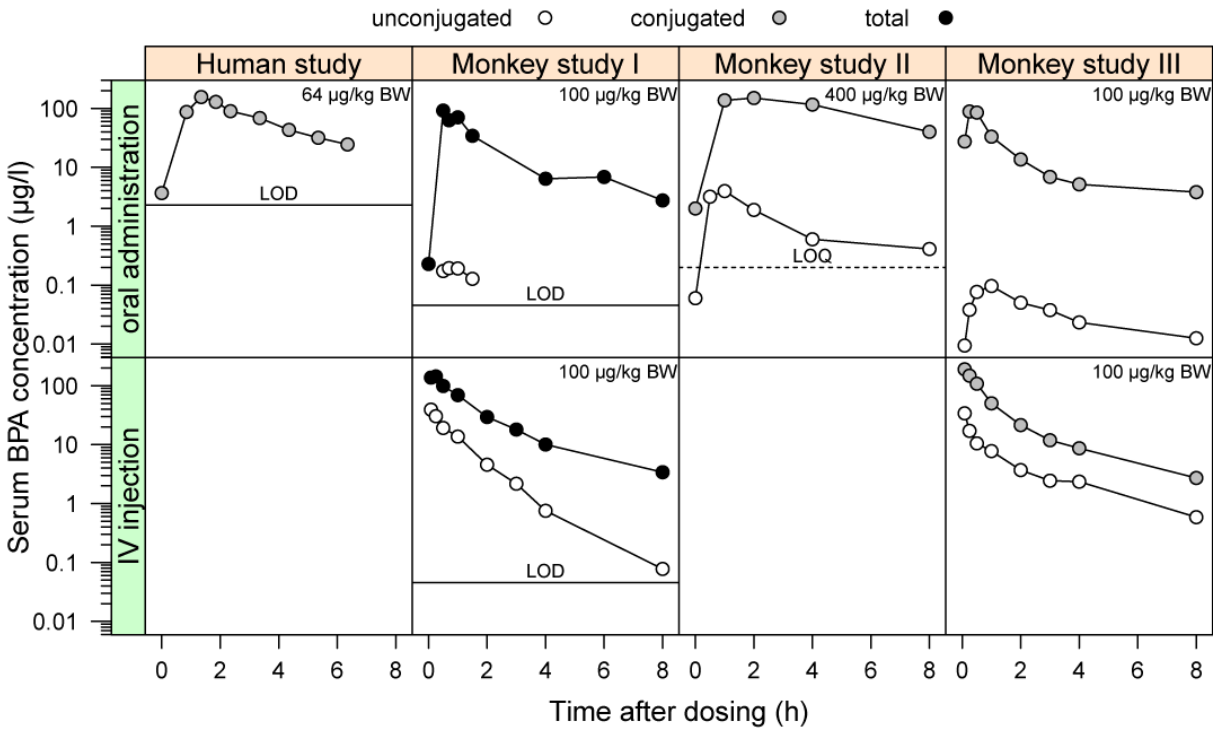


Figure 9: Time course of serum levels of unconjugated, conjugated and total BPA in toxicokinetic studies in adult humans and monkeys with oral administration and intravenous (IV) injection of isotope-labelled (deuterated) BPA. The serum concentrations of BPA are expressed as µg/L of unconjugated BPA. Solid and dashed horizontal lines indicate the LOD and LOQ, respectively. Data shown in the columns from left to right were taken from Völkel et al. (2002), Doerge et al. (2010a), Taylor et al. (2011) and Patterson et al. (2013), with the applied dose given in each column

Biomonitoring studies on urinary BPA levels have indicated daily BPA uptakes in the general population of 36–676 ng/kg bw per day (average-to-high exposure; see medians in Table 27 and 28), which are two to three orders of magnitude lower than the doses administered in the toxicokinetic studies mentioned above. Provided that this daily uptake is mainly food related, and knowing that the kinetics are linear up to a dose of 100 000 µg/kg bw (Taylor et al., 2011), the CEF Panel noted that even peak serum concentrations would be expected to be below 0.1 µg/L for the toxicologically relevant, unconjugated BPA. The CEF Panel considered that detection of such low concentrations of unconjugated BPA without interference from contamination is an analytical challenge. However, a significant uptake through the dermal route would increase the fraction of unconjugated BPA in the total BPA serum concentration. Forward modelling of dermal exposure to BPA from thermal paper (with consideration of the dermal absorption fraction) revealed estimates for high internal exposure to total BPA of <100 ng/kg bw per day (see Table 32). By assuming, as an extreme/unrealistic worst-case scenario, that humans would receive this internal dose (i.e. 100 ng/kg bw) at once by IV injection, a comparison can be made to the above mentioned toxicokinetic studies in monkeys with IV injection (Doerge et al., 2010a; Patterson et al., 2013). Again, since the estimates of high internal exposure to total BPA are more than three orders of magnitude lower than the IV doses given in the monkey studies, and since the kinetics is linear, even peak serum concentrations would be expected to be below 1 µg/L in this unrealistic IV worst-case scenario, and more so in a realistic dermal exposure scenario. Also for the conjugated or total BPA, in a general population having average-to-high daily BPA uptakes of 50–1 000 ng/kg bw per day, serum concentrations would only be expected to exceed rarely a level of 1 µg/L.

These predictions are supported by the findings of a dietary exposure study, in which 24-hour urine and serum profiles of total BPA were measured in 20 human volunteers who received a controlled diet and ingested 100 % of one of three specified meals comprising standard grocery store food items for

breakfast, lunch and dinner (Teeguarden et al., 2011). Subjects were housed in a clinical facility for ~36 h and were possibly less exposed to other potential BPA sources of non-dietary origin. The diet was rich in canned foods (fruits, vegetables, meat, fish and composite food) and juices to represent a potentially high BPA dietary exposure. Table 4 indicates that the canned food items chosen by Teeguarden et al. (2011) all belong to food categories characterised by high BPA concentrations. To ensure the feasibility of regular urine collections, the volunteers ingested large volumes of water per day (5.1 L compared to standard values of 1.2–1.6 L for adults) which resulted in a more diluted urine as indicated by the higher percentage (26%) of non-detectable urinary levels for total BPA compared with results (7.8%) for general public in the US (18–64 years olds, 2009–2010 NHANES; see Figure 7). The CEF Panel emphasised that the high proportion of non-detects need not be misinterpreted as low BPA exposure since the urinary BPA concentration times urinary output rate is the relevant metric to quantify urinary BPA excretion (see below). The study revealed inter- and intra-individual variability in the serum and urine profiles of total BPA which was explained by the uncontrolled nature of dietary BPA exposures (i.e. the food-derived BPA doses were not determined separately), the time it took each volunteer to ingest the meal and the individual variability in absorption, metabolism and elimination. Only 6 out of 20 subjects (i.e. 30 %) showed consistently detectable serum concentrations of total BPA (unconjugated plus conjugated BPA) within a few hours after food uptake (Figure 10). The individual peak serum concentrations in this subset of volunteers ranged from 0.6 to 1.3 µg/L and occurred within two to three hours of food consumption. These transient elevations of serum levels were associated with inter-meal urinary BPA excretion of 183–573 ng/kg bw. Overall, total BPA was detected in 27 % of the 320 serum samples collected from the 20 volunteers. The concentration of unconjugated BPA was always below the LOD of 0.3 µg/L. Comparing the derived doses and the detectable maximum serum concentrations of total BPA of Teeguarden et al. (2011) with those of Völkel et al. (2002) suggests conformity with the assumption of linearity of BPA kinetics and its conjugated metabolites.

A recent publication by Gayrard et al. (2013) addressed the possibility of sublingual absorption in humans by performing a toxicokinetic study in dogs, in which concentrated BPA solutions (50 mg/ml in 40–100% ethanol for a 5 mg/kg bw dose, and 0.5 mg/ml in 1% ethanol in water for a 0.05 mg/kg bw dose) were applied under the tongues of anaesthesized dogs. With regards to the study by Teeguarden et al. (2011), the authors concluded that "Currently, the results of Teeguarden et al. (2011) do not support sublingual absorption as a major contributor of dietary BPA to a much higher than expected human internal exposure". The CEF Panel evaluated the study of Gayrard et al. (2013) (see Section 3.1.2.1 of Part II – Toxicological assessment and risks characterisation) and concluded that detectable levels of unconjugated BPA in serum are unlikely to occur from sublingual absorption in humans for average BPA concentrations in food of <0.1 mg/kg food (see Section 4.3.2.). Obviously, chewing on thermal prining paper may release substantial amounts of BPA into the buccal cavity, with subsequent absorption via the oral mucosa, but since this is considered a behaviour which is not common for the major part of the population, this kind of exposure is not further considered. The CEF Panel noted though that very young children may occasionally put thermal paper into their mouth, and this might result in an uncontrolled but not chronic exposure situation.

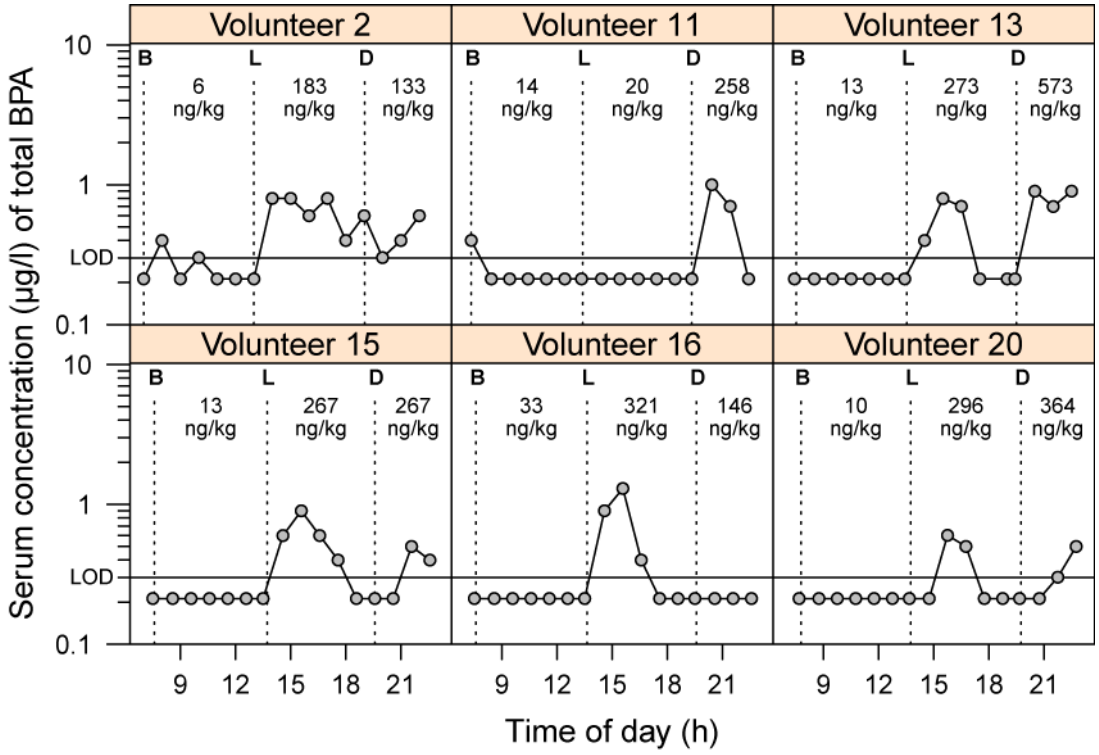


Figure 10: Time course of total BPA serum concentration in human volunteers ingesting a controlled diet enriched with canned food. Shown are the data of a subset of volunteers (6 out of 20) with consistently detectable concentrations of total serum BPA. Total BPA concentrations below the LOD of 0.3 µg/L are set to a value of LOD/√2. Vertical dotted lines indicate the meal times (B, breakfast; L, lunch; D, dinner). The per-body-weight amount of total BPA eliminated via urinary excretion during each inter-meal period is given. Data were taken from Teeguarden et al. (2011)

4.6.3.2. Serum BPA concentrations

Data on serum levels of unconjugated, conjugated and total BPA in humans were retrieved from peer-reviewed scientific papers (published since 2006) which were identified by a systematic literature search. Not included are the biomonitoring data on fetal exposure as this is addressed in Section 3.1.2.4 of Part II – Toxicological assessment and risks characterisation. The analytical methods for the determination of serum BPA comprised LC-UV, LC-FLD (fluorescence detection), LC-ECD (electrochemical detection), LC-MS and LC-MS/MS, GC-MS and GC-MS/MS, and RIA (radio-immunoassay) (see Appendix A for description of the method). Of the 26 HBM studies reporting first-publication data, one study (Sajiki et al., 2008) was excluded as no information on the proportion of values below the LOD/LOQ was available. Also excluded were the patient-related subsets of four studies (Cobellis et al., 2009; Kaddar et al., 2009; Yang et al., 2009; Bloom et al., 2011) and one study reporting only patient-related data (Shao et al., 2012), because patients could have been in contact with BPA-containing medical devices, a scenario not representative for the chronic exposure of the general population.

The study groups comprised the general population (M. Liu et al., 2006; He et al., 2009; Kaddar et al., 2009; Liao and Kannan, 2012) as well as specific age classes such as children (Ye et al., 2012), adolescents (Geens et al., 2009b), adults (Fukata et al., 2006; Dirtu et al., 2008; Genuis et al., 2012; Santhi et al., 2012a) and the elderly (Olsen et al., 2012). Additional data were available for more specific demographic groups such as students (Koch et al., 2012), male partners of female patients undergoing *in vitro* fertilisation (IVF) (Bloom et al., 2011), healthy women (Cobellis et al., 2009), female hospital controls (Yang et al., 2009), nursing women (Gyllenhammar et al., 2012) and pregnant

women (Lee et al., 2008; Padmanabhan et al., 2008; Wan et al., 2010; Chou et al., 2011; Kosarac et al., 2012; Unal et al., 2012). Blood bank samples were also analysed (Ye et al., 2008b, 2009b).

Because of the large number of studies on pregnant women, and also taking account of the terms of reference to consider specifically this group (among others), this demographic group is considered separately from the remaining general population.

For the assessment of reported serum BPA levels, the following aspects were specifically assessed:

- the proportion of detectable/quantifiable values in relation to the LOD/LOQ;
- the fraction of unconjugated BPA in the total BPA serum concentration;
- the average serum concentrations of unconjugated, conjugated and total BPA for studies reporting ≥ 50 % detectable values.

To provide an overview of the study results, a Cleveland dot plot was used to visualise the average serum BPA concentrations and the proportion of detectable values (Figure 11). Pie charts displaying the proportion of detectable values were positioned at the respective LOD/LOQ of the study, and the average serum BPA concentrations (small geometric symbols) are shown for studies reporting ≥ 50 % detectable values. For symbols and pie charts, grey and black filling colours were used for unconjugated BPA and conjugated/total BPA, respectively. The serum concentrations of unconjugated, conjugated and total BPA combined are expressed in µg/L of unconjugated BPA.

To show the influence of decreasing analytical limits on the proportion of detectable BPA levels, the studies were ordered according to their LOD/LOQ, and the pie charts displaying the proportion of detectable values were positioned at the respective analytical limit (Figure 11). Some of the studies report an LOD, some of them an LOQ and some report both LOD and LOQ. In the last case, only the analytical limit that the study authors considered as a censoring limit for reportable and non-reportable concentrations was displayed. Across the different studies, the analytical limit for detecting the different BPA parameters (i.e. unconjugated, conjugated and total BPA concentrations) varied by almost two orders of magnitude (0.01–0.82 µg/L). In spite of this large variation in analytical sensitivity, the CEF Panel noted that a consistent pattern such as an increasing proportion of detectable values with decreasing LOD/LOQ did not emerge. Overall, the detection rate for unconjugated and conjugated and/or total BPA varied largely from 0 % to 100 %. Given the findings of the controlled dietary exposure study in human volunteers (Teeguarden et al., 2011), with unconjugated BPA being undetectable and total BPA being detectable in only 27 % of the 320 serum samples collected from the 20 volunteers, the CEF Panel considered detection rates close to 100 % for conjugated and/or total BPA in serum to be an implausible result. High detection rates for unconjugated BPA in serum are even more implausible.

Only a few studies analysed more than one serum BPA parameter (i.e. unconjugated, conjugated and total BPA). These studies were used to determine the fraction of unconjugated BPA in the total BPA concentration, where both unconjugated and total BPA were detectable and quantifiable in the same sample. Gyllenhammar et al. (2012) reported detection rates of 25 % and 21 % (at slightly different LODs of 0.5 and 0.8 µg/L) for unconjugated and total BPA, respectively. In 15 % of the samples, the authors reported that unconjugated BPA could be detected and accounted for one-half to all of the total BPA. Ye et al. (2008b) reported unconjugated and total BPA in only 1 of 15 blood bank samples at a similar concentration of 1.5 µg/L (i.e. all BPA present was in the unconjugated form). Koch et al. (2012) quantified both unconjugated and total BPA in only 7 of 60 plasma samples, reporting that unconjugated BPA accounted for the predominant share (90–100 %) of total BPA. Similarly, Ye et al. (2012) detected total BPA in only 3 of 24 pooled serum samples, and unconjugated BPA in only two pooled samples. The mean percentage of unconjugated BPA in samples with detectable total BPA was 67 %. Kosarac et al. (2012) reported detection rates of 67 % and 17 % for unconjugated and conjugated BPA, respectively, again implying that serum BPA was essentially unconjugated.

The findings of these authors appear to indicate (i) that the detection of total BPA in a sample made the parallel detection of unconjugated BPA very likely, and (ii) that all serum BPA (if detected) was essentially unconjugated. The CEF Panel considered that this is extremely unlikely given the findings of the toxicokinetic studies mentioned above, in which stable isotope-labelled BPA was administered to avoid any interference by possible contamination of samples with free BPA from environmental sources and medical devices.

Although also providing information on more than one serum BPA parameter (i.e. unconjugated, conjugated and total BPA), the study by Liao and Kannan (2012) is notable for the fact that serum concentrations of unconjugated and conjugated (sulphated, glucuronidated) were directly measured via solid-phase extraction and LC-MS/MS. The LODs of 0.01 µg/L for unconjugated BPA and 0.05 µg/L for conjugated BPA were the lowest reported for all studies reviewed in this opinion (Figure 11). Unconjugated, sulphated and glucuronidated BPA were detected in 75 %, 50 % and 50 % of the samples with GMs of 0.035 µg/L, 0.065 µg/L and 0.115 µg/L (all concentrations values expressed in µg/L of unconjugated BPA). Based on these GM concentrations, unconjugated BPA accounted for only 16 % of total BPA. It should be noted that the authors also analysed the serum samples by enzymatic deconjugation and liquid–liquid extraction (LLE) for the determination of total BPA. Using this method, unconjugated and total BPA were both detected in 100 % of the samples with GMs of 0.049 µg/L and 0.075 µg/L. The GM of 0.049 µg/L for unconjugated BPA (as obtained by LLE but without enzymatic deconjugation) agreed well with the 0.035 µg/L as obtained by solid-phase extraction. The value of 0.075 µg/L for total BPA (as obtained by LLE with enzymatic deconjugation) was, however, considerably lower than would be expected from the sum of the solid-phase extraction-derived concentrations for unconjugated and conjugated BPA forms.

Of the remaining studies not involving pregnant women, six (Dirtu et al., 2008; Kaddar et al., 2009; Yang et al., 2009; Bloom et al., 2011; Olsen et al., 2012; Liao et al., 2012) report detection rates of ≥ 50 % for unconjugated and total BPA and provide statistically feasible descriptive statistics with median concentrations up to 3.8 µg/L (Figure 11, upper panel). The results of two of these studies are presented below as examples.

Olsen et al. (2012) studied the serum concentration of total BPA in 1 016 elderly people (all aged 70 years old) living in the community of Uppsala, Sweden. Blood samples were collected in the morning after overnight fast. Total BPA was detected in 98 % of the samples (LOD 0.2 µg/L) with a median concentration of 3.8 µg/L. Assuming, as a rough calculation, a blood volume of 5 litres, a serum fraction of 0.55 and a body weight of 70 kg, this median concentration would translate into an *instantaneous* body burden of 150 ng/kg bw, the amount of BPA distributed among the other tissues not yet included. Given the large sample size, it could be concluded from these data that half of the population of elderly people in Uppsala had a body burden of higher than 150 ng/kg bw in the morning after an overnight fast. However, taking into account the average-to-high *daily* BPA uptake among the elderly of 60–200 ng/kg bw per day, as estimated from biomonitoring studies on urinary BPA, the CEF Panel found it difficult to envisage a community-wide exposure scenario that could lead to such a high BPA body burden already in the morning after an overnight fast.

As a second example, Bloom et al. (2011) studied the serum concentration of unconjugated BPA in 27 couples undergoing IVF. On the day of oocyte retrieval, fasting and non-fasting blood specimens were collected from female patients and male partners, respectively. Unconjugated BPA was detected in 85 % (women) and 52 % (men) of the samples (LOD 0.3 µg/L) with median concentrations of 3.3 µg/L (women) and 0.48 µg/L (men). The high serum concentration in the women will not be discussed further here, as the female patients could have been in contact with BPA-containing medical devices. For the male partners, however, a simple back calculation can be used to put their serum concentrations into perspective. According to commonly accepted kinetic concepts, the following equation (Renwick, 2008; Mielke and Gundert-Remy, 2009) can be used to calculate the dose rate D (ng/kg bw/h) from the steady-state serum concentration, C_{ss} (µg/L), the serum clearance, Cl (L/h), the fraction absorbed, f_a, and the body weight, bw (kg):

$$D = \frac{C_{ss} \times Cl}{f_a \times bw}.$$

An estimate for the serum clearance (*Cl*) of 100 L/h for a 70-kg human can be derived from the allometric scaling of clearance values (Figure 8A of Part II – Toxicological assessment and risks characterisation). For the steady-state concentration (C_{ss}), the value of 0.48 µg/L is taken, assuming that this value would be representative of the average serum concentration over an observational period of one hour. Assuming further a body weight (*bw*) of 70 kg and a fraction (f_a) of 0.1 of systemically available BPA (e.g. 10 % bioavailability via the dermal route for thermal paper), the calculation yields a dose rate (*D*) of 6 900 ng/kg bw/h. In other words, to sustain an average serum concentration of 0.48 µg/L over a period of, say, one hour would require a continuous external exposure of 6 900 ng/kg bw/h. Considering the strong impact of first-pass metabolism, for oral exposure the same calculation would result in an even higher required dose rate (e.g. 69 000 ng/kg bw/h at f_a = 0.01). According to Bloom et al. (2011), half of the male participants had serum concentrations of unconjugated BPA of 0.48 µg/L or higher under non-fasting conditions. Again, the CEF Panel considered that it is very difficult to envisage a realistic chronic exposure scenario that would lead to exposures equal to or exceeding 6 900 ng/kg bw per hour and even per day through dermal exposure, the route of exposure that results in the highest blood levels of unconjugated BPA.

Given the unrealistic exposure implications for reported serum BPA concentrations in the µg/L range, the CEF Panel considered that it is difficult to explain the high detection rates and the average concentrations of unconjugated and total BPA in the serum of pregnant women (Figure 11). As already discussed elsewhere (Koch et al., 2012), these results may be due to methodological differences in terms of detection technique (selectivity), LOD/LOQ (sensitivity), contamination and within-laboratory and pre-analytical blank issues causing such results, but this can only be a matter of speculation. The CEF Panel noted the specific exposure situation of pregnant women at delivery or termination in a hospital setting, which may involve BPA exposure due to medical intervention and devices as well as a higher risk for BPA contamination through the handling of samples during sample collection. From the data available, it is not possible to differentiate between these two sources because mostly either unconjugated or total BPA was measured. To assess the impact of contamination, information on both unconjugated and conjugated/total BPA is essential.

Figure 12 provides an overview of how the included studies on serum BPA biomonitoring took account of the possible sources of contamination, e.g., by reporting the use of „BPA-free“ collection tubes (glass, polypropylene vials), the inclusion of procedural blanks, or the use of quality assurance (QA) and quality control (QC) materials. It is also indicated whether a check for contamination was performed at sample collection, sample storage, and/or sample work-up and analysis. The overview shows that whilst being aware of sources of contamination in the laboratory only a few studies were evaluating the sources of contamination during sample collection. A check for contamination at this stage of the process involved only the collection tubes (Bloom et al., 2011; Padmanabhan et al., 2008) and was, in one case (Padmanabhan et al., 2008), inappropriate because of the use of spiked serum containing 5 µg/L BPA. None of the studies included field blanks and replicate samples as recommended elsewhere (Calafat and Needham, 2009). In addition, the type of needles for blood collection was reported in only a few studies, but none of these studies checked the needles as a possible source of contamination. As already emphasised elsewhere (Markham et al., 2010), it is of the absolute necessity to elimininate and continually monitor for background contamination from all sources (from collection to analysis).

Overall, whilst contamination of samples from hospitalised persons (e.g., because of release of BPA by medical equipment) is rather likely, because of inappropriate reporting on possible sources of contamination, and of improbable analytical results, the CEF Panel decided to give little weight to reports of unconjugated and total BPA in human plasma samples.

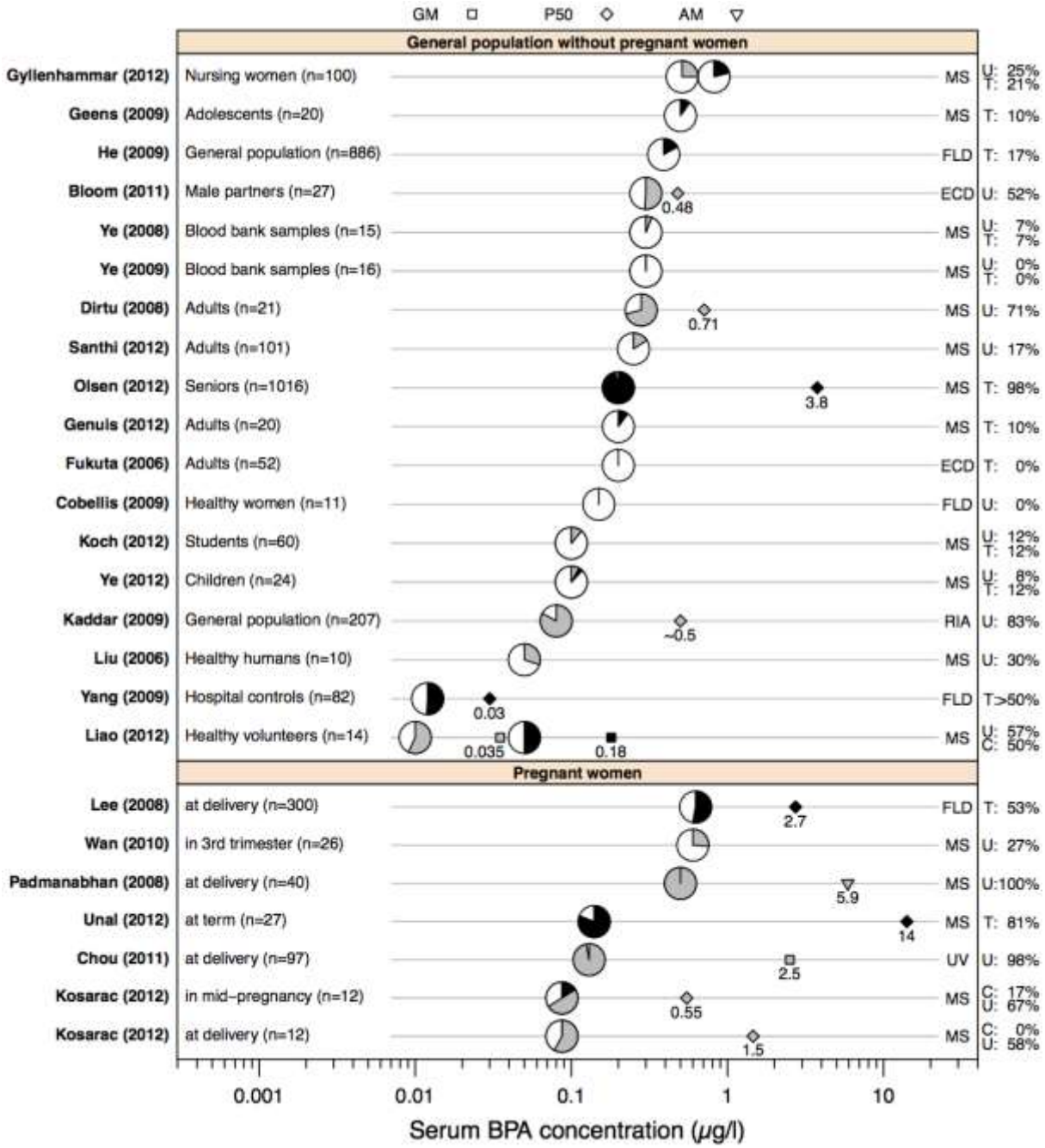


Figure 11: Cleveland dot plot showing the average serum concentrations for unconjugated and conjugated/total BPA (small geometrical symbols) and the proportion of samples with detectable/quantifiable values (pie charts). Pie charts displaying the proportion of detectable/quantifiable values were positioned at the respective LOD/LOQ. A grey filling is used for unconjugated (U) BPA, whereas black filling is used for conjugated (C) and total (T) BPA. Average serum concentrations are shown only for studies reporting ≥ 50 % detects. The different geometrical symbols indicate the geometric mean (squares), the median (diamonds) and the arithmetic mean (triangles). Information on the study groups, the number of subjects (n), the analytical method and the percentage of detectable/quantifiable values are given. All serum concentrations are expressed in µg/L of unconjugated BPA. For each study, only the first author and the year of publication (in parentheses) is given. For complete references, see main text. MS: mass spectrometry, FLD: fluorescence detection, ECD: electrochemical detection, RIA: radioimmunoassay, UV: ultraviolet detection

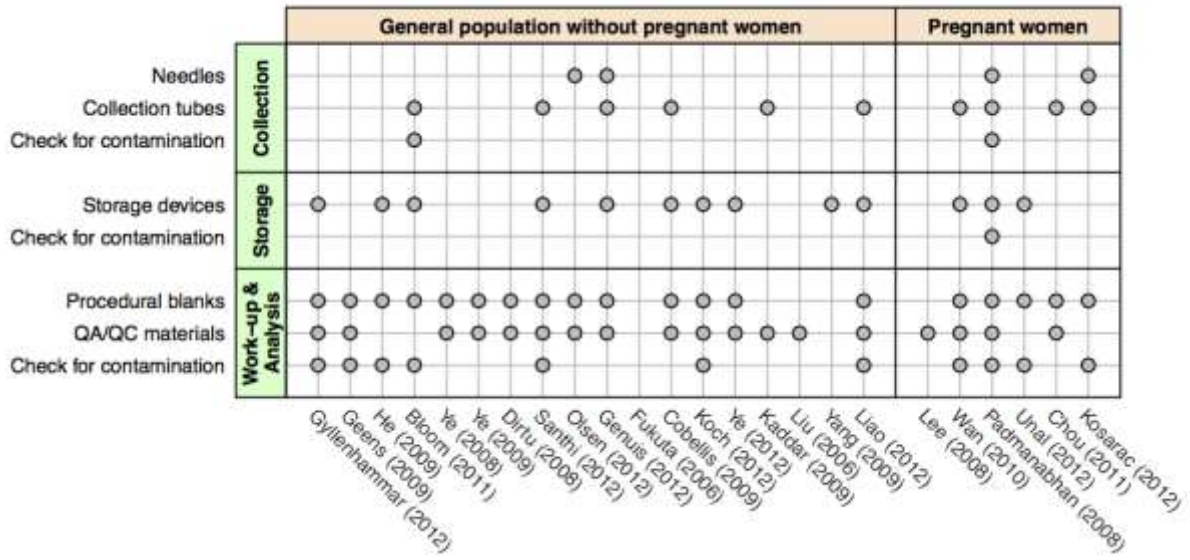


Figure 12: Overview of possible sources of contamination and how they were handled in the studies on serum BPA biomonitoring. Possible sources contamination and control measures were grouped by the different phases comprising sample collection, sample storage, and sample work-up and analysis. A circle symbol indicates the reporting of, e.g., a collection/storage device, a check for contamination, the inclusion of procedural blanks, or the use of QA/QC materials. For each study, only the first author and the year of publication (in parentheses) is given. For complete references, see main text. QA: quality assurance, QC: quality control.

4.6.4. Biomonitoring studies in human milk

Breastfed infants may be exposed to BPA via human milk as a consequence of exposure of lactating mothers. BPA may occur in human milk in the unconjugated and conjugated forms by the lactational transfer from the maternal plasma compartment to the maternal milk compartment. The distribution of both BPA forms between the plasma and milk compartments may vary depending on the milk composition, which changes in terms of protein and fat content within the first three to five days of delivery (Saint et al., 1984). Profound changes occur also in the milk concentration of sodium and chloride during the first 48 hours post partum, which are explained by the closure of tight junctions between the mammary epithelial cells that prevent plasma constituents from passing directly from the interstitial space into the milk (Neville and Walsh, 1996). It is therefore reasonable to consider initial human milk (colostrum), which is collected within the first few days after delivery, and mature human milk separately for exposure assessment. As colostrum is produced from around mid-pregnancy until parturition (lactogenesis stage I; Neville et al., 2001) and accumulates in the mammary gland until being drawn after delivery, the BPA content in colostrum may reflect the pregnant woman's exposure during the second half of pregnancy (Migeot et al., 2013). This contrasts with mature milk, which is produced between feedings, so that the BPA content in mature milk reflects the recent exposure of the mother. Additional arguments for a separate exposure assessment of newborn infants and infants receiving initial and mature human milk are: (i) the three-fold higher activity of a human milk β-glucuronidase in initial milk compared with mature milk (Gourley and Arend 1986); and (ii) the possibility of a treatment-related elevated exposure of mothers staying in the hospital for a few days after delivery.

In the scientific literature covering the period from 2006 until the public consultation, the occurrence of BPA in human milk was analysed in six small-scale studies carried out in Europe (Cariot et al., 2012), North America (Ye et al., 2006, 2008c; Duty et al., 2013) and South-East Asia (Kuruto-Niwa et

al., 2007; Yi et al., 2010). After the public consultation, four additional studies on BPA in breast milk became available, providing new data for Europe (Migeot et al., 2013), North America (Mendonca et al., 2014; Zimmers et al., 2014), and South-East Asia (Yi et al., 2013). Three of these are linked to previous studies: Migeot et al. (2013) is a follow-up of the pilot study by Cariot et al. (2012); Mendonca et al. (2014) is a companion study of Duty et al. (2013); and Yi et al. (2013) is an extended follow-up study of Yi et al. (2010). All studies were assessed according to the inclusion/exclusion and quality criteria (see literature quality table in Appendix I).

4.6.4.1. Colostrum milk

In the French study by Cariot et al. (2012), unconjugated BPA was quantified in initial human milk by isotope-dilution ultra-performance liquid chromatography (UPLC)-MS/MS with a LOD of 0.09 µg/L and a LOQ of 0.40 µg/L. Very much care was taken to avoid cross-contamination by environmental BPA by using solvents and reagents of high analytical quality as well as pre-treated glassware. The milk was drawn manually and directly in pre-treated glass tubes, without any device, materials, wipes or gloves. Quality-control materials and standards were prepared from pooled human milk derived from samples collected over several days from two donors (A. Cariot, University of Poitiers, France, 2013, personal communication) who had been breastfeeding for over one month. Unconjugated BPA was absent in solvent blanks, and it was detected in only some of the pooled (mature) human milk used for standards and quality controls in concentrations (≤ 0.12 µg/L) markedly lower than the LOQ. To test the applicability of their analytical method, the authors analysed three samples that were collected from three donors within a few days after delivery. Unconjugated BPA was detected in all samples in concentrations of 0.80, 3.07, and 3.29 µg/L with a GM of 2.0 µg/L (Figure 13). No information is available on whether the three donors stayed in the hospital and underwent medical procedures, which might have led to an additional, treatment-related non-oral exposure resulting in higher than normal BPA levels in plasma and milk.

In a follow-up study by Migeot et al. (2013), unconjugated BPA was quantified in initial human milk using the same methodology as in Cariot et al. (2012). 21 samples were collected at a hospital in France in 2011 from healthy women within three days of delivery. Unconjugated BPA was detected in 90.5 % (19 out of 21) of the samples, and the concentration ranged from < 0.09 µg/L (i.e. below the LOD) to 6.3 µg/L, with a median of 1.5 µg/L (Figure 13).

Initial human milk (colostrum) was also analysed by Kuruto-Niwa et al. (2007) for the presence of total BPA using an ELISA with an LOD of 0.3 µg/L. Milk samples were collected within three days of delivery from 101 healthy mothers from a local region in Japan in 2000–2001. Glass bottles were used for sample storage to avoid contamination. Total BPA was found in all 101 samples in a concentration range of 1.4–7.1 µg/L with a median of 3.0 µg/L (Figure 13). No information is available on the possible hospitalisation and medical treatment of the donors to exclude a treatment-related non-oral exposure of the mothers. An additional uncertainty comes from the analytical method itself. The ELISA was originally developed for the determination of BPA in urine and proved to be sensitive to both unconjugated and glucuronidated BPA (Kodaira et al., 2000). A method comparison revealed a good correlation between ELISA and HPLC-FLD measurements of BPA in glucuronidase-treated urine samples (Kodaira et al., 2000). However, the cross-reactivity was checked only for a limited number of BPA-related compounds (Kodaira et al., 2000), so that an overestimation of BPA concentration by cross-reactivity with other structurally related compounds cannot be excluded (Dekant and Völkel, 2008; FAO/WHO, 2011; Asimakopoulos et al., 2012). Moreover, the ELISA was obviously not validated for other biological matrices such as human milk.

The CEF Panel noted that the study of Kuruto-Niwa et al. (2007) did not meet the inclusion criteria owing to the non-European origin of the data and the ELISA method (see literature quality table in Appendix I). However, because of the lack of European data for total BPA in colostrum, the CEF Panel decided to take into account the data from Japan, in spite of the methodical shortcomings as well as the fact that the data represent the situation in Japan in or earlier than 2007. The non-specificity of

the ELISA method may tend to overestimate the BPA concentration in colostrum which, however, would be conservative for the exposure assessment of breastfed newborn infants.

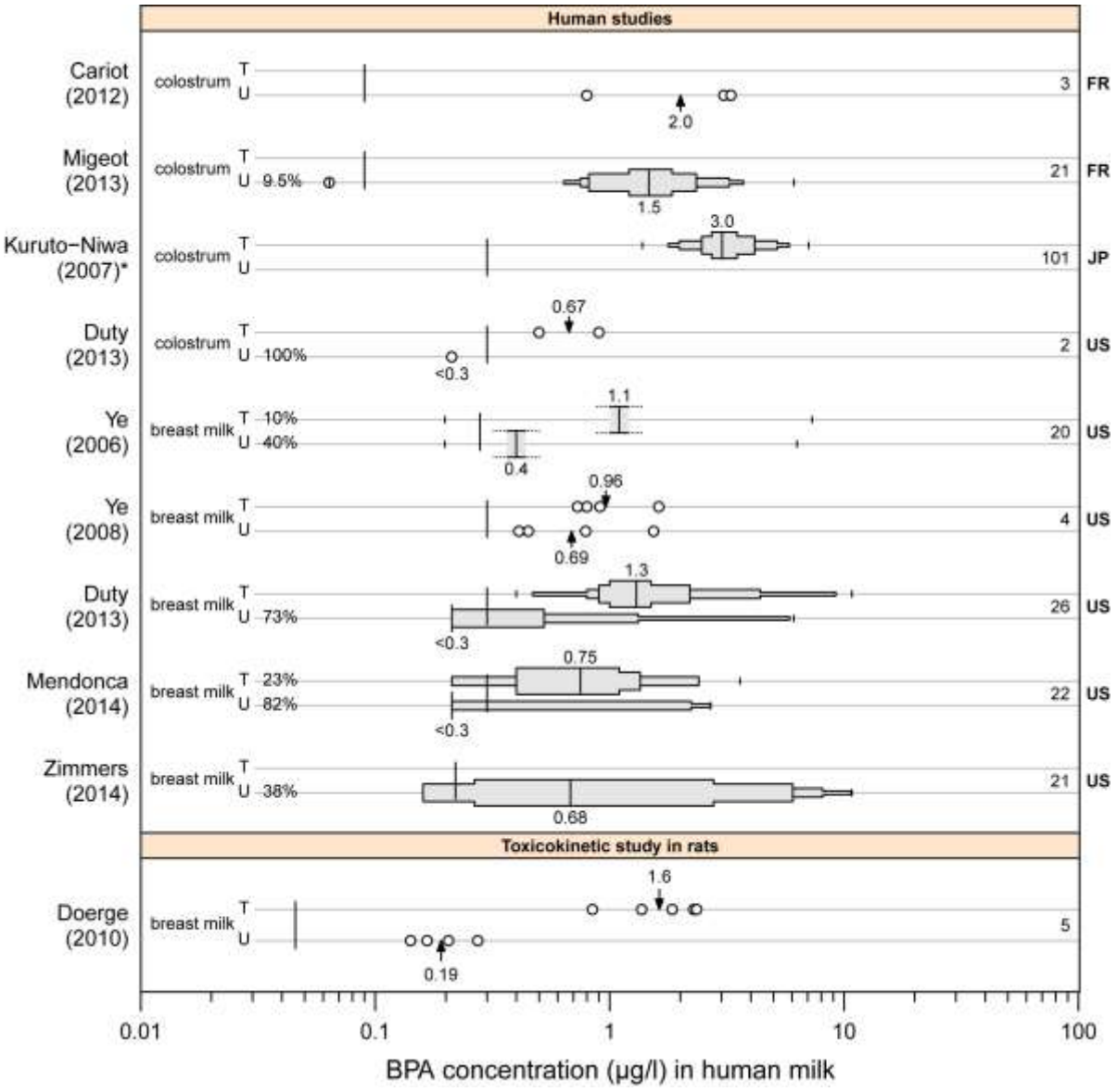


Figure 13: Summary figure of the study results on BPA in human milk. Shown are the concentrations of unconjugated (U) and total (T) BPA on a $\log_{10}$-transformed scale for the eight human studies and the single rat study by Doerge et al. (2010a). Individual measurements (open circles) are shown for studies with small samples sizes (n = 3–4) For larger-scaled studies ($n \geq 20$), box-percentile plots (grey-shaded boxes) are used to depict the distributional characteristics comprising the 5th, 12.5th, 25th, 37.5th, 50th, 62.5th, 75th, 87.5th and 95th percentiles[23], the median (vertical line within the boxes) and the minimum and maximum values (tick marks). Data from studies reporting only the median and the range are shown as incomplete boxplots. Vertical lines indicate the LOD. Concentrations below the LOD are set to a value of LOD/√2. Numbers associated with the data represent either the median value (larger scale studies) or the GM (arrows; small-scale studies). The number of subjects and the country codes are shown on the right. All concentrations are expressed as µg/L of unconjugated BPA. *Study using ELISA instead of an MS-based method

[23] In the moderate-sized studies with n only slightly above 20, the extreme percentiles such as the 95th percentile are associated with high uncertainty and depend sensitively on the type of quantile algorithm used.

4.6.4.2. Mature human milk

Five studies are available for the USA (Ye et al., 2006, 2008c; Duty et al., 2013; Mendonca et al., 2014; Zimmers et al., 2014). The first four of these studies quantified unconjugated and total BPA in human milk samples by isotope-dilution HPLC-MS/MS with an LOD of 0.3 µg/L. All analytical measurements were performed in the Centers for Disease Control and Prevention (CDC) laboratory. Quality control materials for milk blanks were prepared by pooling human milk samples either taken from multiple donors (Ye et al., 2006) or purchased from Mother's Milk Bank between 2002 and 2003 (Ye et al., 2008c). In the first study, Ye et al. (2006) analysed 20 human milk samples from a group of lactating women without known occupational exposure. Unconjugated BPA was detected in 60 % of the samples with a median of 0.4 µg/L and a maximum of 6.3 µg/L (Figure 13). Total BPA was detected in 90 % of the samples with a median of 1.1 µg/L and a maximum of 7.3 µg/L. Comparison of the median concentrations of unconjugated and total BPA yielded a proportion of unconjugated BPA of 36 %. In the second study, Ye et al. (2008c) analysed milk samples of only four donors. The unconjugated and total BPA concentrations were in the range of 0.41–1.54 µg/L and 0.73–1.62 µg/L (Figure 13), respectively. The proportion of unconjugated BPA in the individual samples was quite high (50–99 %), and the authors (Ye et al., 2008c) acknowledged that they could not rule out the potential for contamination, as information on the collection and storage of these four samples was not available.

In the third US study, Duty et al. (2013) analysed milk samples that were collected from 30 mothers with premature infants in a neonatal intensive care unit in 2009–2010. Sample collection devices were pre-screened for BPA, and maternal milk was expressed by mechanical pumping and frozen in BPA-free storage containers. BPA-free breast pump disposable devices were made available to the mothers; however, the use of different systems by some mothers could not be excluded. The analytical measurements were performed by the CDC laboratory. Two human milk samples with concentrations of total BPA of 222 and 296 µg/L and unconjugated BPA of 189 and 252 µg/L were excluded by the authors as statistical outliers. Of the remaining 28 samples, two samples were collected from mothers within three to five days of delivery (S. Duty, Simmons College, Boston, Massachusetts, 2013, personal communication). The concentrations of unconjugated and total BPA in these two colostrum samples were < 0.3 µg/L (i.e. below the LOD) and 0.67 µg/L (GM), respectively. The remaining 26 mature milk samples had median concentrations of < 0.3 µg/L (unconjugated BPA) and 1.3 µg/L (total BPA) with unconjugated BPA accounting for less than 30 % (median value) of total BPA. Remarkably, the box-percentile plots for unconjugated and total BPA (Figure 13; percentiles kindly provided by S. Duty) revealed quite a large variability, which appears to be driven by unconjugated BPA. This variability may be related to the different conditions in the hospital and home environments.

The fourth US study by Mendonca et al. (2014) is a companion study of Duty et al. (2013), which used the same methodology. 23 samples were collected from mothers with healthy infants 3–15 months old at the mothers' home between 2006 and 2008. A breast milk specimen was either hand expressed or obtained using a breast pump after the infant had been fed. The storage containers were of PP and were reported to be not known to contain BPA. The samples remained on ice until processing in the CDC lab. Within the laboratory, rigorous quality control measures were used to ensure valid BPA concentrations (Ye et al., 2006, 2008c). The analysis of the raw data (kindly provided by S. Duty) revealed that about 20 % of the samples did not have detectable concentrations of free and total BPA; in ~ 65 % of the samples the total BPA concentration exceeded that of free BPA, and in 13 % of the samples the situation was reversed. The maximum concentrations of free and total BPA of 23.6 and 22.6 µg/L, which were observed in the same sample, were almost an order of magnitude higher than the next highest values. The CEF Panel regarded this sample as an outlier, proposed to be due to contamination. The next four highest values showed some kind of alternation with total BPA slightly exceeding free BPA and vice versa, but the CEF Panel expected the values for free and total BPA for these four samples, and also those for the excluded sample, to be within the measurement uncertainty of the analytical method. There is a likelihood that, in addition to the values of the excluded sample, the next four highest values could also be outliers and may contain a contribution from contamination;

the CEF Panel included these four values to be on the conservative side. Based on the 22 data points included, box-percentile plots were calculated (Figure 13) and median concentrations of < 0.3 µg/L (unconjugated BPA) and 0.8 µg/L (total BPA) were obtained.

The fifth US study by Zimmers et al. (2014) focused on developing a sensitive method to detect free BPA in human breast milk. BPA was isolated from mature breast milk by solid-phase extraction, derivatised to improve sensitivity and analysed by isotope-dilution UPLC-MS/MS with an LOD of 0.22 µg/L. 21 samples were selected from an archive of a larger national study for a secondary analysis of environmental contaminants. The sample selection was based on the body mass index of the donors, who lived in 14 different states and were of different race. The breast milk samples were drawn by breast milk pumps of different brands, collected in acid-washed glass bottles, shipped on ice to the laboratory and stored at –20 °C until analysis. All necessary precautions were reported to be taken to avoid background BPA contamination during sample preparation. Unconjugated BPA was detected in 62 % of the milk samples (range < 0.22–10.8 µg/L) with a median of 0.68 µg/L (Figure 13). The authors reported a significant influence of race on BPA concentration with Caucasian women having higher levels of unconjugated BPA in their breast milk than non-Caucasian women. The CEF Panel noted that no confirmation was provided that the different breast milk pumps were BPA free. Given that, and given the lack of information on total BPA concentration, no inference could be made about the possible contamination of the samples during milk collection. As only the total BPA concentration in breast milk is used in the present opinion for deriving exposure estimates for breastfed infants, this study was not taken into consideration for deriving exposure estimates for breastfed infants.

The two remaining studies on BPA in human milk were carried out in South Korea (Yi et al., 2010, 2013). These studies were excluded because they did not meet the method/quality inclusion criteria (see literature quality table in Appendix I).

To put the data on BPA in human milk in perspective, the results from animal studies should be taken into consideration. Valuable information on the lactational transfer of BPA and on the relative proportion of unconjugated BPA in animal milk is available from a controlled study in rats (Doerge et al., 2010a), in which dams were administered a daily oral dose of 100 µg/kg bw of stable isotope-labelled BPA. The isotope-labelled BPA was used to avoid contamination problems, and the dose was selected to be within the linear pharmacokinetic range at a level as close as possible to the range of proposed human exposure, yet high enough to measure both BPA forms (Doerge et al., 2010a). The analysis of milk samples, which were collected on day 7 post partum at one hour after dosing when BPA serum levels are maximal (Doerge et al., 2010b), revealed median concentrations of 0.19 µg/L and 1.6 µg/L for unconjugated and total BPA, respectively (Figure 13). The proportion of unconjugated BPA in the individual samples was low (8.7–12 %). So for an oral dose of 100 µg/kg bw, which is very high for humans, the median concentration of total BPA in rat milk is, unexpectedly, of the same order of magnitude as that in human milk. Physiological differences between rats and humans cannot be excluded. For unconjugated BPA, the median concentration is an order of magnitude lower in rat milk compared with that reported for initial human milk (colostrum). Finally, the proportion of unconjugated BPA in rat milk is markedly lower than the reported proportions of < 40 % (Mendonca et al., 2014), < 30 % (Duty et al., 2013), ~ 36 % (Ye et al., 2006), and 50–99 % (Ye et al., 2008c) for mature human milk.

To conclude, although anti-contamination measures have been taken during sample work-up and the analytical procedure, the issue of potential contamination during the collection and storage of human milk samples is not completely solved. Even if the collection procedure is under strict control, an uncertainty about a possible hospitalisation and medical treatment-related non-oral exposure of the mothers remains. The measurement of only unconjugated BPA introduces an additional uncertainty about the concentration of conjugated BPA that should be taken into consideration in the exposure assessment. Given the presence of intestinal β-glucuronidases of bacterial origin in rats (Koldovský et al., 1972; Rød and Midtvedt, 1977; Gadelle et al., 1985) and of a β-glucuronidase in human milk (Gaffney et al., 1986; Gourley and Arend 1986; Grazioso and Buescher 1996), there may be

glucuronidase activity in the infant gut that may lead to a deconjugation of ingested glucuronidated BPA. Even if the infant's gut microflora is not fully developed and the ingested β-glucuronidase in milk is inactivated by the acidic conditions of the infant's stomach, there is the additional possibility that the β-glucuronidase is already active before the milk is consumed. There are several possible reasons why the proportions of unconjugated and conjugated BPA in collected human milk samples may vary. The first is the differences in the production of colostrum and mature milk that are associated with changes in the blood-to-milk transfer (Neville and Walsh, 1996), milk composition (Saint et al., 1984) and the activity of the milk β-glucuronidase (Gourley and Arend 1986). The elevated β-glucuronidase activity in initial milk compared with mature milk (Gourley and Arend 1986) is remarkable in so far as colostrum is produced (and accumulates in the mammary gland) from around mid-pregnancy until parturition (Neville et al., 2001), a period during which the β-glucuronidase activity in serum was found to be substantially increased compared with the first half of pregnancy and the postpartum period (McDonald and Odell, 1947; Lombardo et al., 1984). Another possibility is the maternal exposures via non-oral routes which, for toxicokinetic reasons, may result in higher plasma fractions of unconjugated BPA.

To cover both average and high exposures, estimates of the central tendency and of a UB level should be derived. Estimates of the central tendency were obtained from the average BPA concentrations of selected human studies (Table 29). For initial human milk, the average concentration of 1.5 µg/L for unconjugated BPA was taken from the French study by Migeot et al. (2013). For total BPA, an average concentration of 3.0 µg/L was taken from the Japanese study by Kuruto-Niwa et al. (2007), being aware that the non-specificity of the ELISA method may tend to overestimate the BPA concentration. For unconjugated and total BPA in mature human milk, sample size-weighted means of ~ 0.3 µg/L and 1.1 µg/L, respectively, were calculated from the moderately sized US studies of Ye et al. (2006), Duty et al. (2013) and Mendonca et al. (2014).

Table 29: Database of average BPA concentrations (µg/L) in human milk used for exposure assessment. The average values represent either the median (larger scale studies) or the GM (small-scale studies)

Study/Author	Type of milk	No of samples	Average BPA concentration (µg/L)	
			Unconjugated	Total
Cariot et al. (2012)	Initial	3	2.0	n/a
Migeot et al. (2013)	Initial	21	1.5	n/a
Kuruto-Niwa et al. (2007)	Initial	101	n/a	3.0
Duty et al. (2013)	Initial	2	< 0.3	0.7
Ye et al. (2006)	Mature	20	0.4	1.1
Ye et al. (2008c)	Mature	4	0.7	1.0
Duty et al. (2013)	Mature	26	< 0.3	1.3
Mendonca et al. (2013)	Mature	22	< 0.3	0.8
Zimmers et al. (2014)	Mature	21	0.7	n/a

n/a, not available.

A concentration estimate for high exposure to unconjugated and total BPA in initial breast milk was obtained by using the 95th percentile of 3.7 µg/L from Migeot et al. (2013) and 5.8 µg/L from Kuruto-Niwa et al. (2007), respectively. The CEF Panel noted that the 95th percentile is not a reliable estimate for moderately sized studies such as Migeot et al. (2013), as the estimate may sensitively depend on the type of the quantile algorithm that is implemented in the statistical software package used (Hyndman and Fan, 1996). An alternative solution circumventing this problem was not chosen, as the 95th percentile for total BPA, which finally entered the exposure assessment of breastfed newborn infants, was derived from the larger sized study of Kuruto-Niwa et al. (2007). For total BPA in mature milk, however, an alternative solution was chosen based on the more robust interquartile range (IQR) estimates of the moderately sized studies of Duty et al. (2013) and Mendonca et al. (2014). By noting that the $\log_{10}$-transformed BPA concentrations approximately follow a normal distribution (Figure 13), and that the standard deviation (σ) of a normal distribution is related to the IQR by IQR = 1.35 × σ,

individual estimates for σ of 0.29 and 0.39 could be derived (which agreed well with the parametric estimates for σ of 0.32 and 0.40). These individual estimates yielded an average σ of 0.34 on the $\log_{10}$-transformed scale. A naive 95 % one-sided confidence interval was finally obtained by calculating a factor, $k = 10^{1.64 \times \sigma} = 3.6$, which was then multiplied with the average concentration of 1.1 µg/L to yield a high concentration estimate of 4.0 µg/L for total BPA in mature breast milk. For unconjugated BPA in mature breast milk, a high-concentration estimate could not be derived in a reliable way, given the potential bias owing to the possible contribution from contamination.

Table 30 summarises the derived estimates for the average and high concentration of total BPA in initial and mature breast milk. These estimates were used for the exposure assessment of breastfed newborn infants and infants.

Table 30: Average and high values used (µg/L) to estimate exposure to BPA from human milk

Type of milk	Total BPA concentration (µg/L)	
	Average [(a)]	High
Initial	3.0	5.8
Mature	1.1	4.0

(a): Individual median or mean of medians.

In the 2006 opinion, EFSA used a concentration of unconjugated BPA of < 1.0 µg/L in human milk as a conservative estimate of potential dietary exposure to BPA.

In conclusion, the estimates for the average concentration of unconjugated and total BPA in mature breast milk are supported by several medium-sized studies from the USA. A high concentration estimate was derived from the same studies for total BPA only because this estimate is potentially less biased by sample contamination than an estimate for unconjugated BPA. The high concentration estimate for total BPA in mature milk was used for the exposure assessment of breastfed infants which is a conservative decision, given the uncertainty about the extent by which the conjugated BPA becomes deconjugated in the infant's gut. For initial breast milk, concentration estimates for unconjugated and total BPA were obtained from a medium-sized study from Europe and a larger sized study from Japan, respectively. The uncertainty in these estimates results from the low number of studies and, in the case of the Japanese study, from the past sampling period (2000–2001) and the non-specificity of this ELISA method, which may tend to overestimate the BPA concentration. The high concentration estimate for total BPA in initial breast milk was used for the exposure assessment of breastfed newborn infants, which again is a conservative decision. The uncertainty in the estimates for initial breast milk is further increased by the fact that milk production during the first days after delivery is of a transitional character owing to the transition from stage I of lactogenesis to stage II (Neville et al., 2001). The milk production rate increases more or less linearly during the first days after delivery, reaching a plateau of ~ 600 mL/day on day 5 (Neville and Walsh, 1996). This process is accompanied by compositional changes in protein and fat content (Saint et al., 1984) and in β-glucuronidase activity (Gourley and Arend 1986), which may affect the proportion of unconjugated to total BPA of maternal origin. Last but not least, there is the possibility of exposure from medical devices of mothers staying in hospital for a few days after delivery.

4.6.5. Comparison of results from backward with forward exposure calculation

The exposure part of the opinion focuses on the route-specific external exposure of consumers to BPA. In order to compare this external exposure derived by forward calculation with the internal exposure levels derived by backward calculation, the external exposure values have to be transformed to internal exposure levels summed up over all routes. The focus is on total BPA (conjugated plus unconjugated) in order to provide validation for the external exposure levels. In order to sum up the internal exposure to total BPA over routes, different absorption factors have to be considered for the different routes of exposure. These absorption factors are further described below. The CEF Panel notes that the exposure levels here summed up over different routes are valid only for comparison with biomonitoring. As the information on the proportion of unconjugated and conjugated BPA is not included, they cannot be used for risk assessment. For deriving sound estimates for the internal levels of unconjugated and conjugated BPA for the different routes a more complicated procedure is necessary, which is described in detail in Section 3.1.7 of Part II of this opinion – Toxicological assessment and risk characterisation.

The opinion also systematically evaluates the uncertainty in both forward and backward internal estimates for total BPA (Section 4.7.2).

4.6.5.1. Absorption factor for ingestion

For ingestion it is assumed that 100 % is absorbed, i.e. the absorption fraction of 1 was used.

4.6.5.2. Absorption factor for inhalation

For inhalation the same absorption factor as for ingestion, i.e. 1, was assumed.

4.6.5.3. Absorption factors for dermal uptake

Dermal absorption studies are discussed in detail in Appendix D of Part II – Toxicological assessment and risk characterisation. It has been shown that only studies with pig or human skin are useful for deriving human dermal absorption fractions. From an *in vitro* study with human skin exposed in Franz cells, where the scenario of dermal exposure to thermal paper was simulated (Demierre et al., 2012), an absorption fraction of 0.1 was derived for dermal exposure to thermal paper.

For exposure to BPA in cosmetics, however, this study cannot be used, as BPA was applied in Demierre et al. (2012) in aqueous solution, i.e. without a vehicle that may enhance absorption. Therefore, for BPA in cosmetics a different approach was used.

In Biedermann et al. (2010), an attempt is reported to investigate dermal penetration by exposing living humans. Here, not the transfer to blood (i.e. absorption) was assessed, but BPA was applied in different forms to the fingertips of a human volunteer (e.g. by pressing thermal paper, or by applying BPA in ethanolic solutions). Recovery from the fingertips was determined for different exposure times by measuring BPA in the ethanolic extraction solution. The calculated amounts that remained in the skin after extraction can be seen as a UB for dermal absorption, even if not all BPA remaining in the skin will finally reach the bloodstream.

In one experiment BPA was dissolved in ethanol (10 mg/mL) and 1 µL of this solution was applied directly to the skin of the fingertips. For this experiment a recovery of 40 % after 1.5 hours was reported (determined by extraction from skin with ethanol over 30 seconds), from which a maximal dermal absorption fraction of 0.6 can be deduced. Another experiment with the same amount of BPA in a larger volume of solvent (10 µL, 1 mg/mL) showed a recovery < 5 %, which implies that the maximal dermal absorption of BPA can reach 95–100 % if BPA is applied dissolved in ethanol. Ethanol may act as a transport mediator for BPA into the skin, thus enhancing the absorption fraction. Therefore, the dermal absorption fraction derived for BPA in ethanol may be used for BPA in formulations that have similar vehicle properties as ethanol (e.g. emulsions such as body lotions and creams).

In emulsions and creams, apart from lipophilic substances, a high percentage of water is also present. Therefore, the vehicle effect of ethanol will overestimate the vehicle effect of cosmetic formulations. The dermal absorption fraction for non-intentional trace amounts of BPA in cosmetics can be assumed to be larger than the 0.1 determined for solid BPA from thermal paper and smaller than the absorption fraction of 1 from the recovery study described by Biedermann et al. (2010). For BPA in cosmetics, therefore, an absorption fraction of 0.5 was assumed.

Table 31: Average internal exposure to BPA from all sources in the general population (ng/kg bw per day); for inhalation and ingestion internal equals external exposure

Source	Infants (0–6 months), breastfed			Infants (0–6 months), formula fed	Infants (6–12 months)	Toddlers (1–3 years)	Children (3–10 years)	Adolescents (10–18 years	Women (18–45 years)	Men (18–45 years)	Other adults (45–65 years)	Elderly/ very elderly (65 years and over)
	1–5 days	6 days to 3 months	4–6 months									
Ingestion												
Dust		8.8	8.8	8.8	8.8	7.3	2.9	2.0	0.6	0.6	0.6	0.6
Toys		0.2	0.2	0.2	0.2	0.01						
Dietary exposure from food and beverages	225	165	145	30	375	375	290	159	132	126	126	116
Sum of all ingestion sources	225	174	154	39	384	382	293	161	133	127	127	117
Inhalation												
Air	0.7	0.7	0.7	0.7	0.7	0.7	0.4	0.4	0.2	0.2	0.2	0.2
Sum of all inhalation sources	0.7	0.7	0.7	0.7	0.7	0.7	0.4	0.4	0.2	0.2	0.2	0.2
Dermal												
Thermal paper [(a)]							6.9	9.4	5.9	5.9	5.9	5.9
Cosmetics [(b)]		2.4	2.4	2.4	2.4	1.4	1.1	1.2	1.0	1.0	1.0	1.0
Sum of all dermal sources	0	2.4	2.4	2.4	2.4	1.4	8.0	10.6	6.9	6.9	6.9	6.9
Average internal exposure to total BPA summed up over routes for comparison with biomonitoring	226	177	157	42	387	384	301	172	140	134	134	124

(a): Assuming an absorption fraction of 0.1.
(b): Assuming an absorption fraction of 0.5.

Table 32: High internal exposure to BPA from all sources in the general population (ng/kg bw per day); for inhalation and ingestion internal equals external exposure

Source	Infants (0–6 months), breastfed			Infants (0–6 months), formula fed	Infants (6–12 months)	Toddlers (1–3 years)	Children (3–10 years)	Adolescents (10–18 years	Women (18–45 years)	Men (18–45 years)	Other adults (45–65 years)	Elderly/ very elderly (65 years and over)
	1–5 days	6 days to 3 months	4–6 months									
Ingestion												
Dust		14.6	14.6	14.6	14.6	12.2	4.9	3.3	1	1	1	1
Toys		0.6	0.6	0.6	0.6	0.01						
Dietary exposure from food and beverages	435	600	528	80	857	857	813	381	388	335	341	375
Sum of all ingestion sources	435	615	543	95	872	869	818	384	389	336	342	376
Inhalation												
Air	1.4	1.4	1.4	1.4	1.4	1.1	0.6	0.6	0.3	0.3	0.3	0.3
Sum of all inhalation sources	1.4	1.4	1.4	1.4	1.4	1.1	0.6	0.6	0.3	0.3	0.3	0.3
Dermal												
Thermal paper [(a)]							55.0	86.3	54.2	54.2	54.2	54.2
Cosmetics [(b)]		4.7	4.7	4.7	4.7	2.8	2.1	2.4	2.0	2.0	2.0	2.0
Sum of all dermal sources		4.7	4.7	4.7	4.7	2.8	57.1	88.7	56.2	56.2	56.2	56.2
High internal exposure to total BPA summed up over routes for comparison with biomonitoring	436	621	549	101	878	873	876	473	446	393	399	433

(a): Assuming an absorption fraction of 0.1.
(b): Assuming an absorption fraction of 0.5.

4.6.5.4. Internal exposure levels combined over all routes

The external exposure values as derived by forward calculation were transformed into internal exposure levels by applying the route- and source-specific absorption factors. The Tables 31 and 32 show the estimates for the average and high internal exposure to total BPA in the general population.

4.6.5.5. Comparion of results from backward and forward exposure calculation

The estimates for the average and high internal exposure to total BPA in the general population, as calculated by forward modelling, are compared with those calculated by backward modelling. The average exposure values are compared in Table 33, the high exposure values in Table 34.

By forward modelling, the average internal exposure to total BPA for the age class "Infants" ranged from 42 ng/kg bw per day (formula-fed, 0–6 months old) via 157 ng/kg bw per day (breastfed, 4–6 months old), 177 ng/kg bw per day (breastfed, 6 days to 3 months old), 226 ng/kg bw per day (breastfed, 1–5 days old) to 387 ng/kg bw per day (6–12 months old). Based on only a single study, backward modelling estimated the average internal exposure to total BPA for infants one to two months old to be < 10 ng/kg bw per day, which is at least four-fold lower than the modelled estimate of 42 ng/kg bw per day for formula-fed infants.

The average internal exposure of toddlers to total BPA was estimated only by forward modelling, as no biomonitoring data were available. Forward modelling gave an estimate of 384 ng/kg bw per day.

For children 3–10 years old, an average internal exposure to total BPA of 301 ng/kg bw per day was obtained by forward modelling. Backward modelling gave estimates of 107 and 49 ng/kg bw per day for three- to five-year old children and 5–10 year old children, respectively, which were three- to six-fold lower than the figure obtained by forward modelling.

For the adolescents, adults, women of childbearing age and the elderly and very elderly, a decreasing trend of BPA exposure from 172 via 134–140 to 124 ng/kg bw per day was observed in the modelled estimates. Similarly, backward modelling indicated a decreasing trend with values of 48, 39 and 36 ng/kg bw per day for adolescents, adults and women of childbearing age. The somewhat higher value of 56 ng/kg bw per day for backward modelling in the elderly may be biased towards higher values because of the low number (only two) of biomonitoring studies. Again, the estimates from backward modelling are two- to four-fold lower than those obtained by forward modelling.

To summarise, the estimates for the average internal exposure to total BPA, as obtained by forward and backward modelling, agree with each other within an order of magnitude. More specifically, forward modelling gave estimates that were approximately four-fold higher (42–387 ng/kg bw per day vs. < 10–107 ng/kg bw per day) than those obtained by backward modelling. There are two important aspects that may contribute to these discrepancies. The first one is the statistical procedure by which averages are derived. The second one is the scenario for modelling the dietary and non-dietary exposure.

The exposure estimation by forward modelling (ingestion, dermal and inhalation exposure) was based on the calculation of AMs, whereas the backward modelling was based on GMs. In the case of backward modelling, the decision to use GMs was justified by the log-normal distribution shape of the urinary BPA data (see Section 4.6.2.1). To convert GM-based estimates into AM-based estimates, which are then comparable to those obtained by the modelling approach, a multiplicative conversion factor of 1.8 was derived (see Section 4.6.2.1). The different statistical procedures for calculating central tendencies may at least partly explain the discrepancies between the two approaches.

The second source for the discrepancies could be the scenario chosen for modelling the dietary exposure. Two scenarios (with LB, MB and UB handling of left-censored data) were considered in the dietary exposure estimation (see Section 4.5.2.5). In scenario 1, only foods specifically codified as

canned in the dietary survey are assigned the corresponding occurrence level for BPA. In scenario 2, any food at FoodEx level 4 which has been codified as canned in at least one survey is always considered to be consumed as canned in all dietary surveys considered in the Comprehensive Database. Scenario 2 and the MB approach was chosen for the exposure estimation. As scenario 2 might overestimate the dietary exposure, this may also partly explain the discrepancies between the estimates from forward and backward modelling.

An additional source of discrepancy may be related to the conservativeness of the assumptions made to assess exposure to non-food sources.

Table 33: Average internal exposure to total BPA, as estimated by forward and backward exposure modelling. For some age classes, such as infants and children, several values are given which refer to subgroups among the age classes

Age class	Age(years)	Average internal exposure (ng/kg bw per day)	
		Forward modelling [(a)]	Backward modelling [(b)]
Infants	0–1	42/157/177/226/387	< 10
Toddlers	1–3	384	Not available
Children	3–10	301	49/107
Adolescents	10–18	172	48
Adults	18–65	134/134/140	39
Women of cba	18– 2	140	36
Elderly/very elderly	≥65	124	56

cba, childbearing age.
(a) Internal exposure assessed by combining exposure over all routes. For some age classes several values are given that refer to subgroups among the age class (see Table 31 for details).
(b) When biomonitoring data were available for more than one age class, several values are given.

By forward modelling, the high internal exposure to total BPA for the age class "Infants" ranged from 101 ng/kg bw per day (formula-fed, 0–6 months old) to 549 ng/kg bw per day (breastfed, 4–6 months old), 621 ng/kg bw per day (breastfed, 6 days to 3 months old), 436 ng/kg bw per day (breastfed, 1–5 days old) to 878 ng/kg bw per day (6–12 months old). Based on only a single study, backward modelling estimated the high internal exposure to total BPA for infants one to two months old to be 161 ng/kg bw per day, which was 1.6-fold higher than the forward-modelled estimate for formula-fed infants but 3.9-fold lower than the forward-modelled estimate for breastfed infants three months old or less. Although the biomonitoring study did not differentiate between formula-fed and breastfed infants, the comparison provides a first indication that the forward-modelled estimate for breastfed infants three months old or less could possibly overestimate the exposure because the CEF Panel assumed, for conservative reasons, that the conjugated BPA in breast milk would become deconjugated by milk and intestinal β-glucuronidases.

The high internal exposure of toddlers to total BPA was estimated only by forward modelling, as no biomonitoring data were available. Forward modelling gave an estimate of 873 ng/kg bw per day.

For children 3–10 years old, a high internal exposure to total BPA of 876 ng/kg bw per day was obtained by forward modelling. Backward modelling gave estimates of 676 and 380 ng/kg bw per day for three- to five-year old and 5–10 year old children, respectively, which were 1.3- to 2.3-fold lower than the figure obtained by forward modelling.

For adolescents, adults, women of childbearing age and the elderly and very elderly, high internal exposures to total BPA of 473, 393–446, and 433 ng/kg bw per day were obtained by forward modelling. Backward modelling gave values of 256, 290, 234, and 203 ng/kg bw per day. Again, the backward calculated estimates are 1.4- to 2.1-fold lower than those obtained by forward modelling.

To summarise, the estimates for the high internal exposure to total BPA, as obtained by forward and backward modelling, agree well with each other. More specifically, forward modelling gave estimates that were 1.3- to 2.3-fold higher than those obtained by backward modelling. An exception are the toddlers, for which no biomonitoring data are available, and the breastfed infants three months old or less, for which there are indications from a single biomonitoring study for a higher fold difference between the forward and backward-modelling estimates. Again, as discussed above, the statistical procedures used for the high exposure estimates and the scenario for modelling dietary exposure may explain the discrepancies.

Both forward and backward modelling use the 95th percentile of the distribution of the dietary daily intakes and of the urinary total BPA concentration to derive high-exposure estimates. In the biomonitoring, however, the 95th percentile of the urinary total BPA concentration has different interpretations depending on whether spot urine samples, first morning urine samples or 24-hour samples are used. For spot urine samples, the 95th percentile is related to the 95 % probability that a single, randomly collected sample from a randomly selected subject has a urinary BPA concentration not exceeding the 95th percentile. This is important, as urinary BPA concentrations of repeated urine collections from individuals may vary by up to two orders of magnitude. There are some studies that indicate that the total variance can be subdivided into 70 % within-day variability, 21 % between-day variability and 9 % between person variability. Thus, taking the 95th percentile of the urinary BPA concentration as a measure for deriving high-exposure estimates is a conservative approach, as the real long-term average value for high exposure is lower. It can therefore be concluded that the two-fold discrepancy between estimates derived by forward and backward modelling could be somewhat higher.

An important source of the discrepancy between the two modelling approaches is probably the scenario chosen for modelling the dietary exposure, which is discussed in detail above. Moreover, as the biomonitoring studies for the European region are generally not based on a representative sampling of the population, one may argue that they have not captured high levels of exposure that may occur in specific geographic areas or specific population groups. However, as the European biomonitoring estimates (i.e. GMs, 95th percentiles) are quite similar to those of the largest sized US NHANES (see Figure 8), which is a nation-wide representative survey and therefore includes highly exposed population groups, there is no evidence for assuming the biomonitoring estimates to be less conservative or too liberal. Furthermore, as mentioned above, an additional source of discrepancy may be related to the conservativeness of the assumptions made to assess high exposure to non-food sources.

Table 34: High internal exposure to total BPA, as estimated by forward and backward modelling

Age class	Age (years)	High internal exposure (ng/kg bw per day)	
		Forward modelling approach	Backward modelling
Infants	0–1	101/436/549/621/878	161
Toddlers	1–3	873	Not available
Children	3–10	876	380/676
Adolescents	10–18	473	256
Adults	18–65	393/399/446	290
Women of cba	18–52	446	234
Elderly and very elderly	≥65	433	203

cba, childbearing age.
(a): Internal exposure assessed by combining exposure over all routes. For some age classes several values are given which refer to subgroups among the age class (see Table 32 for details).
(b): When biomonitoring data were available for more than one age class, several values are given.

4.6.5.4. Overall conclusion

Backward modelled exposure estimates based on urinary BPA concentrations are in good agreement with forward modelled estimates of internal exposure to total BPA, suggesting that it is likely that no

major exposure sources have been missed for the modelled exposure assessment. It is, however, important to highlight that the modelled internal exposure includes conservative assumptions resulting in a probable overestimation of exposure that could in theory have hidden other possible sources of exposure. The CEF Panel also noted that there are considerable uncertainties in both estimates.

4.7. Discussion of exposure estimates

4.7.1. Comparison with values from other exposure assessments

According to its terms of reference, the present opinion considers only European data on food consumption, BPA occurrence and migration and urinary BPA concentration for estimating the exposure of the general population in the European region via modelling and biomonitoring approaches. The CEF Panel noted that there are other extensive exposure estimations outside Europe such as those based on urinary biomonitoring data from the US NHANES and the Canadian CHMS surveys (Lakind et al., 2012). For NHANES, which covers the periods from 2003–2004 to 2009–2010, there is a pronounced temporal variability in urinary BPA concentration, with indications of a decline in urinary BPA concentration (Melzer et al., 2010; Lakind et al., 2012; Wells et al., 2013), especially in 6- to 11-year-olds (Wells et al., 2013), which suggests that exposure may have decreased over the last decade. However, the EFSA evaluation focuses on European data, where, given the data available, detection of trends in changes in exposure (whether decreases or increases) is not yet possible. For the purpose of exposure comparison, data on dietary exposure (expressed as external doses and distinguished by age group, when possible) from this and other recent assessments are presented in Table 35.

4.7.1.1. FAO/WHO Expert Meeting on Bisphenol A

The FAO/WHO Expert Meeting on Bisphenol A (FAO/WHO, 2011) estimated dietary exposure to BPA in adults by means of model diets based on the budget method and concentration data on canned food (average and maximum concentrations) retrieved from the literature or based on expert judgement. The Expert Meeting considered a variety of possible scenarios with respect to the frequency of consumption of packaged food, from the worst-case scenario (100 %) to the best-case scenario (25 %). Consequently, a number of estimates were derived for the mean and 95th percentile exposure. The potential dietary exposure for children from 6 to 36 months of age was also based on the budget method and considered a variety of food patterns related to the consumption of liquid food (human milk or infant formula) and the introduction of solid food (fruits, desserts, vegetables and meat), primarily packaged in glass with coated metal lids. Dietary exposure to BPA in infants (0–6 months of age) was assessed by means of consumption data on infant formula and human milk retrieved from the literature. The Expert Meeting assumed a mean consumption of 130 mL/kg bw per day and a 95th percentile consumption of 174 mL/kg bw per day for all food consumption patterns based exclusively on infant formula or human milk or mixtures of the two. Six scenarios were considered in order to cover different patterns with respect to the consumption of human milk (breast, glass or PC bottles), liquid infant formula (glass or polycarbonate bottles) and powdered infant formula (glass or polycarbonate bottles). Except for human milk, all concentration data used in the calculations were expressed as unconjugated BPA.

The mean exposure of exclusively breastfed babies (0–6 months) to BPA was estimated to be 0.3 µg/kg bw per day, and exposure at the 95th percentile was estimated to be 1.3 µg/kg bw per day. Exposure estimates were generally higher for infants fed with liquid compared with powdered formula and for infants fed using PC compared with non-PC bottles. The highest estimated exposure occurred in infants zero to six months of age fed with liquid formula out of PC bottles: 2.4 µg/kg bw per day at the mean and 4.5 µg/kg bw per day at the 95th percentile. For children older than three years, the highest exposure estimates did not exceed 0.7 µg/kg bw per day at the mean and 1.9 µg/kg bw per day at the 95th percentile. For adults, highest exposure estimates did not exceed 1.4 µg/kg bw per day at the mean and 4.2 µg/kg bw per day at the 95th percentile.

Based on the limited published or review data available on exposure to BPA from non-food sources, the Expert Meeting considered that the upper range of mean exposure from inhalation of free BPA (concentrations in indoor and outdoor air) was approximately 0.003 µg/kg bw per day for the general population. Indirect ingestion (dust, soil and toys) was considered to be approximately 0.03 µg/kg bw per day in infants and approximately 0.0001 µg/kg bw per day in children and adults. The Expert Meeting was unable to provide an estimate of exposure from thermal papers because of insufficient data on dermal absorption and observational studies on use patterns. Exposure to BPA from dental treatment was not taken into account because it was considered as short term and unlikely to contribute substantially to chronic exposure.

4.7.1.2. ANSES

The assessment of exposure carried out by ANSES (ANSES, 2013) within its risk assessment of BPA is the only assessment quantifying sources of exposure other than the diet in Europe. A systematic approach was used here to identify and characterise the sources, routes and levels of exposure, as well as the categories of population to be studied. Two groups referred to as the general population (including vulnerable populations) and professionals handling end products intended for the general public as part of their activities (outside of fabrication, processing, distribution and disposal) were investigated. In the former group, children over three years of age, adults and pregnant women were classified as three subgroups. In its exposure assessment ANSES took into account the oral route (food and beverage, drinking water, dust), inhalation route (indoor and outdoor air) and dermal route (thermal paper).

ANSES analysed 1 319 composite food and beverage samples which were collected in the context of a total dietary study conducted between 2007 and 2009 for unconjugated BPA concentrations. Concentration data of BPA in matrices other than foods were retrieved from the scientific literature and from reports of especially commissioned French studies on indoor air and dust from 30 selected homes, on tap water from the water distribution network and bottled water (spring water, natural mineral water, waters made drinkable through treatment) and on the frequency and concentration of BPA in 50 receipts collected in various French retail stores.

Total exposure to BPA was estimated by combining exposure levels from the various matrices by means of a probabilistic Monte Carlo approach, which also included other variables, such as food consumption (in terms of type and quantity), body weight and respiratory volume. In order to accommodate for the reduced systemic bioavailability of unconjugated BPA from food, the exposure estimates were multiplied by a factor of 0.03 (equivalent to 3 % systemic bioavailability) to give the internal exposure from this particular source. The individual estimated exposure values derived from air, dust and food were then combined to calculate a total internal dose. In addition, the internal exposure caused by handling thermal tickets was calculated separately.

The dietary source was identified as the major contributor to the total average internal exposure, with values of 84 % (pregnant women), 78 % (adults) and 70 % (for children > 3 years). When analysing this source further it became apparent that food products packed in cans (representing approximately 50 % of total dietary exposure), some food items of animal origin (with meat, offal and charcuterie representing 17 % of total dietary exposure) and a background level contamination (representing 25–30 % of total exposure) were responsible for these high levels. ANSES reported that about 85 % of the 1 207 food samples analysed were reported to be contaminated with a BPA background level of < 5 µg/kg.

The exposure resulting from thermal paper is calculated separately and not included in the total exposure because of the high uncertainty. The values are reported as internal exposure but can also be taken as external exposure because the conversion factor is 1. For the study population "Consumers—pregnant women handling thermal receipts", the internal dose varies from 0.029 to 140 ng/kg bw per day, for the exposure model using an absorption flow determination, to 0.009 to 260 ng/kg bw per day, for the exposure model using an absorption rate determination. The 95th percentiles used for the

comparison with the toxicological points of reference in the risk assessment, are 50 ng/kg bw per day and 80 ng/kg bw per day, respectively. The average for both is 20 ng/kg bw per day.

For the study population "Consumers—adults handling thermal receipts", the internal dose varies from 0.017 to 150 ng/kg bw per day, for the exposure model using an absorption flow determination, to 0.021 to 260 ng/kg bw per day, for the exposure model using an absorption rate determination. The 95th percentiles are 58 and 89 ng/kg bw per day, respectively, and the averages are 20 and 30 ng/kg bw per day (ANSES, 2013).

4.7.1.3. Belgium

Dietary exposure to BPA was assessed in Belgium (Geens et al., 2010) by means of analytical data from 45 canned beverages and 21 canned food items from the Belgian market. Using detailed information from the national food consumption survey, the BPA intake of adults through canned foods and beverages was estimated to be 0.015 and 0.086 µg/kg bw per day for the mean and the 95th percentile, respectively.

4.7.1.4. FACET

BPA was also used, as an example, to validate software developed within the Directorate General Research-funded project FACET, to assess the exposure to chemical migrants from food packaging. In order to estimate exposure to BPA, concentration distributions in foods packed in light metal packaging, such as food and beverage cans, metal closures, aerosol cans and tubes, were linked probabilistically via the software tool to the amounts of each food item consumed, as recorded in the UK National Diet and Nutrient Survey (NDNS) involving 19- to 64-year-olds. The output from the FACET tool has also been verified using a semi-deterministic approach using packaging data from the UK.

The estimates of exposure to BPA from foods packed in light metal packaging using the probabilistic FACET tool were 0.13 µg/kg bw per day (mean) and 0.59 µg/kg bw per day (97.5th percentile) in UK consumers of these foods. The major contributors were canned foods such as beer, soup, cider, carbonates, preserved pasta and ready meals, and fruit and vegetables. Values obtained by probabilistic modelling were within the minimum and maximum ranges obtained by using a semi-deterministic approach.

4.7.1.5. Conclusions

- Exposure to BPA carried out by the FAO/WHO Expert Meeting on Bisphenol A are far higher than others owing to the use of a conservative model diet.
- Other exposure estimates are of the same order of magnitude.
- Only EFSA and ANSES estimated exposure to BPA from sources other than foodstuffs.
- EFSA considered the contribution of all exposure routes (oral, dermal and inhalation), whereas ANSES evaluated that provided by the oral and dermal routes.
- Exposure from canned food is one of the major contributors to dietary exposure to BPA for all age groups.
- Exposure levels are higher in children aged over three years.

Table 35: Estimates of external exposure to BPA

Population groups	Reference	Source of exposure	Exposure to BPA (ng/kg bw per day)		
			Mean	**95th percentile/ High**	**Conservative estimate based on standard assumptions**
Adults	ANSES , 2013	Diet (food, beverages) and drinking water)	40	87	
Children aged over 3 years			56	141	
Pregnant women			60	130	
Infant (3 months)	EFSA, 2006a	Human milk only			200
		Infant formula fed with glass or non-PC bottle			2 300
		Infant formula fed with PC bottle			11 000 [(b)] (4 000 [(c)])
Infant (6 months)		Infant formula fed with PC bottle and commercial foods/beverages			13 000 [(b)] (8 300 [(c)])
Children (1.5 years)		2 kg commercial foods/ beverages			5 300
Adults		3 kg commercial foods/ beverages			1 500
Infants (breastfed, 1–5 days)	EFSA, 2014	Diet (food, beverages)	225	435	
Infants (0–6 months, formula fed)			30	80	
Infants (6 days to 3 months)			165	600	
Infants (4–6 months)			145	528	
Infants (6–12 months)			375	857	
Toddlers (1–3 years)			375	857	
Children (3–10 years)			290	813	
Adolescents (10–18 years)			159	381	
Men (18–45 years)			126	335	
Women (18–45 years)			132	388	
Other adults (45–65 years)			126	341	
Elderly/very elderly (65 years and over)			116	375	

Population groups	Reference	Source of exposure	Exposure to BPA (ng/kg bw per day)		
			Mean	95th percentile/ High	Conservative estimate based on standard assumptions
Adults	FACET	Canned food and beverages	130	590	
Adults	Geens et al., 2010	Canned food and beverages	15	86	
Adults	FAO/WHO, 2011	Canned food and beverages	1 400	4 200	
Children (6–36 months)			700	1 900	
Infants (0–6 months)		Infant formula and/or human milk	300	1 300	

(a): Only for adults and pregnant women.
(b): Based on the upper value of 50 µg BPA/l of infant formula.
(c): Based on the typical value of 10 µg BPA/l of infant formula..

4.7.2. Evaluation of uncertainty in internal exposure to total BPA through expert judgement

It is important to characterise the uncertainties affecting exposure assessment both for transparency (EFSA, 2009) and so that they can be taken into consideration in risk management (Codex, 2014).

Two complementary approaches were used to address uncertainty in the CEF Panel's exposure assessment for BPA. First, independent estimates of exposure from forward modelling and biomonitoring were compared to assess the degree of agreement between them: the results of those comparisons are presented in section 4.6.5.5. Second, the uncertainty of both the forward modelling and biomonitoring estimates was assessed by a combination of expert judgement and sensitivity analysis, as reported in the present section. This provides an approximate range around each exposure estimate and enables the uncertainties to be taken into account when comparing the forward modelling and biomonitoring results (see below).

Uncertainties affecting the forward modelling estimates for each source of exposure, and the biomonitoring estimates, were assessed by expert judgement and presented in a tabular format of the type suggested by EFSA (EFSA, 2006b). A detailed description of the approach is provided in Appendix H, together with the results. The CEF Panel expressed its judgement of uncertainties affecting each estimate using a scale of symbols representing the degree to which the real exposures might be higher or lower than the estimate (Figure 14). It is important to note that the scale is used to indicate the expected direction and width of the uncertainty, but the relative likelihood of different values within the range was not assessed. Thus, if the uncertainty is described with – –/+, it indicates that the real value may fall in an interval ranging from five times lower than the estimate to two times higher than the estimate; it does not necessarily imply that there is a higher probability that the real value has been overestimated than underestimated.

Results of these assessments are shown in Table 36, for women aged 18-45 years. This group was chosen because it represents women of child-bearing age, and therefore includes one of the groups specified for attention in the Terms of Reference (pregnant women).

As in section 4.6.5.5, it is necessary to convert the forward modelling estimates of external exposure to internal exposures to total BPA and then combined across sources of exposure in order to compare them with the estimate from biomonitoring, as the latter is a measure of internal exposure to total BPA including contributions from all sources. It would be possible to assess the uncertainty of the combined forward modelling estimates by using expert judgement to combine the uncertainty evaluations for each source. However, this requires taking account of the relative magnitude of different sources as well as their different degrees of uncertainty, and is difficult to assess reliably by expert judgement. Instead, therefore, the CEF Panel combined the evaluations for different sources by calculation.

First, the evaluations of uncertainty in the forward modelling estimates for each source of exposure were re-expressed in quantitative terms. This was done by replacing the symbols representing uncertainty for each external exposure estimate with quantitative factors corresponding to the lower and upper ends of the ranges for those symbols in the scale that was used by the CEF Panel in evaluating the uncertainties (Figure 14). This is a conservative approach, tending to over-state the uncertainty, because when evaluating uncertainty the CEF Panel always 'rounded up', assigning the range of symbols that was as large or larger than its assessment of the uncertainty. The factors obtained from this conversion were then applied to the CEF Panel's estimate, producing a range representing an upper and lower bound for the uncertainty of that source of exposure. These ranges are shown in the top right column of Table 36.

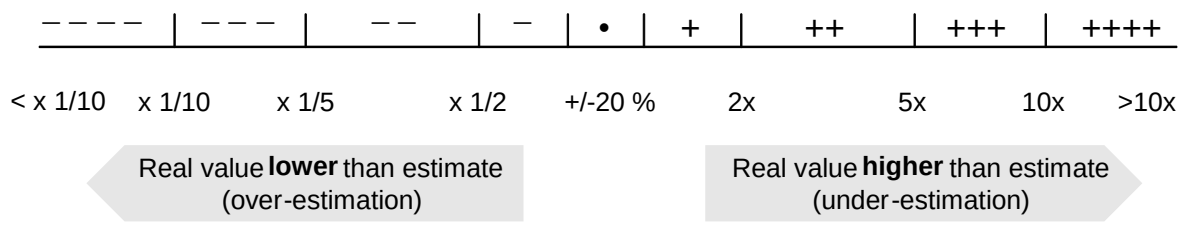


Figure 14: Scale used for evaluating the impact of uncertainties on estimates of exposure to BPA.

To illustrate this conversion, consider the first row in Table 36. The CEF Panel's estimate of average exposure of women aged 18-45 by the dietary route is 0.132 µg/kg bw per day, with an uncertainty evaluation (from Appendix H) of –/●. These symbols correspond to a range of factors from ×½ to +20%, as can be seen from the scale in Figure 14. Applying these to the estimate of 0.132 gives a range from 0.066 to 0.158 µg/kg bw per day, which represents an upper bound of the CEF Panel's evaluation of the uncertainty around the estimated value. The same process was repeated for the uncertainty evaluations for all the sources of exposure that were considered, and also for the estimated dermal absorption fractions and the estimates of exposure from biomonitoring, as shown in Table 36.

Estimates of internal exposure to total BPA were calculated using the following equation:

$$Internal\ exposure\ to\ total\ BPA = Dietary + Dust + Air + Paper \times Absorption_{paper} + Cosmetic \times Absorption_{cosmetic} +,$$

For this calculation, Dietary, Dust, Air, Paper and Cosmetic refer to external exposures. For Dietary, Dust and Air, absorption factors of 1 are assumed and not shown in the equation.

As in other parts of this opinion, both 'average' and 'high' estimates of exposure are considered. In order to be protective for the whole of Europe, international calculations should provide exposure estimates that are equal to or greater "than the best estimates carried out at national levels" (EFSA, 2005). It was therefore assumed that the purpose of the high exposure assessment is to estimate high BPA exposure in the EU country where this estimate is highest. The 95th percentile was considered as an approximate target percentile for each population group assessed. The exposure assessment is therefore aimed at estimating the 95th percentile of exposure for each population group in the EU country where this is highest. This was done explicitly in the dietary exposure assessment, where the highest 95th percentile from different countries was used. Similarly, the highest 95th percentile was taken from the available biomonitoring studies. Assessment of non-dietary sources of exposure did not distinguish different EU countries, but was aimed at the same objective.

The uncertainty analyses were therefore aimed at evaluating how much higher or lower than the calculated estimate the real 95th percentile of exposure for each population group might be, in the EU country where this is the highest. For each individual source of exposure, 'average' and 'high' estimates have been made as approximate estimates for the mean and 95th percentile. The CEF Panel explored different exposure combinations of average and high estimates. Air is a very minor contribution to the combined exposure: the CEF Panel took the high estimate of inhalation exposure for all estimates but it has negligible influence on the total. Tables 36 show four combinations (C1-C4) of estimates for each population group:

1. Averages for both dietary exposure and non-dietary exposure (Combination 1)
2. High estimates for dietary exposure and averages for non-dietary exposure exposure (Combination 2)
3. Averages for dietary exposure and high estimates for non-dietary exposure (Combination 3)
4. High estimates for both dietary and non-dietary exposure (Combination 4).

Combination 1 is an approximate estimate of the average combined exposure. It is expected that the 95th percentile combined exposure will be in the region of the higher of Combinations 2 and 3, and below Combination 4, which is expected to approximate a 99th percentile or higher. Together combinations C1-C4 provide an indication of where the 95th percentile exposure is likely to be. To obtain firmer estimates of 95th percentile combined exposure would require probabilistic exposure modelling, as it will depend on the detailed shape and variance of the distributions for each route of exposure and any dependencies between them.

The results of these evaluations for women aged 18-45 years are presented in Table 36, Figure 15 (individual sources of exposure) and Figure 16 (combined exposure). These show four combinations of average and high internal exposure estimates (Combinations C1-C4, as explained above). Estimates of internal exposure to total BPA derived from biomonitoring data also shown, for comparison.

The estimated internal exposures to total BPA from different sources range over several orders of magnitude, so are plotted on a log scale in Figure 15. It can be seen from the Figure 15 that:

1. The forward modelling estimate of average dietary exposure lies between the average and high estimates from biomonitoring. The forward modelling estimate of high dietary exposure lies above the high estimate from biomonitoring, but their uncertainty ranges overlap and the estimate of each lies within the uncertainty range of the other.

2. The contributions to internal exposure to total BPAfrom thermal paper and cosmetics are much more uncertain than those from diet. This is partly due to uncertainty of the external exposure estimates for the dermal sources and partly due to uncertainty about the dermal absorption fractions.

3. The biomonitoring estimates represent combined exposure. The fact that the estimates for dietary exposure are close to this may suggest that the contributions from thermal paper and cosmetics are over-estimated. However, the average estimate for thermal paper and both the average and high estimates for cosmetics are an order of magnitude lower than the biomonitoring and dietary estimates, but taking into account the uncertainties of all the estimates, they do not contradict each other. This is reinforced by consideration of Figure 16.

The alternative estimates of combined internal exposure to total BPA (i.e. C1-C4) are within a single order of magnitude, so are plotted on a natural scale in Figure 16. It can be seen from Figure 16 that:

1. All of the forward modelling estimates of combined internal exposure to total BPA (Combinations C1-C4) lie within the uncertainty range of the biomonitoring data. Thus all the forward modelling estimates are consistent with the biomonitoring data, although some combinations show a greater overlap of their uncertainty intervals.

2. Values in the upper part of the uncertainty range for Combination 4 are above the uncertainty range for the biomonitoring estimate and therefore less probable. However, this is not a surprise, because since Combination 4 combines high exposures (approximate 95th percentiles) for both oral and dermal sources, it is expected to exceed the true 95th percentile for combined exposure.

3. Combination 2 and 3 would be expected to be closer to the true 95th percentile exposure. They lie either side of the high estimate from biomonitoring, and their uncertainty ranges each largely overlap with the uncertainty range for the biomonitoring estimate, so both are compatible with the biomonitoring estimate.

4. Although the high biomonitoring estimate is closer to the estimate for Combination 3, values up to the estimate for Combination 2 are still plausible because it derives mostly from the high dietary estimate, which has lower uncertainty than the other sources (see Figure 15). Overall,

therefore, it might be reasonable to conclude that the true 95th percentile (in the EU country where this is the highest) is likely to lie in the range between the estimates for Combinations 2 and 3, which also includes the high biomonitoring estimate.

The analysis presented in this section relates to women aged 18-45. Comparisons between the estimates from forward modelling and biomonitoring for other age groups can be seen in section 4.6.5.5 (Tables 33 and 34). Although similar uncertainty analyses have not been completed for other age groups, it can be expected that the uncertainty ranges around both the forward modelling and backward modelling (biomonitoring) estimates would be larger than those for women aged 18-45, as they are supported by less (and, in some cases, much less) biomonitoring data and dietary survey data.

Table 36: Evaluation of uncertainties affecting assessment of internal exposure to total BPA for females aged 18-45.

Source of uncertainty	Estimates for each component	Uncertainty of the estimates	Approximate maximum plausible range*
EXTERNAL EXPOSURE BY EACH ROUTE:			
Average Oral exposure			
Average dietary exposure to BPA (µg/kg bw per day)	0.132	–/●	0.066 - 0.158
Average exposure from dust (µg/kg bw per day)	0.0006	– –/●	0.00012 - 0.001
High Oral exposure			
High dietary exposure to BPA (µg/kg bw per day)	0.388	–/●	0.194 - 0.4656
High exposure from dust (µg/kg bw per day)	0.001	– – –/+	0.0001 - 0.002
Average Dermal exposure			
Average exposure from dermal contact with thermal paper (µg/kg bw per day)	0.059	– – –/++	0.006 - 0.295
Average exposure from cosmetics (µg/kg bw per day)	0.002	– –/++	0.0004 - 0.010
High Dermal exposure			
High exposure from dermal contact with thermal paper (µg/kg bw per day)	0.542	– –/++	0.108 - 2.710
High exposure from cosmetics (µg/kg bw per day)	0.004	– –/++	0.0008 - 0.020
High inhalation exposure			
Assessment of high exposure from air (µg/kg bw per day)	0.0003	–/++	0.00015 - 0.0015
Dermal absorption factors			
Dermal absorption factor for thermal paper	0.1	– –/+	0.02 - 0.200
Dermal absorption factor for cosmetics	0.5	– –/+	0.1 - 1.000
Internal dermal exposures to total BPA after applying absorption factors			
Average internal exposure from thermal paper (µg/kg bw per day)	0.006		0.000 - 0.059
Average internal exposure from cosmetics (µg/kg bw per day)	0.001		0.000 - 0.010
High internal exposure from thermal paper (µg/kg bw per day)	0.054		0.002 - 0.542
High internal exposure from cosmetics (µg/kg bw per day)	0.002		0.000 - 0.020
COMBINED INTERNAL EXPOSURES TO TOTAL BPA:			
C1. Average Dietary + Average Non-Dietary (µg/kg bw per day)	0.140		
- range based on uncertainties for each route of exposure (µg/kg bw per day)			0.066 - 0.230
C2. High Dietary + Average Non-Dietary (µg/kg bw per day)	0.396		
- range based on uncertainties for each route of exposure (µg/kg bw per day)			0.194 - 0.54
C3. Average Dietary + High Non-Dietary (µg/kg bw per day)	0.190		
- range based on uncertainties for each route of exposure (µg/kg bw per day)			0.068 - 0.72
C4. High Dietary + High Non-Dietary (µg/kg bw per day)	0.446		
- range based on uncertainties for each route of exposure (µg/kg bw per day)			0.196 - 1.03
INTERNAL EXPOSURE TO TOTAL BPA ESTIMATED FROM BIOMONITORING DATA			
Estimate of average internal exposure derived from biomonitoring data	0.036	–/+	0.018 - 0.072
Estimate of high internal exposure derived from biomonitoring data	0.234	–/+	0.117 - 0.468

**Using full width of range implied by -/+ symbols*

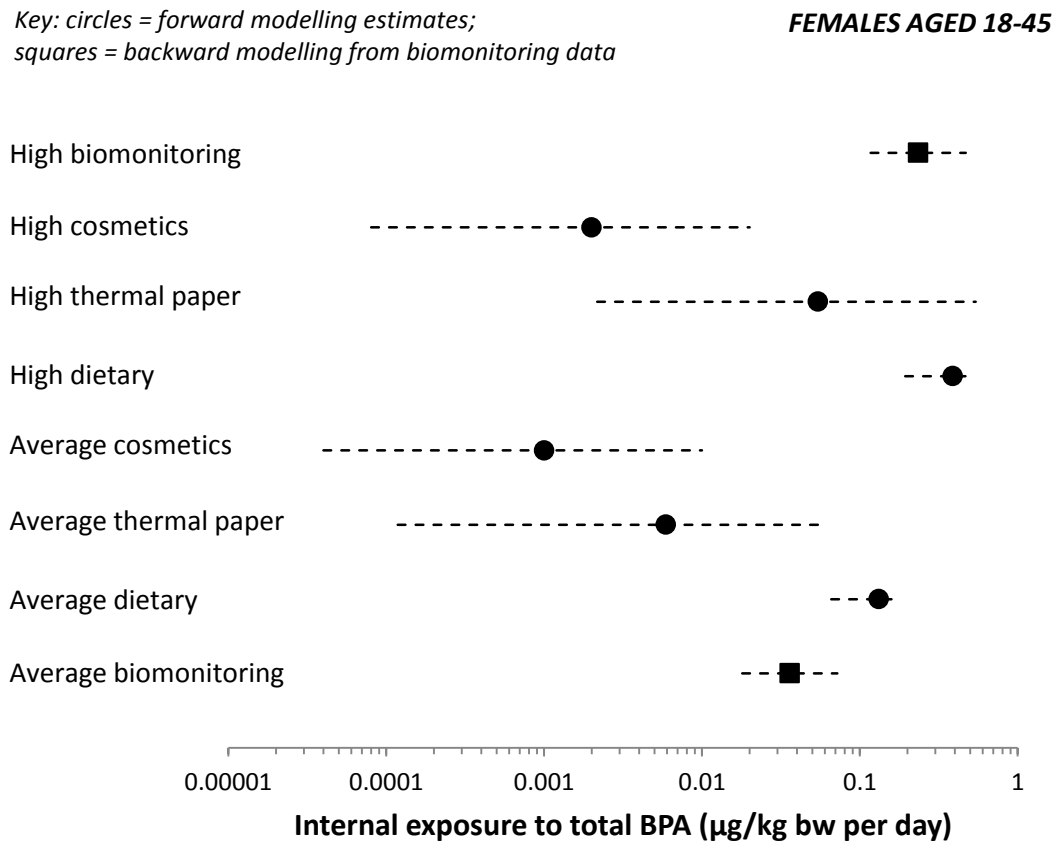


Figure 15: Analysis of uncertainty affecting comparison of estimated internal exposure to total BPA based on biomonitoring data with forward-modelling estimates for the largest individual sources of internal exposure for women of child-bearing age (18-45 years). Note the exposures are plotted on a $\log_{10}$ scale, with labels in the natural scale. Dashed lines show approximate ranges for the uncertainty of the estimates.

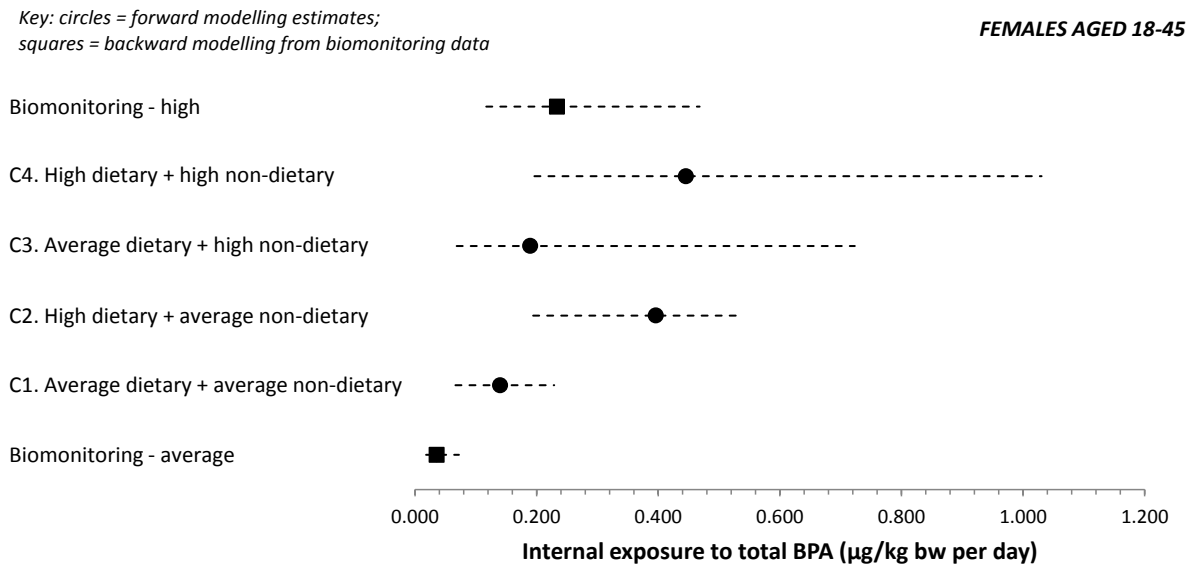


Figure 16. Comparison of forward modelling estimates of combined internal exposure to total BPA for females aged 18-45 with estimates from biomonitoring, plotted on the natural scale. Dashed lines

show approximate uncertainty ranges for each estimate. C1-C4 denote the four alternative Combined estimates, see text and table 36.

5. Conclusions

The exposure assessment involved the estimation of consumer exposure in terms of the following three different metrics:

- External exposure to BPA (in Part I – Exposure assessment)

  The assessment of external exposure considered the different routes (ingestion, inhalation, dermal uptake) and sources (e.g. diet, drinking water, air, thermal paper). It estimated the source-specific doses reaching the physical barriers in the gastrointestinal and respiratory tracts and of the skin. Route-specific external exposures to BPA were calculated via the so-called forward modelling approach by multiplying source concentrations with the corresponding use frequencies (e.g., food intake, handling of thermal paper).

- Internal exposure to total BPA (in Part I – Exposure assessment)

  The assessment of internal exposure to total BPA considered the route- and source (thermal paper/cosmetics)-specific absorption fractions to estimate the doses that passed the physical barriers to enter the body. For this purpose the estimates for average and high internal exposure to total BPA from all sources and over all routes were combined (Combinations C1-C4).

  These internal doses are expressed as doses of total BPA (as no differentiation is made between the unconjugated and conjugated BPA). As BPA is completely eliminated via urine, the sum of these internal doses is directly comparable to exposure estimates obtained by the so-called backward modelling approach from urinary biomonitoring data.

- Aggregated exposure to unconjugated BPA (in Part II – Toxicological assessment and risk characterisation)

  The assessment of aggregated exposure used PBPK modelling to translate the contributions from the relevant sources (diet and house dust for the oral route, thermal paper and cosmetics for the dermal route) into a toxicologically relevant dose metric, the area under the curve (AUC) for the serum concentration of unconjugated BPA. A translation into AUC is necessary because, in contrast to dermally absorbed BPA, BPA absorbed from the gastrointestinal tract is subjected to the first-pass metabolism before entering the systemic circulation. Based on the AUC information, external dermal exposures (thermal paper, cosmetics) were converted to equivalent oral exposures which could then be summed up with the external oral exposures (diet, house dust) to arrive at an aggregated exposure estimate.

The assessment of exposure to BPA from all sources showed that diet is the main source in all population groups for external exposure only Specifically, canned food and non-canned meat and meat products are the two main dietary contributors to external BPA exposure in the large majority of countries and age classes. The pattern was different for aggregate exposure (see Section 5 in Part II-toxicological assessment and risk characterisation).

While canned food as a main source of external dietary exposure to BPA is confirmed by the data presented in this opinion, exposure from non-canned meat and meat products and fish had not been anticipated until the 2013 report of ANSES on concentrations of BPA in French food. Investigation of these findings is currently under way, but, until further results are available, there is no substantiated explanation for the presence of unconjugated BPA in foods of animal origin.

Among the population older than six months, infants (6-12 months) and toddlers had the highest estimated external average (0.375 µg/kg bw per day) and high (0.857 µg/kg bw per day) dietary exposure. This was mainly due to their higher consumption of foods and beverages per kilogram body weight. The modelled dietary exposure for adolescents, adults (including women of childbearing age) and elderly/very elderly ranged from 0.116 to 0.159 µg/kg bw per day for the average external exposure and from 0.335 to 0.388 µg/kg bw per day for the high exposure, respectively. Dietary exposure to BPA estimated by EFSA in 2006 in the population older than six months was far higher (up to 5.3 µg/kg bw per day in toddlers) compared with the current assessment (up to 0.857 µg/kg bw per day for the high exposure of toddlers), owing to the lack of data at that time which led to the use of very conservative assumptions in relation to both the level of consumption of canned food and the estimated BPA concentration in these foods.

The availability of more data now, as compared to 2006, has allowed the CEF Panel to carry out a more refined dietary exposure assessment for infants. According to the current estimate, BPA exposure for infants up to six months (0.03 to 0.225 µg/kg bw per day for average external exposure) is much lower than that estimated by EFSA in 2006 for infants within six months of age (≤ 11 µg/kg bw per day)bw per daybw per day. This was due to the use at that time of very conservative assumptions in relation to BPA concentration in infant formula and to BPA migration from PC bottles to account for the lack of data.

Dietary external exposure in women of childbearing age (0.132 and 0.388 µg/kg bw per day for average and high exposure, respectively) was similar to that in men of the same age (0.126 and 0.335 µg/kg bw per day for average and high external exposure, respectively). The minimal differences may be related to women consuming different food items, as reported in the individual surveys.

The uncertainty around the estimates of dietary exposure was judged as relatively low compared to other sources of exposure such as thermal paper.

Thermal paper was the second largest source of external exposure in all population groups above three years of age. The modelled estimates for 3–10 years old children, adolescents, adults (including women of childbearing age) and elderly/very elderly ranged from 0.059 to 0.094 µg/kg bw per day for the average exposure and from 0.542 to 0.863 µg/kg bw per day for the high external exposure, respectively. The CEF Panel considers that more data would be needed for BPA absorption through the skin, on skin metabolism and for patterns of thermal paper handling by the general population in order to provide a refined estimate of exposure through this source to reduce the uncertainty in the estimate.

In children under the age of three years (except for infants in the first few days of life) dust was the second largest source of external exposure to BPA and ranged from 0.009 to 0.015 µg/kg bw per day for average and high external exposure, respectively.

Average external exposure to BPA from other sources such as toys and cosmetics was estimated to be less than 0.001 µg/kg bw per day and 0.005 µg/kg bw per day, respectively, in all population groups.

For the four age classes covering infants from 1 day up to 6 months, the average internal exposure to total BPA, as estimated by forward modelling, ranged from 0.042 µg/kg bw per day to 0.226 µg/kg bw per day. The average internal exposure for the population older than six months ranged from 0.301 to 0.387 µg/kg bw per day in children aged 3 to 10 years and infants aged 6 to12 months and from 0.124 to 0.172 µg/kg bw per day in the elderly/very elderly and adolescents.

For the four age classes covering infants from 1 day up to 6 months the high internal exposure to total BPA ranged from 0.101 µg/kg bw per day to 0.621 µg/kg bw per day. The high internal exposure for populations older than six months ranged from 0.873 to 0.878 µg/kg bw per day in toddlers and infants aged 6 to 12 months, and from 0.393 to 0.473 µg/kg bw per day in men and adolescents.

Internal exposures to total BPA, as estimated by forward modelling, are in good agreement with the backward-modelling estimates obtained from urinary biomonitoring, suggesting that it is likely that no major exposure sources have been missed for the forward-modelled exposure assessment. It is, however, important to highlight the fact that the internal exposure estimation of total BPA includes conservative assumptions resulting in likely overestimation of exposure that could in theory have hidden other possible sources of exposure. The CEF Panel noted also that there are considerable uncertainties in the forward and backward estimates of internal exposure.

The CEF Panel has carried out an assessment of aggregated dietary and non-dietary exposure tounconjugated BPA using PBPK modelling. 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).

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ABBREVIATIONS

ABS	acrylonitrile-butadiene-styrene
AM	arithmetic mean
ANSES	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (French Agency for Food, Environmental and Occupational Health and Safety)
BADGE	bisphenol A-diglycidyl ether
BPA	bisphenol A
bw	body weight
CDC	(US) Centers for Disease Control and Prevention
CEF Panel	EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CHMS	Canadian Health Measures Survey
CI	confidence interval
DMA	dimethacrylate
ECD	electrochemical detection
EEA	European Economic Area
ELISA	enzyme-linked immunosorbent assay
EMA	ethoxylate dimethacrylate
EU	European Union
FDA	(US) Food and Drug Administration
FLD	fluorescence detection
GC	gas chromatography
GM	geometric mean
GMA	glycidyl methacrylate
GSD	geometric standard deviation
HBM	human biomonitoring
HDPE	high-density polyethylene
HPLC	high-performance liquid chromatography
ICRP	International Commission on Radiological Protection
LB	lower bound
LC	liquid chromatography
LDPE	low-density polyethylene
LLE	liquid–liquid extraction
LOD	limit of detection
LOQ	limit of quantification
MB	middle bound

MS	mass spectrometry
NHANES	(US) National Health and Nutrition Examination Survey
PA	polyamide
PC	polycarbonate
PEI	polyetherimide
PES	polyethersulphone
PET	polyethylene terephthalate
PM10	particulate matter with diameter less then 10 µm
PP	polypropylene
PS	polystyrene
PVC	polyvinylchloride
RIA	radio-immunoassay
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SML	specific migration limit
TBBPA	tetrabromobisphenol A
TDI	tolerable daily intake
UB	upper bound
UV	ultraviolet

Appendices

Appendix A. Sampling and methods of analysis

This appendix describes the criteria considered for the inclusion of data in the assessment of the exposure to BPA, as well as for assessment of the quality of the biomonitoring studies.

When considering the inclusion of data in the assessment of the exposure to BPA it is essential that the methodology used to derive the data is of an appropriate quality. This appendix describes the quality criteria applied to ensure, as far as possible, the quality of the data considered in this opinion.

The criteria for inclusion/exclusion of data (and methodology) for consideration for the opinion for BPA are given below and are based on the performance characteristics of the method. Performance characteristic means functional quality that can be attributed to an analytical method. This may be, for instance, specificity, accuracy, trueness, precision, repeatability, reproducibility, recovery, detection capability and ruggedness. The European Commission`s Joint Research Centre (JRC) guidelines on performance criteria and validation procedures of analytical methods used in controls of food contact materials were used as the basis for defining the criteria for all methods considered in this opinion (JRC, 2009).

In terms of method performance the main criteria to consider are:

- the recovery of the method;
- the repeatability of the method;
- the LOD and/or LOQ.

Recovery

Recovery means the percentage of the true concentration of a substance recovered during the analytical procedure. For inclusion the recovery should be in a range, as described in Table 37.

Table 37: Ranges of recovery

Concentration	Mean recovery (%)
≤ 10 parts per billion (ppb, µg/kg)	40–120
100–10 ppb	60–110
≥ 100 ppb	80–110

For the purpose of the exposure assessment in this report, data were not corrected for the recovery. Correction for recovery is aimed at reducing the uncertainty in concentration data, but as the technique used to estimate it varies among laboratories, such a correction may in the end introduce even more uncertainty in the concentration data. Data derived from analytical determinations with recoveries outside the above-mentioned criteria were excluded.

Repeatability

Repeatability is defined by IUPAC as precision under repeatability conditions (i.e. the same operator, instrument and laboratory and within a short time interval). Repeatability (r) is often expressed as a relative standard deviation RSD_r (%) derived from replicate analyses of either a certified reference material or a fortified material. For inclusion of data the criterion applied was that the repeatability (RSD_r) should not exceed the level calculated by the Horwitz equation. The Horwitz equation actually describes the reproducibility (R) between different labs as a function of concentration and expressed as relative standard deviation RSD_R (%). Setting the reproducibility measure (RSD_R) as the limit for the repeatability (RSD_r) is explained by the fact that the RSD_r is generally one-half to two-thirds of the RSD_R. For very low concentrations, the reproducibility is somewhat better than expected from the

Horwitz equation and approaches a constant value of 33 % (Horwitz, 2003). Similarly, Thompson (2000, 2004) concluded that an invariant value for concentrations below 10 ppb was 20–25 %. In Table 38, a limit value of 25 % was chosen for concentrations of 1 and 10 ppb.

Table 38: The RSD calculated using the Horwitz equation for a concentration range from 1 ppb to 1 ppm

Concentration	Relative standard deviation (RSD_r, %)
1 ppb	25 [(a)]
10 ppb	25 [(a)]
100 ppb	22.6
1 ppm	16.0

(a): The RSD calculated using the Horwitz equation is > 25 %. However it has been shown (Thompson, 2000, 2004; Horwitz, 2003) that at concentrations of less than 10 ppb there is a tendency for an invariant RSD of 20–25 % and so 25 % was selected as the criterion for acceptable repeatability.

Limit of detection/limit of quantification

Analytical LODs are usually expressed as multiples of the signal-to-noise ratio (S:N) of the (chromatographic) background signal with the LOD being 3 × S:N and LOQ being 10 × S:N. In some biomonitoring studies reporting the unavoidable presence of background BPA contamination (e.g. Völkel et al., 2011), somewhat higher multiples of the S:N are used to report only values above the background contamination.

Food samples below the LOQ or limit of reporting (left-censoring limit) were handled through the substitution method: the lower bound (LB) value was obtained by assigning a value of zero to all the samples reported as less than the left-censoring limit, the midlle bound (MB) value by assigning half of the left-censoring limit and the upper bound (UB) by assigning the left-censored limit as the sample result (see Section 4.3.2, "Occurrence data in food"). The average BPA concentration in each food category was therefore assessed as LB, MB and UB. Therefore, in a study in which all samples give a quantifiable BPA concentration, the LOD/LOQ are of no relevance in the assessment of average LB, MB or UB BPA concentrations. In a study in which BPA concentrations are reported in some samples as < LOD or < LOQ, the MB and UB average BPA concentration of the specific food category will be influenced by the left-censoring limits, and this will influence the assessment of exposure to BPA. Criteria were therefore set to avoid the possibility that samples with a very high left-censoring limit would artificially increase the assessment of average MB and UB BPA concentration in some food categories. For occurrence data in food, methods reporting LOD values greater than 15 µg/kg or LOQ values greater than 50 µg/kg were excluded from the assessment of average BPA concentration, and therefore from the exposure assessment. For biomonitoring data methods reporting LOD values greater than 0.4 µg/kg or LOQ values greater than 1.3 µg/kg were excluded from the exposure assessment.

Supplementary criteria to be considered when assessing method performance were:

- the selectivity of the method, i.e. whether or not interferences had been considered (e.g. Ackerman et al., 2010);
- whether or not measures had been taken to reduce or avoid background contamination;
- Whether or not the method-performance data described have been derived for an appropriate matrix and at a concentration relevant to the levels measured in the samples.

Specifically for biomonitoring studies, it is necessary to detect and quantify BPA in different biological matrices (urine, serum, human milk) in the unconjugated and the conjugated form. Complicating problems for all of these matrices are: (i) the artefactual contamination with trace levels of unconjugated BPA from environmental sources; and (ii) the instability of BPA conjugates owing to

spontaneous or enzymatic hydrolysis during collection, storage and analysis (Vandenberg et al., 2010; Hengstler et al., 2011; WHO, 2011a). Therefore, the documentation of measures to preserve sample integrity and to reduce external contamination was taken into account when deciding whether a study is considered valid and relevant to be included in this opinion.

Many different approaches have been reported for the determination of BPA and conjugated BPA. These are reviewed below.

Samples

No quality criteria were established for sampling methods. The country of origin of the samples was considered and, in most cases, non-EU data were excluded (see Section 4.2). Where information was provided samples taken for determination of BPA concentration or of migration of BPA were considered to be representative of those available on the market. However, in many cases this information was not given.

1. Methods of analysis

The approach used to extract BPA from any sample (including all of the potential sources of exposure given in Section 3) is dependent on the matrix being tested. Methodology typically involves extraction of the analyte from the matrix and may be followed by clean-up of the extracts to eliminate any interferences, concentration to achieve the desired method sensitivity and/or derivatisation to provide BPA in a form suitable for analysis. Analytical approaches described in the literature include: LC with UV, FLD, ECD, MS or MS/MS detection, GC with MS detection and immunoaffinity methods (e.g. ELISA). An overview of the methodology for the determination of BPA in and migrating from food contact materials, in foods, in biological samples, in non-food potential sources of exposure (including outdoor air, surface water, dust, indoor air, paper products, children toys and pacifiers with PC shield and medical devices) is presented below. Ballesteros-Gómez et al. (2009) reviewed methods describing the determination of BPA in foods and a WHO/FAO background paper on "Chemistry and analytical methods for determination of BPA in food and biological samples" was prepared by Cao (WHO, 2011b).

1.1. Extraction and migration of BPA from food contact materials

Material types that may contain BPA and that are used in food contact applications include PC plastics, epoxy coatings applied to metal substrates and recycled paper and board. To extract all of the residual BPA from a material or article requires some degree of interaction between the material and the extraction solvent. This interaction, referred to for plastics as swelling of the polymer, allows for extraction from the entire material rather than just from the surface. For polar materials such as paper and board and PC plastics the greatest interaction occurs with polar solvents. For less polar materials such as epoxy resins the greatest interaction occurs with less polar solvents. The solubility of the BPA in the extraction solvent must also be considered. BPA is soluble in acetic acid and is very soluble in ethanol, benzene and diethyl ether (Lide, 2004). Only a limited number of methods has been reported for the determination of BPA in food contact materials and articles, as in most cases a migration test into a food simulant or solvent rather than an exhaustive extraction has been carried out.

1.1.1 Extraction tests

Mercea (2009) and Ehlert et al. (2008) described the determination of residual BPA in PC by dissolution of the polymer in dichloromethane followed by subsequent precipitation with methanol. Dissolution of PC in methylene chloride and precipitation with acetone has also been described to determine residual BPA concentration in the polymer (Nam et al., 2010). In such studies all of the BPA will remain in solution and so is amenable to direct analysis by techniques such as LC-FLD. When determining the concentration of residual BPA in a PC plastic, care should be taken to avoid hydrolysis of the polymer, as this could lead to an overestimation of the BPA levels present that could migrate into a foodstuff under normal conditions of use. Alkaline conditions have been reported to hydrolyse the PC polymer, and the hardness of the water has also been postulated to play a role in the

degradation (Biedermann-Brem et al., 2008; Biedermann-Brem and Grob, 2009). For epoxy-coated metal substrates for which the coating is usually < 10 µm it is generally accepted that acetonitrile affords exhaustive extraction. Given the solubility of BPA in ethanol and the polarity of paper and board substrates, then extraction in this solvent is conventionally used for the exhaustive extraction of this matrix. It is rare that sensitivity is an issue when analysing extracts of PC- or epoxy-coated food contact materials and articles, and therefore the extracts generated are usually analysed directly.

1.1.2 Migration

Regulation (EU) No 10/2011 (EU, 2011) defines food simulants and migration test conditions for food contact plastics and is applicable to PC plastics. These food simulants intended to mimic the migration of a given substance that could, under the worst foreseeable conditions of use, migrate into a foodstuff. For consumer protection purposes it is the intention that migration into food simulants should exceed that which will occur into a food. A CEN Technical Specification was published in 2005 describing methodology for the determination of BPA in conventional EU food simulants (CEN, 2005). In this procedure aqueous food simulants are analysed directly by LC-UV and oil samples dissolved in hexane and extracted into methanol/water. The methanol/water extracts are then analysed directly by LC-UV. The aforementioned regulation also permits the substitution of food simulants with more severe extraction solvents, provided that the substitution is based on scientific evidence that the substitute food simulants (extraction solvent) used overestimate the migration compared with the regulated food simulants. The majority of the methods available for food contact materials and articles describe the determination of BPA in these regulated or substituted food simulants (solvents). The exposed simulants/solvents may be analysed directly by LC-FLD or LC-MS/MS (e.g. Santillana et al., 2011), analysed using solid-phase micro-extraction and GC-MS (e.g. Cao and Corriveau, 2008b), concentrated using solid phase extraction (SPE) and analysed by GC-MS (e.g. Guart et al, 2011; Fasano et al., 2012), concentrated using SPE, derivatised and analysed by GC-MS (e.g. Ehlert et al., 2008; Kubwabo et al., 2009). Direct analysis of water as a food simulant using an ELISA method has also been reported (Cooper et al., 2011), however concerns regarding sensitivity, selectivity and cross-reactivity have been raised for this method of analysis (s. point 2.3).

1.2. Extraction of BPA from food

For foodstuffs solvent extraction is the most common technique used for the isolation of BPA from the food matrix. The solvent used and the extraction conditions are dependent on the specific food type. Acetonitrile is the most commonly used extraction solvent for solid foodstuffs. In addition to the extraction of BPA, acetonitrile will also precipitate any proteins that are present, thereby effectively performing a clean-up step alongside the extraction. In addition to the removal of proteins from the matrix, the separation of the BPA from the fat also facilitates improved analytical performance, and this has been reported to be achieved using alkanes (hexane, heptanes and isooctane) along with the acetonitrile. For liquid foodstuffs and beverages BPA extraction using ethyl acetate, chloroform or dichloromethane has been reported (Ballesteros-Gómez et al., 2009); however, SPE techniques are more extensively used to isolate the BPA from these matrices (e.g. Maragou et al., 2006; Ackerman et al., 2010; Gallart-Ayala et al., 2011; Bono-Blay et al., 2012). Other extraction techniques reported in the literature have been summarised by Ballesteros-Gómez et al. (2009) and include pressurised liquid extraction (Ferrer et al., 2011), coacervative microextraction (García-Prieto et al., 2008; Pérez Bendito et al., 2009), microwave assisted extraction (Pedersen and Lindholst, 1999; Basheer et al., 2004), solid-phase micro-extraction (Cao and Corriveau, 2008b), stir bar sorptive extraction (Magi et al., 2010), molecularly imprinted polymers (Baggiani et al., 2007, 2010) and matrix solid phase dispersion extraction (Shao et al., 2007a).

Although some methods report the direct analysis of the solvent extracts using LC and GC separation techniques, in most cases additional sample clean-up and concentration steps are required to achieve the desired selectivity and sensitivity. SPE clean-up is the most commonly reported technique (Grumetto et al., 2008; Yonekubo et al., 2008; Cao et al., 2009a); however, some methods describing the use of immunoaffinity columns for sample clean-up have also been reported (Brenn-Struckhofova

and Cichna-Markl, 2006; Podlipna and Cichna-Markl, 2007), along with others describing gel permeation chromatographic methods (Poustka et al., 2007; Gyllenhammar et al., 2012).

As mentioned in Section 4.3.2 of this opinion, animals that have been exposed to BPA via diet or water have the potential to contain conjugated BPA, and furthermore relatively high concentrations of unconjugated BPA were observed (average of 9.4 and 7.4 µg/kg in meat and fish, respectively (Table 4, column "All—average BPA"), and so food products of animal origin may further contribute to BPA exposure. The methods used to derive the BPA data for animal products and used in the exposure assessment in this opinion were scrutinised to assess whether or not the reported concentration was that of unconjugated BPA or total BPA (conjugated + unconjugated). None of these methods, published in the scientific literature or obtained through the EFSA call for data, described deconjugation steps in the approach. For several methods BPA concentrations were determined after derivatisation (Cao et al., 2008; Geens et al., 2010; Cunha et al., 2011; Feshin et al., 2012). In these examples it is possible that deconjugation would occur during the derivatisation step, especially if a strong acid or base were used. However, no scientific data are available to support this, and therefore it was assumed that the reported BPA concentrations for all data are for unconjugated BPA only. Given the rapid elimination and the short half-live of BPA, it seems unlikely that significant concentrations of the conjugates will accumulate in animals intended for food following exposure during their lifetime. ANSES (ANSES, 2013) reported that the levels of unconjugated BPA and total BPA (conjugated + unconjugated) were similar in the meat products that they tested.

1.3. Extraction of BPA from biological samples

A number of sensitive methods have been developed to quantify low concentrations of BPA in blood and urine samples from unintentionally exposed human subjects (Dekant and Völkel, 2008; WHO 2011b; Asimakopoulos et al., 2012). In biological samples BPA can exist in both the conjugated and the unconjugated form. BPA glucuronide is the most commonly found BPA conjugate along with lower levels of BPA sulphate. Consequently, methods to determine total BPA in biological samples include an enzymatic deconjugation step using β-glucuronidase and sulphatase. Even if a study is focused only on unconjugated BPA, the information on total or conjugated BPA is needed for quality control purposes. Additional quality criteria include the information on extraction recovery and the use of surrogate standards to monitor the extent of the deconjugation reaction. In addition to the deconjugation step, sample work-up procedures comprise the clean-up, which is generally based on SPE and/or LLE. The most common solvent used for the extraction of BPA from biological samples is acetonitrile. As discussed above for foodstuffs, one advantage of using acetonitrile as the extraction solvent is the simultaneous precipitation of endogenous proteins in the matrix (Völkel et al., 2011). Recent trends for biomonitoring of BPA have been described by Asimakopoulos et al. (2012) and include an overview of the methodology applied to these matrices. The authors summarise that "ethyl acetate (Schöringhumer and Cichna-Markl, 2007), chloroform (Kuroda et al., 2003), diethyl ether (Ouchi and Watanabe, 2002), isopropanol (Atkinson et al., 2002) and ammonium hydroxide (Kaddar et al., 2009) were also reported for analyte(s) extraction or/and protein precipitation purposes. n-Hexane, ethanol and petroleum ether were particularly used for lipid removal from matrix (Sajiki, 2003; Lin et al., 2009)." As for liquid foodstuffs SPE extraction can be applied to liquid matrices (usually following dilution with water and deconjugation with enzymes) or it can be applied as a clean-up and concentration step to achieve the sensitivity required for these matrices. Examples of the use of SPE in sample extraction, clean-up and concentration include BPA determination in urine (Moors et al., 2007; Calafat et al., 2008; Teeguarden et al., 2011), human colostrom (Kuruto-Niwa et al., 2007) and human milk (Cariot et al., 2012). Additional information is given in Section 4.6 of the opinion.

1.4. Extraction of BPA from non-food sources

1.4.1 Environmental samples—outdoor air

To determine the concentration of BPA in air samples, the sample is first collected onto a filter and the filter is extracted using solvent. Sample clean-up methods, concentration and derivatisation steps are

then all similar to other matrices. Fu and Kawamura (2010) used an aerosol sampling technique to obtain the samples. The resulting filters were ultrasonicated in dichloromethane/methanol (2:1, v/v), evaporated to dryness and derivatised with BSTFA with 1 % trimethylsilyl chloride in pyridine. Following dilution with hexane the derivatives were analysed by GC-MS. Sangiorgi et al. (2013) compared indoor and outdoor BPA in particulate matter. The filter samples were extracted with methanol and analysed directly by LC-MS/MS. Wilson et al. (2007) described methodology for the sampling of outdoor air using a 10 mm inlet, to collect targeted chemicals in a glass cartridge containing a quartz fibre filter followed by XAD-2 resin. Soxhlet extraction of the filter was done with dichloromethane, sample concentration by SPE using fluorisil and analysis by GC-MS.

1.4.2 Environmental samples—surface water

Many of the extraction techniques described for the determination of BPA in surface water are consistent with those reported and described above for food and beverages and for food simulants. Other examples include the extraction of BPA with coacervates made up of decanoic acid reverse micelles with analysis using LC-FLD (Ballesteros-Gómez et al., 2007), SPE methodology using magnetic multiwalled carbon nanotubes followed by GC-MS/MS to determine BPA in river water, as well as in snow and drinking water (Jiao et al., 2012) and detection via inhibition of luminol chemiluminescence (CL) by BPA on the silver nanoparticles (AgNPs)-enhanced luminol-$KMnO_4$ CL system (Chen et al., 2011). Krapivin et al. (2007) reviewed a range of ELISA methods for the determination of BPA in surface water samples.

1.4.3 Indoor air

Methods described for the determination of BPA in indoor air are consistent with those for outdoor air.

1.4.4 Dust

Wilson et al. (2007) described the collection of house dust using a high-volume surface sampler (HVS3) (ASTM, 1997). Dust samples were sonicated with 10 % diethyl ether/hexane to extract the BPA from the matrix. Sample concentration and analysis was consistent with the air samples. Geens et al. (2009a) reported similar methodology for dust samples, with the BPA being extracted into hexane:acetone (3:1), clean-up by SPE using fluorisil but with analysis by LC-MS/MS. Völkel et al. (2008) measured BPA in dust collected by residents in homes using regular vacuum cleaners. Sonication of the dust in methanol released the BPA and, following the addition of water, the extracts were analysed using SPE-LC-MS/MS. Loganathan and Kannan (2011) determined BPA in house dust. The BPA was extracted into ethyl acetate, solvent swapped into methanol and analysed by LC-MS/MS.

1.4.5 Paper products (including thermal papers)

As mentioned above, paper is a polar matrix and so to ensure exhaustive extraction polar solvents are generally used to extract the BPA. Biedermann et al. (2010) extracted BPA from thermal paper samples by immersion in methanol overnight at 60 °C, extracts were then diluted prior to analysis by LC-FLD. Liao and Kannan (2011a, b) and Geens et al. (2012b) also used methanol to extract BPA from paper samples. Mendum et al. (2011) used ethanol as the extraction solvent for thermal receipts. Another study reported the use of pyrolysis GC-MS to determine BPA in paper samples (Becerra and Odermatt, 2012) although the authors state that "The reliability of quantification with an internal standard should be further investigated."

1.4.6 Children's toys and teats

Methods of analysis reported for the determination of BPA in plastic toys are consistent with those for the extraction of BPA from plastic food contact materials, e.g. dissolution in a solvent with subsequent polymer precipitation, solvent extraction using microwave digestion and solvent extraction. Atkins (2012) described the dissolution of PVC toys in tetrahydrofuran with polymer precipitation using hexane and compared the extraction efficiency with that of a simpler microwave digestion method.

Another method for determination of BPA released from toys described the use of water and 0.07 M hydrochloric acid. The contact conditions were 24 hours at 40 °C for water according to EN 14372 and 24 hours at 37 °C for the acidic medium. In this study the extraction methods used were intended to mimic the exposure of children to BPA from this source (Troiano and Goodman, 2010). In this the transfer of BPA to water or to a saliva simulant to determine exposure from these articles was considered, as well as the concentration of BPA in the plastic portion of the toys itself. Methods of analysis for the determination of BPA in saliva simulant include ultrasound-assisted emulsification liquid–liquid microextraction (Viñas et al., 2012). The methodology for the determination of BPA in plastic toys and in physiological saline solution was described by KEMI (2012). Ground plastics were soxhlet extracted with either methanol or dichloromethane and analysed directly by GC-MS. The toys were also exposed to physiological saline solution (37 °C, 10 minutes, 30 minutes and 2 hours with stirring) and the extract analysed by GC-MS. Other samples were exposed to artificial saliva (24 °C, 24 hours).

1.4.7 Medical devices (dental sealants)

The extraction media used for the determination of BPA in resin-based dental materials are included in the review of the exposure from these sources (Van Landuyt et al., 2011). The extraction solvents included water, acetonitrile, ethanol, ethanol/water, artificial saliva or saliva simulant, phosphate buffer or citrate/phosphate buffer.

2. Instrumental analysis

The analytical methods reported to be used for the determination of BPA in all matrices described above include: LC-UV, LC-FLD, LC-ECD, LC-MS and LC-MS/MS, GC-MS and GC-MS/MS and ELISA.

2.1. GC methods

Although some methods describe the direct analysis of solvent extracts containing BPA by GC-MS or GC-MS/MS, many involve derivatisation to achieve repeatable data. Cao (WHO, 2011b) concluded that "derivatisation is always recommended for quantitative analysis by GC-MS". Improved accuracy and sensitivity can be achieved by the derivatisation of the free hydroxyl functional groups on BPA (WHO, 2011b). Silylation using BSTFA (Fu and Kawamura, 2010; Viñas et al., 2010) or MTBSTFA (Becker et al., 2009) and acetylation using acetic anhydride (Cao and Carriveau, 2008b, Cao et al., 2009a, b; Viñas et al., 2010; Cunha et al., 2011) are the most common derivatisation techniques used for BPA. The use of isopropyl chloroformate to form diether derivatives (Feshin et al., 2012), pentafluorobenzylbromide (Kuklenyik et al., 2003), pentafluorobenzoylchloride (Geens et al., 2009b, 2012b), pentafluoropropionic anhydride (Dirtu et al., 2008) and trifluoroactic anhydride (Varelis and Balafas, 2000) has also been described.

2.2. LC methods

The majority of the LC methods reported using reverse phase chromatography for the determination of BPA. More recently the use of UPLC methods has also been described (Lacroix et al., 2011; Xiao et al., 2011; Cariot et al., 2012; Pérez-Palacios et al., 2012) for the determination of BPA in biological samples. Although BPA is a weak chromophore and so can be detected by UV, the sensitivity of the analysis is low when compared with other detectors. The CEN technical specification for the determination of BPA (CEN, 2005) uses UV detection at 280 nm to determine BPA concentrations in food simulants; however, none of the more recently developed methods use this detector. LC-FLD methodology with excitation wavelengths in the range 224 to 235 nm or 275 nm and emission wavelengths in the range 300 to 320 nm have been described and reviewed by Cao (WHO, 2011b). Although BPA is a relatively strong fluorophore (owing to the conjugation) the addition of a stronger fluorophore to BPA using 4-(4,5-diphenyl-1H-imidazol-2-yl)benzoyl chloride (Watanabe et al., 2001; Sun et al., 2002; Kuroda et al., 2003) or *p*-nitrobenzoyl chloride (Mao et al., 2004) prior to analysis by LC-FLD has also been proposed to improve the method sensitivity. The lack of selectivity of these methods compared with MS methods means that the data derived may overestimate the concentration

of BPA present in the samples. Although ECD affords better selectivity than UV and FLD methods (it is electrically specific for phenolic compounds) there are only limited applications described in the literature. Sajiki et al. (2007) used LC-ECD and LC-MS for the detection of BPA in canned foods and concluded that although LC-ECD is specific for phenols and MS for the mass of BPA the best selectivity is afforded by the tandem MS/MS techniques and so this is preferred for quantifying BPA.

For both GC-MS and LC-MS methods of analysis isotope-dilution mass spectrometry based on stable isotope-labelled (^{2}H or ^{13}C) BPA as an internal standard is considered as the most specific, selective, accurate and precise detection method for measuring trace levels of BPA (WHO, 2011b).

2.3. ELISA methods (Fukata et al, 2006)

Commercial ELISA kits for the determination of BPA are available and have been used to determine BPA in biological samples. ELISA cannot differentiate between conjugated and unconjugated BPA and therefore is not selective for the unconjugated form and so concentrations measured using this technique are for total BPA. It has also been reported that cross-reactivity occurs with other structurally similar substances. In this evaluation, data generated for biological samples derived using ELISA methodology were included only where there was a data gap, and in all cases the data derived using this technique were considered with caution.

Appendix B. EFSA call for data

This appendix contains details on the quality of data received through the EFSA call for data, for the following categories: food and beverages intended for human consumption; migration data from food contact materials; and occurrence data in food contact materials.

In total 3 609 results were submitted to EFSA, 2 076 results for BPA occurrence in food, 988 results for BPA migration from food contact materials and 545 results for BPA occurrence in food contact materials.

These data were obtained on samples collected in the EEA countries (European Union, plus Iceland, Liechtenstein, Norway and Switzerland). The vast majority of the samples were collected from 2006 (some food samples from 2004) to 2012.

Data were sent by governmental institutions (3 115 results), academia (417 results), food manufacturers and two associations (Fédération romande des consommateurs (FRC) and PlasticsEurope) (77 results).

1. Food and beverages intended for human consumption

Regarding the 1 592 results submitted on unconjugated BPA determination the method was accredited by ISO/IEC 17 025 procedure for 71 % of the results and internally validated for 29 %. Regarding the 484 results submitted on determination of bisphenol total, the method was accredited by ISO/IEC 17 025 procedure for 12 % of the results, the procedure was internally validated for 42 % and not validated for 12 %, no information was provided for 33 % of the results (12 % of results submitted from accredited laboratories and 21 % of results submitted from non-accredited laboratories).

Information about the method of analysis was provided for 100 % of the results. The following methods were reported for the determination of bisphenol unconjugated in 1 592 samples analysed: GC-MS-MS (71 % of the samples); and LC-MS/MS (29 % of the samples). The following methods were reported for the determination of bisphenol total in 484 samples analysed: LC-MS/MS (48.1 % of the samples); GC-MS (18.4 % of the samples); HPLC-FD (12.8 % of the samples); HPLC-UV (8.5 % of the samples); GC-MS-MS (6.4 % of the samples); and HPLC with standard detection methods (5.8 % of the samples).

For the determination of bisphenol unconjugated, LODs were reported as below the limit of 15 µg/kg for 693 results (ranging from 0.008 to 13.9 µg/kg) and greater than 15 µg/kg for one result (29.8 µg/kg). LOQs were reported as below the limit of 50 µg/kg for 717 results (ranging from 0.024 to 41.7 µg/kg) and greater than 50 µg/kg for one result (89.4 µg/kg).

For the determination of bisphenol total, LODs were reported as below the limit of 15 µg/kg for 344 results (ranging from 0.0003 to 3.667 µg/kg) and greater than 15 µg/kg for 34 results (ranging from 16.67 to 105 µg/kg). LOQs were reported as below the limit of 50 µg/kg for 396 results (ranging from 0.001 to 50 µg/kg) and greater than 50 µg/kg for 33 results (210 µg/kg).

The food samples across food groups classified according to the FoodEx classification system level 1 were: drinking water (23 %); vegetables and vegetable products (15 %); meat and meat products (10 %); composite food (8 %); milk and dairy products (7 %); grains and grain-based products (7 %); fish and other seafood (7 %); fruit and fruit products (5 %); alcoholic beverages (4 %); non-alcoholic beverages (4 %); legumes, nuts and oilseeds (3 %); starchy roots and tubers (2 %); snacks, desserts, and other foods (2 %); animal and vegetable fats and oils (1 %); herbs, spices and condiments (1 %); sugar and confectionery (1 %); eggs and egg products (1 %); and fruit and vegetable juices (1 %).

The vast majority of the samples at the second level of the FoodEx classification were: tap water (13 %); bottled water (9 %); fruiting vegetables (4 %); fish meat (4 %); and livestock meat (4 %).

Some of the analysed foods were canned, in tinplate varnished or partly varnished (5 %), in metal (4 %) and tinplate (2 %).

2. Migration data from food contact materials

The method for the determination of BPA was accreditated by ISO/IEC 17 025 procedure for 34 % of the 988 submitted results, the procedure was validated internally for 30 % (including results from non-accreditated laboratories) and accredited by a different third-party quality assessment procedure for 36 %.

Information about the method of analysis was provided for 100 % of the results. The following methods were reported: HPLC-FL (52 % of the samples); HPLC with standard detection methods (23 % of the samples); HPLC-UV (11 % of the samples); GC-MS (6 % of the samples); LC-MS-MS (6 % of the samples); and LC-MS (2 % of the samples).

LODs were reported as below the limit of 15 µg/kg for 748 results (ranging from 0.006 to 15 µg/kg) and greater than 15 µg/kg for 92 results (ranging from 20 to 40 µg/kg). LOQs were reported as below the limit of 50 µg/kg for 872 results (ranging from 0.018 to 50 µg/kg) and greater than 50 µg/kg for 103 results (ranging from 60 to 500 µg/kg).

All the data and results are converted to µg/kg. If the result of the overall migration in the original results was expressed as mg/dm^2, the conversion rate was 1 mg/dm^2 equal to 6 mg/kg of packaged food, as reported in Consideration No 26 of Regulation EU No 10/2011.

3. Occurrence data in food contact materials

The method for the determination of BPA was validated internally for 1 % of the samples analysed. No information was provided on the accreditation of the method for the remaining 99 % of the sample analysed.

Information about the method of analysis was provided for 43 % of the 545 submitted results. The following methods were reported: HPLC with standard detection methods (25 % of the samples); GC-MS (16 % of the samples); and HPLC-FL (1 % of the samples). Classification of the method of analysis was not possible for 57 % of the samples (submitted as "EG-Referenzmethode" and "Nicht in einer offiziellen Sammlung enthaltene Methode").

LODs were reported as below the limit of 15 µg/kg for 321 results (ranging from 0.0033 to 10 µg/kg) and greater than 15 µg/kg for 212 results (ranging from 20 to 10 000 µg/kg). LOQs were reported as below the limit of 50 µg/kg for 330 results (ranging from 0.01 to 40 µg/kg) and greater than 50 µg/kg for 203 results (ranging from 90 to 42 800 µg/kg).

Appendix C. Food categories

This appendix provides a comprehensive description of all data made available in relation to BPA concentration in food and beverages. Data are described separately for "Canned food categories" and "Non-canned food categories", making use of the EFSA FoodEx categories. European data from the literature and from the EFSA call for data are first described separately and then pooled. Non-European data are then described for comparison only. Note that in this appendix the term "BPA" means unconjugated BPA.

1. Canned food categories

For canned food, the overall number of samples was 633, of which 327 samples were from the literature and 306 samples were from the call for data.

1.1. "Grains and grain-based products", canned

One sample for "Grains and grain-based products" was available from the literature in Belgium (Geens et al., 2010). The maize grain sample had a BPA concentration of 67.4 µg/kg.

Concentration data from "Grains and grain-based products" was provided through the call for data by France and Ireland, with a total of 18 samples. The samples were mainly maize grains. The BPA concentrations ranged from 23.1 µg/kg (maize grain, France) to 47.5 µg/kg (maize grain, France). Mean BPA concentration (MB) was 34.9 µg/kg.

When all European data for canned grains and grain-based products were pooled, average BPA concentration (MB) was 36.6 µg/kg.

Concentration values for samples from Singapore (Sun et al., 2006), Japan (Sajiki et al., 2007), Korea (Lim et al., 2009a, Kawamura et al, 2014, Canada (Cao et al., 2011), China (Niu et al., 2012) and Iran (Ahmadkhaniha et al., 2013) were within the same range as the samples from Europe.

The FAO/WHO opinion (2011) assigned an overall BPA value of 36.7 µg/kg to the solid canned food, while in the EFSA opinion (2006a) 50 µg/kg was used for canned solid foods.

1.2. "Vegetables and vegetable products", canned

Concentration data from 50 samples of canned "Vegetables and vegetable products" were available from the literature in Russia (Feshin et al., 2012), Belgium (Geens et al., 2010), Spain (García-Prieto et al., 2008) and Italy (Grumetto et al., 2008). Most of the analysed samples referred to canned tomato products (Grumetto et al., 2008). The BPA concentrations ranged from below LOD/LOQ (40 %) to 116.3 µg/kg (mushrooms, Geens et al., 2010). Mean BPA concentration (MB) was 26.0 µg/kg.

Concentration data for canned "Vegetables and vegetable products" were provided through the call for data by Germany, Switzerland, Ireland, Finland and Norway for a total of 73 samples. Around half of the samples were sweetcorn, while coconut milk, sauerkraut, tomatoes and other vegetable products constituted the other half. The BPA concentrations ranged from below LOD/LOQ (18 %) to 100.1 µg/kg (mushrooms, Germany). Mean BPA concentration (MB) was 21.7 µg/kg.

When all European data for canned vegetable and vegetable products were pooled, average BPA concentration (MB) was 23.5 µg/kg.

Concentration values for samples from Singapore (Sun et al., 2006), Japan (Sajiki et al., 2007; Yonekubo et al., 2008; Kawamura et al, 2014), Korea (Lim et al., 2009a), Iran (Ahmadkhaniha et al., 2013) and Canada (Cao et al., 2010a) were within the same range as the samples from Europe.

The FAO/WHO opinion (2011) assigned an overall BPA value of 36.7 µg/kg to the solid canned food, while in the EFSA opinion (2006a) 50 µg/kg was used for canned solid foods.

1.3. "Legumes, nuts and oilseeds", canned

Concentration data for two samples of canned "Legumes, nuts and oilseeds" were available from the literature in Spain (García-Prieto et al., 2008). The peas had a BPA concentration of 69.0 µg/kg and the green beans had a BPA concentration of 103.0 µg/kg. The average BPA concentration (MB) was 120.5 µg/kg.

Concentration data for legumes, nuts and oilseeds were provided through the call for data by Ireland, Germany, France and Finland for a total of 18 samples. The samples were of beans and peas. The BPA concentration ranged from below LOD/LOQ (33 %) to 137.0 µg/kg (green peas, Ireland). The average BPA concentration (MB) was 28.8 µg/kg.

When all European data for legumes, nuts and oilseeds samples were pooled, average BPA concentration (MB) was 34.6 µg/kg.

Concentration values for samples from Singapore (Sun et al., 2006), Japan (Sajiki et al., 2007), Korea (Lim et al., 2009a) and Canada (Cao et al., 2010a, 2011) were in the same range as the samples from Europe. However, one study from the USA (Noonan et al., 2011) showed BPA concentrations of some canned beans and peas with BPA values up to 730 µg/kg, while the average BPA concentration in canned vegetables in the Noonan et al. (2011) study was 87.8 µg/kg.

The FAO/WHO opinion (2011) assigned an overall BPA value of 36.7 µg/kg to the solid canned food, while in the EFSA opinion (2006a) 50 µg/kg was used for canned solid foods.

1.4. "Fruit and fruit products", canned

Concentration data for seven samples of canned "Fruit and fruit products" were available from the literature in Belgium (Geens et al., 2010) and Spain (García-Prieto et al., 2008). The analysed samples were from canned fruit. BPA concentrations varied from 7.8 µg/kg (canned mixed fruit, García-Prieto et al., 2008) to 24.4 µg/kg (canned mango, García-Prieto et al., 2008). Mean BPA concentration (MB) was 15.9 µg/kg.

Concentration data for fruit and fruit products were provided through the call for data by Ireland, Germany, France and Norway for a total of 14 samples. The samples were mostly of canned fruit, in addition to two samples of dried prunes and one sample of jam. The BPA concentration varied from below LOD/LOQ (21 %) to 107.0 µg/kg (dried prunes, Ireland). Mean BPA concentration (MB) was 12.2 µg/kg.

When all European canned fruit and fruit products were pooled, average BPA concentration (MB) was 13.4 µg/kg.

Concentration values in fruit and fruit products from Japan (Sajiki et al., 2007; Kawamura et al, 2014), Korea (Lim et al., 2009a), Canada (Cao et al., 2011) and the USA (Noonan et al., 2011) and most of the concentrations from Singapore (Sun et al., 2006) were within the same range as the samples from Europe. However, Sun et al. (2006) reported canned mango with a BPA concentration of 160 µg/kg.

The FAO/WHO opinion (2011) assigned an overall BPA value of 36.7 µg/kg to the solid canned food, while in the EFSA opinion (2006a) 50 µg/kg was used for canned solid foods.

1.5. "Meat and meat products", canned

Concentration data in 31 samples of canned "Meat and meat products" were available from the literature in the Czech Republic (Poustka et al., 2007), Russia (Feshin et al., 2012), Spain (Pérez-Bendito et al., 2009) and Belgium (Geens et al., 2010). The analysed samples were mostly of pâté from pork liver (16 samples) and luncheon meat (11 samples). BPA concentrations ranged from below the LOQ (39 %) to 51.1 µg/kg (luncheon meat, Czech Republic). Mean BPA concentration (MB) was 14.7 µg/kg.

Concentration data for meat and meat products were provided through the call for data by Ireland, Finland and France for a total of 16 samples. The samples were of different meat and meat products. The BPA concentration ranged from below the LOQ (38 %) to 203.0 µg/kg (bacon, Ireland). Mean BPA concentration (MB) was 64.2 µg/kg.

When all European data for canned meat and meat products were pooled, average BPA concentration (MB) was 31.5 µg/kg.

Concentration values in meat samples from Singapore (Sun et al., 2006), Japan (Sajiki et al., 2007; Kawamura et al, 2014), Korea (Lim et al., 2009a) and Canada (Cao et al., 2011) were in the same range as the samples from Europe.

The FAO/WHO opinion (2011) assigned an overall BPA value of 36.7 µg/kg to the solid canned food, while in the EFSA opinion (2006a) 50 µg/kg was used for canned solid foods.

1.6. "Fish and other seafood", canned

Concentration data for 107 samples of canned "Fish and seafood" were available from the literature in the Czech Republic (Poustka et al., 2007), Portugal (Cunha et al., 2012), Belgium (Geens et al., 2010), and Spain (Pérez-Bendito et al., 2009). The analysed samples were of tuna, mackerel, sardines and other fish and seafood. The BPA concentrations ranged from below LOD/LOQ (20 %) to 169.3 µg/kg (tuna in oil, Geens et al., 2010). Mean BPA concentration (MB) was 39.5 µg/kg.

Concentration data for fish and other seafood were provided through the call for data by Germany, Finland, Switzerland, Ireland, Norway and France for a total of 67 samples. The samples were of tuna, sardines, mackerel and other fish and seafood. The BPA concentration ranged from below LOD (33 %) to 198 µg/kg (cod and whiting, Ireland). Mean BPA concentration (MB) was 33.0 µg/kg.

When all European data for canned fish and seafood samples were pooled, average BPA concentration (MB) was 37.0 µg/kg.

Concentration values in samples from Singapore (Sun et al., 2006), Japan (Sajiki et al., 2007; Yonekubo et al., 2008; Kawamura et al, 2014), Korea (Lim et al., 2009a) and Canada (Cao et al., 2011) were within the same range as that of the samples from Europe.

The FAO/WHO opinion (2011) assigned an overall BPA value of 36.7 µg/kg to the solid canned food, while in the EFSA opinion (2006a) 50 µg/kg was used for canned solid foods.

1.7. "Milk and dairy products," canned

Concentration data from 19 samples of canned "Milk and dairy products" were available from the literature in Spain (Molina-Garcia et al., 2012) and Greece (Maragou et al., 2006). The analysed samples were of liquid milk (nine samples), evaporated milk (seven samples), and milk powder (three samples). BPA concentrations varied from below the LOD (63 %) to 15.2 µg/kg (evaporated milk, Maragou et al., 2006). Mean BPA concentration (MB) was 2.6 µg/kg.

Concentration data from milk and dairy products were provided through the call for data by Germany for three samples. The samples were of liquid milk. BPA concentration varied from 0.7 µg/kg to 35.9 µg/kg. Mean BPA concentration (MB) was 19.8 µg/kg.

When all European data for canned milk and dairy products were pooled, average BPA concentration (MB) was 4.9 µg/kg.

The concentration value in evaporated milk from Canada (Cao et al., 2011) was in the same range as that in the European samples.

The FAO/WHO opinion (2011) and the EFSA opinion (2006a) did not assigned a specific BPA value for canned milk and diary products.

1.8. "Sugar and confectionery", canned

The only sample in this food category was available from the literature in Belgium (Geens et al., 2010). The BPA concentration fruit sauce was 0.2 µg/kg.

This concentration value was used in the exposure assessment. However, the only foods consumed in this category were fruit sauce and molasses, and these foods were not consumed in large quantities and do not have an impact on the exposure.

1.9. "Fruit and vegetable juices," canned

Concentration data from five samples of canned "Fruit and vegetable juice" were available from the literature in Belgium (Geens et al., 2010). The analysed samples of fruit juice varied in BPA concentrations from 0.8 µg/kg to 4.7 µg/kg. The average BPA concentration (MB) was 2.7 µg/kg.

The FAO/WHO opinion (2011) assigned an BPA value of 23.2 µg/kg to the canned non-carbonated liquids, while in the EFSA opinion (2006a) 10 µg/kg was used for canned liquid beverages.

1.10. "Non-alcoholic beverages", canned

The food category "Non-alcoholic beverages" includes canned beverages such as soft drinks, both carbonated and non-carbonated, coffee and tea. Concentration data from 54 samples of canned "Non-alcoholic beverages" were available from the literature in Belgium (Geens et al., 2010), Portugal (Cunha et al., 2011) and Spain (Gallart-Ayala et al., 2011; Cacho et al., 2012). The samples were of canned soft drinks (49 samples) and canned tea (5 samples). The BPA concentrations ranged from below LOD (26 %) to 8.1 µg/kg (citrus soda, Geens et al., 2010). Mean BPA concentration (MB) was 0.5 µg/kg.

Concentration data on "Non-alcoholic beverages" were provided through the call for data by Germany and Norway for a total of 11 samples. Two of the samples were coffee and the rest soft drinks. BPA concentration ranged from below the LOD (27 %) to 1.5 µg/kg (in coffee, Germany). Mean BPA concentration (MB) was 0.5 µg/kg.

When all European data for canned non-alcoholic beverages were pooled, average BPA concentration (MB) was 0.5 µg/kg.

From the literature outside Europe, Lim et al. (2009a) found high BPA concentrations in seven out of eight samples of canned coffee and tea from Korea. The highest BPA concentration was 136.14 µg/kg, and six of the samples were in the range 10.64–38.28 µg/kg (Lim et al., 2009a). Concentration values in samples from Canada (Cao et al., 2009b, 2010a, 2011) and Japan (Kawamura et al, 2014) were in the same range as that of the samples from Europe.

Based on these data, the FAO/WHO opinion (2011) assigned a different BPA concentration to carbonated beverages (cola, beer, soda, tonic) and non-carbonated beverages (tea, coffee, other), owing to high values in canned tea and coffee in the Korean study (Lim et al., 2009a). The carbonated beverages were given a BPA concentration of 1.0 µg/kg in the exposure assessment, while the non-carbonated beverages were given a higher BPA concentration of 23.2 µg/kg. The EFSA opinion (2006a) used 10 µg/kg as the BPA concentration for canned beverages.

The CEF Panel observed that the high values in canned tea and coffee in the Korean study were not confirmed by any other study. Contrary to FAO/WHO (2011), the CEF Panel decided not to distinguish between carbonated and non-carbonated soft drinks.

1.11. "Alcoholic beverages", canned

Concentration data in 18 samples of canned alcoholic beverages were available from the literature in Portugal (Cunha et al., 2011), Belgium (Geens et al., 2010), and Spain (Gallart-Ayala et al., 2011; Cacho et al., 2012). The analysed samples were all of beer. BPA concentrations ranged from below the LOD (17 %) to 4.7 µg/kg (beer, Cunha et al., 2011). Mean BPA concentration (MB) was 0.9 µg/kg.

Concentration data in 49 samples of canned alcoholic beverages were provided through the call for data by United Kingdom and Germany. The samples were mostly of beer. The BPA concentration ranged from below the level of qunantification (35 %) to 4.5 µg/kg (beer, Germany). Mean BPA concentration (MB) was 0.8 µg/kg.

When all European data for canned alcoholic beverages were pooled, average BPA concentration (MB) was 0.8 µg/kg.

The concentration values in alcoholic beverages from Canada (Cao et al., 2010a, 2011) and Japan (Kawamura (personal communication, 2013) were within the same range as the European samples.

The FAO/WHO opinion (2011) assigned a BPA value of 23.2 µg/kg to the canned non-carbonated liquids, while the EFSA opinion (2006a) used 10 µg/kg for canned beverages.

1.12. "Drinking water", canned

There was one European sample of canned drinking water available from the literature. The BPA concentration (MB) was 0.004 µg/kg. However, there was no reported consumption of canned water, and the concentration value has therefore not been used in the exposure assessment.

1.13. "Herbs, spices and condiments", canned

Concentration data from two samples of canned "Herbs, spices and condiments" were provided through the call for data by Germany. The samples were of dressing and curry sauce, and the BPA concentrations were 0.6 µg/kg and 82.1 µg/kg, respectively. The average BPA concentration (MB) was 41.4 µg/kg.

The two widely differing values imply a high uncertainty about the average concentration for this food category. However, this will have little impact on the assessment because the foods in this category were not consumed in large quantities.

The FAO/WHO opinion (2011) assigned an overall BPA value of 36.7 µg/kg to the solid canned food, while in the EFSA opinion (2006a) 50 µg/kg was used for canned solid foods.

1.14. "Food for infants and small children", canned

Concentration data from 10 samples of canned "Food for infants and small children" were available from the literature in Portugal (Cunha et al., 2011), Spain (Molina-Garcia et al., 2012) and Russia (Feshin et al., 2012). The analysed samples were of infant formula powder. The BPA concentrations ranged from below the LOQ (70 %) to 2.2 µg/kg (Feshin et al., 2012). Mean BPA concentration (MB) was 0.3µg/kg, and the highest BPA concentration was 2.2 µg/kg.

The European Dietetic Food Industry Association has confirmed that canned liquid infant formula is currently not used in Europe (email to EFSA dated 27 June 2013) but is used in other parts of the world. Values from European manufactured canned infant formula were therefore not included in the opinion.

Cao et al., 2008 (Canada) analysed 16 samples of infant formula from USA and Canada. BPA concentration ranged from 2.27 µg/kg to 10.23 µg/kg. Mean BPA concentration was 5.98 µg/kg. Ackerman et al. (2010, USA) provided BPA concentrations in 71 samples of canned infant formula.

The infant formulas were both ready-to-feed and concentrated liquid. The BPA concentrations in liquid formula ranged from 0.56 to 11 µg/kg, with an average BPA concentration of 5.74 µg/kg. In addition Ackerman et al. (2010, USA) detected BPA in 1 sample of 14 powder formula products (0.40 µg/kg).

Earlier opinions have chosen different BPA concentrations for exposure from infant formula. The FAO/WHO report (2011) uses two average BPA concentration values for liquid infant formula of 4 µg/kg for the ready-to-feed formula and 3.5 µg/kg for the concentrated liquid formula.

The EFSA opinions (2006a) assumed a very conservative value BPA concentration of 100 µg/kg for both beverages and solid canned food consumed by infants.

1.15. "Products for special nutritional use", canned

Concentration data from 14 samples of canned "Products for special nutritional use" were available from the literature in Portugal (Cunha et al., 2011), Belgium (Geens et al., 2010), Spain (Gallart-Ayala et al., 2011) and Russia (Feshin et al., 2012). All the 14 samples for special nutritional use from the European literature were canned soft drinks. The BPA concentration ranged from below LOD/LOQ (36 %) to 4.8 µg/kg (energy drink, Geens et al., 2010). The average BPA concentration (MB) was 1.2 µg/kg.

The FAO/WHO opinion (2011) assigned a BPA value of 23.2 µg/kg to the canned non-carbonated liquids, while the EFSA opinion (2006a) used 10 µg/kg for canned beverages.

1.16. "Composite food", canned

Concentration data from only six samples of canned "Composite food" were available from the literature in Belgium (Geens et al., 2010) and Spain (Bendito et al., 2009). The analysed samples were soups and other dishes. The BPA concentrations ranged from below the LOQ (one sample) to 73.1 µg/kg (in ravioli, Geens et al., 2010). Mean BPA concentration (MB) was 25.9 µg/kg.

Concentration data from 25 samples of canned composite food were provided through the call for data by Germany, Ireland, Finland, Norway and France. The samples were of soups, bean-based meals, pasta and other composite foods. The BPA concentrations ranged from below the LOQ (20 %) to 110 µg/kg (meat balls, Ireland). Mean BPA concentration (MB) was 39.6 µg/kg.

When all European data for canned composite foods were pooled, average BPA concentration (MB) was 37.0 µg/kg.

The concentration values in composite foods from Singapore (Sun et al., 2006), Japan (Sajiki et al., 2007; Yonekubo et al., 2008; Kawamura et al, 2014), Canada (Cao et al., 2010a) and the USA (Noonan et al., 2011) were within the same range as that of European samples. However, Sajiki et al. (2007) reported a canned creamed soup with a value of 156 µg/kg and canned brown sauces with very high BPA concentrations (428, 547 and 842 µg/kg). Yonekubo et al. (2008) reported a canned gratin sauce with a BPA concentration of 235 µg/kg.

The FAO/WHO opinion (2011) assigned an overall BPA value of 36.7 µg/kg to solid canned food, while in the EFSA opinion (2006a) 50 µg/kg was used for canned solid foods.

1.17. "Snacks, desserts, and other foods", canned

Concentration data from one sample of canned "Snacks, desserts, and other foods" were provided through the call for data by Ireland. The sample was of starchy pudding, and the BPA concentration was 52.0 µg/kg. This BPA concentration was used in the exposure assessment.

There are few concentration data in this food category. However, the foods in this category were only custard and undefined snacks, and neither was consumed in large quantities.

The FAO/WHO opinion (2011) assigned an overall BPA value of 36.7 µg/kg to the solid canned food, while in the EFSA opinion (2006a) 50 µg/kg was used for canned solid foods.

2. Non-canned food categories

For non-canned food, concentration data from the literature were scarce, with only 246 samples overall, of which 159 were water samples. However, the call for data provided 1 637 samples of non-canned food, to which France is the main contributor with 1 433 samples (88 % of the total non-canned food samples).

2.1. "Grains and grain-based products", non-canned

Concentration data from one sample of non-canned "Grains and grain-based products" were available from the literature in Belgium (Geens et al., 2010). The maize grain sample had a BPA concentration of 0.9 µg/kg.

Concentration data for grains and grain-based products were provided though the call for data by France, Ireland and Norway for a total of 95 samples. The samples were of grains, bread, cakes, breakfast cereals and other grain products. The BPA concentration ranged from below LOD/LOQ (43 %) to 11.9 µg/kg (flan, France). Mean BPA concentration (MB) was 1.0 µg/kg.

When all European data for non-canned grains and grain-based products were pooled, average BPA concentration (MB) was 1.0 µg/kg.

A market basket study from Sweden (Gyllenhammar et al., 2012) observed a BPA concentration from cereal products within the same range as that of the European data.

Concentration values in samples from Japan (Sajiki et al., 2007) and Canada (Cao et al., 2011) were within the same range as that of the samples from Europe. However, one sample of cookies from Japan (Sajiki et al., 2007) had a BPA concentration of 14 µg/kg.

Neither the EFSA opinion (2006a) nor the FAO/WHO opinion (2011) assigned a BPA value to non-canned food.

2.2. "Vegetables and vegetable products", non-canned

Concentration data from four samples of non-canned "Vegetables and vegetable products" were available from the literature in Belgium (Geens et al., 2010). The BPA concentration in the varied vegetables ranged from 0.1 µg/kg to 1.0 µg/kg. Mean BPA concentration (MB) was 0.4 µg/kg.

Concentration data for non-canned "Vegetables and vegetable products" were provided through the call for data by France (199 samples), Norway (1 sample) and Ireland (1 sample) for a total of 201 samples. The BPA concentrations for the varied vegetables ranged from below LOD/LOQ (34 %) to 5.3 µg/kg (leaf vegetables, France). Mean BPA concentration (MB) was 1.2 µg/kg.

When all European data for canned vegetables and vegetable products were pooled, average BPA concentration (MB) was 1.2 µg/kg.

A market basket study from Sweden (Gyllenhammar et al., 2012) observed a BPA concentration from vegetables within the same range as the European data.

Concentration values in samples from Canada (Cao et al., 2011), and USA (Noonan et al., 2011; Lu et al., 2012, 2013) were within the same range as the samples from Europe.

Neither the EFSA opinion (2006a) nor the FAO/WHO opinion (2011) did assign a BPA value to non-canned food.

2.3. "Starchy roots and tubers", non-canned

No BPA concentration data for non-canned "Starchy roots and tubers" were found in the European literature.

Concentration data for non-canned starchy roots and tubers were provided through the call for data by France (44 samples), and Ireland (one sample) for a total of 45 samples. All the samples were of potatoes. The BPA concentrations ranged from below LOD/LOQ (16 %) to 2.6 µg/kg (fried potatoes, France).

The average BPA concentration (MB) for starchy roots and tubers was 0.7 µg/kg.

A market basket study from Sweden (Gyllenhammar et al., 2012) observed a BPA concentration from potatoes within the same range as that of the European data.

Concentration values in samples from Canada (Cao et al., 2011) were within the same range as the samples from Europe. Potatoes from the USA (Lu et al., 2012, 2013) had a BPA concentration of 4.3 µg/kg.

2.4. "Legumes, nuts and oilseeds", non-canned

No BPA concentration data were found in the European literature.

Concentration data for non-canned "Legumes, nuts and oilseeds" were provided through the call for data by France (three samples), and Ireland (two samples) for a total of five samples. The samples were of oilseeds, beans, tree nuts and other seeds. The BPA concentration ranged from below LOD/LOQ (60 %) to 0.5 µg/kg (beans, France).

The average BPA concentration (MB) for legumes, nuts and oilseeds was 0.2 µg/kg.

Concentration values in samples from Singapore (Sun et al., 2006) and Japan (Sajiki et al., 2007) were within the same range as the samples from Europe. However, one sample of shelled seeds from Canada (Cao et al., 2011) had a BPA concentration of 0.7 µg/kg.

Neither the EFSA opinion (2006a) nor the FAO/WHO opinion (2011) did assign a BPA value to non-canned food.

2.5. "Fruit and fruit products", non-canned

Concentration data in three samples of non-canned "Fruit and fruit products" were available from the literature in Belgium (Geens et al., 2010). The BPA concentration in pineapple and olives ranged from 0.1 µg/kg to 1.3 µg/kg. Mean BPA concentration (MB) was 0.5 µg/kg.

Concentration data for non-canned "Fruit and fruit products" were provided through the call for data by France (79 samples), and Ireland (six samples) for a total of 85 samples. The samples were of different fruits, dried fruits and jam. The BPA concentration ranged form below the LOQ (73 %) to 2.1 µg/kg (grapefruit, France). Mean BPA concentration (MB) was 0.3 µg/kg.

When all European data for non-canned fruit and fruit products were pooled, average BPA concentration (MB) was 0.3 µg/kg.

A market basket study from Sweden (Gyllenhammar et al., 2012) observed a BPA concentration from fruits in the same range as that of the European data.

Concentration values in samples from Japan (Sajiki et al., 2007) were within the same range as that of the samples from Europe. Fruit samples from the USA (Lu et al., 2012, 2013) had a BPA concentration above the European level, with the highest BPA concentration for citrus of 9.0 µg/kg.

Neither the EFSA opinion (2006a) nor the FAO/WHO opinion (2011) did assign a BPA value to non-canned food.

2.6. Glucuronated BPA in food of animal origin

Any BPA to which food production animals are exposed may conjugate and so may be present in their tissues as glucuronated BPA (ANSES, 2013). When BPA is measured in food of animal origin (e.g. meat, milk, eggs), it is possible that deconjugation occurs. Another potential source of unconjugated BPA in meat products is its migration from any food contact materials or from articles used in the processing of the product. With the exception of the data submitted by France through the EFSA call, none of the methods, published in the scientific literature or obtained through the EFSA call, described deconjugation steps and so it was assumed that the BPA concentrations reported were for unconjugated BPA only. The levels of total and unconjugated BPA in foods of animal origin were reported by ANSES to be virtually the same (ANSES, 2013). Therefore, the data on total BPA reported by France were merged with the other data from the EFSA call for data.

2.7. "Meat and meat products", non-canned

Concentration data from one sample of non-canned "Meat and meat products" were available from the literature in Belgium (Geens et al., 2010). The BPA concentration of sausages was 0.9 µg/kg.

Concentration data for non-canned meat and meat products were provided through the call for data by France (172 samples), Ireland (12 samples) and Norway (seven samples) for at total of 191 samples. The samples were of meat types, sausages and pâtés. The BPA concentration ranged from below the LOQ (5 %) to 394.8 µg/kg (edible offal, France). The BPA concentration (MB) was 9.5 µg/kg.

When all European data for non-canned meat and meat products were pooled, average BPA concentration (MB) was 9.4 µg/kg.

A market basket study from Sweden (Gyllenhammar et al., 2012) observed a BPA concentration from meat within the same range as that of the European data.

Concentration values in samples from China (Shao et al., 2007b), Canada (Cao et al., 2011 and Japan (Sajiki et al., 2007) were within the same range as that of the samples from Europe. Neither the EFSA opinion (2006a) nor the FAO/WHO opinion (2011) assigned a BPA value to non-canned food.

2.8. "Fish and other seafood", non-canned

Concentration data from eight samples of non-canned "Fish and other seafood" were available from the literature in Spain (Salgueiro-Gonzalez et al., 2012a) and Belgium (Geens et al., 2010). Most of the analysed samples were of mussels. The BPA concentrations ranged from below LOD/LOQ (75 %) to 11.2 µg/kg (mussels, Salgueiro-Gonzalez et al., 2012a). The BPA concentration (MB) was 1.9 µg/kg.

Concentraton data for non-canned fish and other seafood were provided through the call for data by France (66 samples), and Norway (2 samples) for a total of 68 samples. The samples were mostly of mussels, shrimps, salmon and trout. The BPA concentration ranged from below LOD/LOQ (3 %) to 97.9 µg/kg (salmon and trout, France). The BPA concentration (MB) was 8.1 µg/kg.

When all European data for non-canned fish and other seafood were pooled, average BPA concentration (MB) was 7.4 µg/kg.

A market basket study from Sweden (Gyllenhammar et al., 2012) observed a BPA concentration from fish within the same range as that of the European data.

Concentration values in samples from China (Shao et al., 2007a, Wei et al., 2011), and Canada (Cao et al., 2011) were within the same range as the samples from Europe. Some fish and seafood samples

from Malaysia (Santhi et al., 2012b) had a BPA concentration above the European level, with the highest BPA concentration for squid of 729.0 µg/kg dry weight.

Neither the EFSA opinion (2006a) nor the FAO/WHO opinion (2011) assigned a BPA value to non-canned food.

2.9. "Milk and dairy products", non-canned

Concentration data from one sample of non-canned "Milk and dairy products" were available from the literature in Greece (Maragou et al., 2006). The BPA concentration was below LOD/LOQ, and the MB value was 2.6 µg/kg.

Concentration data for non-canned milk and dairy products were provided through the call for data by France (139 samples), Ireland (eight samples), and Norway (four samples) for a total of 151 samples. The samples were mostly of yoghurt, cow's milk and other cheeses and types of milk. The BPA concentration ranged from below LOD/LOQ (52 %) to 6.1 µg/kg (Chantal cheese, France). The BPA concentration (MB) was 0.3 µg/kg).

When all European data for non-canned milk and dairy products were pooled, average BPA concentration (MB) was 0.3 µg/kg.

A market basket study from Sweden (Gyllenhammar et al., 2012) observed a BPA concentration from dairy products within the same range as that of the European data.

Concentration values in samples from China (Shao et al., 2007a; Liu et al., 2008), Canada (Cao et al., 2011) and Japan (Sajiki et al., 2007) were within the same range as that of the samples from Europe.

Neither the EFSA opinion (2006a) nor the FAO/WHO opinion (2011) did assign a BPA value to non-canned food.

2.10. "Eggs and egg products", non-canned

No BPA concentration data for non-canned "Eggs and egg products" were found in the European literature.

Concentration data for non-canned eggs and egg products were provided through the call for data by France (13 samples), Ireland (one sample) and Norway (one sample) for a total of 15 samples. The samples were mostly whole eggs. The BPA concentration ranged from below LOD/LOQ (20 %) to 4.5 µg/kg (whole eggs, France).

The BPA concentration (MB) of non-canned eggs and egg products was 0.9 µg/kg.

A market basket study from Sweden (Gyllenhammar et al., 2012) observed a BPA concentration from eggs within the same range as that of the European data. Concentration values in samples from China (Shao et al., 2007a) were within the same range as the samples from Europe. However, one in ten egg samples from China (Shao et al., 2007a) had a BPA concentration of 10.45 µg/kg.

Neither the EFSA opinion (2006a) nor the FAO/WHO opinion (2011) assigned a BPA value to non-canned food.

2.11. "Sugar and confectionery", non-canned

Concentration data from one sample of non-canned "Sugar and confectionery" was available from the literature in Belgium (Geens et al., 2010). The BPA concentration was 0.3 µg/kg.

Concentration data for non-canned sugar and confectionery were provided through the call for data by France (14 samples), Ireland (four samples) and Norway (one sample) for a total of 19 samples. The

samples were mostly chocolate and sugars. The BPA concentration ranged from below LOD/LOQ (42 %) to 2.6 µg/kg (molasses and other syrups, France). The average BPA concentration (MB) was 0.5 µg/kg.

When all European data for non-canned sugar and confectionery were pooled, average BPA concentration (MB) was 0.5 µg/kg.

Concentration values in samples from Japan (Sajiki et al., 2007) and Canada (Cao et al., 2011) were within the same range as that of the samples from Europe.

Neither the EFSA opinion (2006a) nor the FAO/WHO opinion (2011) assigned a BPA value to non-canned food.

2.12. "Animal and vegetable fats and oils", non-canned

No BPA concentration data for non-canned "Animal and vegetable fats and oils" were found in the European literature.

Concentration data for non-canned animal and vegetable fats and oils were provided through the call for data by France (20 samples), Ireland (four samples) and Norway (two samples) for a total of 26 samples. The samples were mostly butter and vegetable oils. The BPA concentrations ranged from below LOD/LOQ (46 %) to 1.4 µg/kg (margarine and olive oil, France).

The BPA concentration (MB) of non-canned animal and vegetable fats and oils was 0.5 µg/kg.

A market basket study from Sweden (Gyllenhammar et al., 2012) observed a BPA concentration from fats within the same range as that of the European data.

Neither the EFSA opinion (2006a) nor the FAO/WHO opinion (2011) assigned a BPA value to non-canned food.

2.13. "Fruit and vegetable juices", non-canned

Concentration data from two samples of non-canned "Fruit and vegetable juices" were available from the literature in Belgium (Geens et al., 2010). The BPA concentrations were below LOD/LOQ of 0.01 µg/kg.

Concentration data for non-canned fruit and vegetable juices were provided through the call for data by France (12 samples), Ireland (one sample) and Norway (one sample) for a total of 14 samples. The samples were all fruit juices. The BPA concentrations ranged from below LOD/LOQ (71 %) to 6.0 µg/kg (orange juice, France). The average BPA concentration (MB) was 0.8 µg/kg.

When all European data on non-canned fruit and vegetable juices were pooled, average BPA concentration (MB) was 0.7 µg/kg.

Concentration values in samples from Japan (Sajiki et al., 2007) were within the same range as that of the samples from Europe.

Neither the EFSA opinion (2006a) nor the FAO/WHO opinion (2011) assigned a BPA value to non-canned food.

2.14. "Non-alcoholic beverages", non-canned

Concentration data from one sample of non-canned "Non-alcoholic beverages" were provided from the literature in Belgium (Geens et al., 2010). The BPA concentrations were below LOD/LOQ of 0.01 µg/kg.

Concentration data for non-canned non-alcoholic beverages were provided from the call for data by France (68 samples), Ireland (three samples), and Norway (one sample) for a total of 72 samples. The samples were mostly from coffee, tea and hot chocolate. The BPA concentration ranged from below LOD/LOQ (64 %) to 1.7 µg/kg (black tea infusion, Ireland). The BPA concentration (MB) was 0.2 µg/kg.

When all European data for non-canned non-alcoholic beverages were pooled, average BPA concentration (MB) was 0.2 µg/kg.

Concentration values in samples from Japan (Sajiki et al., 2007) and Canada (Cao et al., 2010a) were within the same range as the samples from Europe.

Neither the EFSA opinion (2006a) nor the FAO/WHO opinion (2011) did assign a BPA value to non-canned food.

2.15. Alcoholic beverages, non-canned

Concentration data in 59 samples of non-canned "Alcoholic beverages" were available from the literature in Austria (Brenn-Struckhofova and Cichna-Markl, 2006). All the samples were of wine. The BPA concentrations ranged from below LOD/LOQ (22 %) to 2.1 µg/kg (wine, Brenn-Struckhofova and Cichna-Markl, 2006). The BPA concentration (MB) was 0.5 µg/kg.

Concentration data for non-canned alcoholic beverages were provided through the call for data by the United Kingdom (14 samples), Germany (8 samples), France (8 samples), and Ireland (5 samples) for a total of 35 samples. The samples were of beer and wine. The BPA concentrations ranged from below LOD/LOQ (71 %) to 1.6 µg/kg (wine, France). The average BPA concentration (MB) was 0.5 µg/kg.

When all European data for non-canned alcoholic beverages were pooled, average BPA concentration (MB) was 0.5 µg/kg.

Concentration values in samples from Japan (Sajiki et al., 2007) and Canada (Cao et al., 2010a, 2011) were within the same range as that of the samples from Europe.

Neither the EFSA opinion (2006a) nor the FAO/WHO opinion (2011) assigned a BPA value to non-canned food.

2.16. "Water", non-canned

BPA may be present in drinking water as a result of environmental contamination and/or epoxy resin linings in the drinking water distribution network and/or migration from PC water dispensers or water filters.

Concentration data from 159 non-canned samples of "Water" were available from the literature in Spain (Guart et al., 2011; Bono-Blay et al., 2012) and Belgium (Geens et al., 2010). The samples were from well water, bottled water and water stored in PC carboys.

BPA was detected in only 6 samples out of 131 samples of well water to be used for bottling water in Spain (LOD 0.009 µg/kg; maximum 0.2 µg/kg) (Bono-Blay et al., 2012). BPA was not detected in one sample of bottled water from Belgium (Geens et al., 2010). BPA was not detected in any sample of bottled water in Spain made of HDPE (n = 7) or PET (n = 10) (LOD = 0.009 µg/kg) (Guart et al., 2011). However, BPA was detected in all 10 samples of water stored in PC coolers in Spain (Guart et al., 2011). The BPA concentrations ranged from below LOD/LOQ (90 %) to 4.4 µg/kg. The average BPA concentration (MB) was 0.2 µg/kg.

Concentration data for non-canned water were provided through the call for data by France (396 samples), Germany (42 samples), Spain (17 samples), Ireland (two samples), PlasticsEurope (two

samples) and Norway (one sample) for a total of 460 samples. All types of non-canned waters where pooled, as most consumers drink a variety of water from different sources. The samples were mostly from tap water but also from water bottled in PET, glass and PC coolers. The BPA concentrations ranged from below LOD/LOQ (84 %) to 4.5 µg/kg (water stored in PC carboy, France). The average BPA concentration was 0.2 µg/kg.

When all European data for non-canned water were pooled, average BPA concentration (MB) was 0.2 µg/kg.

Concentration values in samples from Japan (Sajiki et al., 2007) were within the same range as that of the samples from Europe.

The EFSA opinion (2006a) did not assign a BPA value to non-canned water. In its exposure assessment, FAO/WHO (2011) observed that most BPA concentrations in tap water were below 0.01 µg/L, whereas BPA concentrations in water packaged in PC bottles were just below 1 µg/L. This last value was used by FAO/WHO in the exposure assessment as a conservative scenario.

2.17. "Herbs, spices and condiments", non-canned

Concentration data in two samples of non-canned "Herbs, spices and condiments" were available from the literature in Belgium (Geens et al., 2010). The samples were from pickles and vegetable sauce with the same BPA concentration of 0.3 µg/kg.

Concentration data on non-canned herbs, spices and condiments were provided through the call for data by France (eight samples), Ireland (eight samples) and Norway (one sample) for a total of 17 samples. The samples were mainly soy sauce, dressing and some stock cubes. The BPA concentrations ranged from below LOD/LOQ (71 %) to 2.5 µg/kg (dressing, France). The average BPA concentration was 1.3 µg/kg.

When all European data on non-canned herbs, spices and condiments were pooled, average BPA concentration (MB) was 1.2 µg/kg.

Concentration values in samples from Canada (Cao et al., 2011) were within the same range as that of the samples from Europe.

Neither the EFSA opinion (2006a) nor the FAO/WHO opinion (2011) assigned" a BPA value to non-canned food.

2.18. "Food for infants and small children", non-canned

Concentration data for one sample of non-canned infant formula was available from the literature from Greece (Maragou et al., 2006). The BPA concentration was below LOD/LOQ, and the MB BPA concentration was 0.9 µg/kg.

Concentration values in samples of baby foods contained in glass jars with metal lids from Canada (Cao et al., 2009a, 2011) were in the ranged below LOD to BPA concentration of 1.7 µg/kg.

Earlier opinions have chosen different BPA concentrations for exposure from infant formula. The FAO/WHO report (2011) used two average BPA concentration values for liquid infant formula of 4 µg/kg for the ready-to-feed formula and 3.5 µg/kg for the concentrated liquid formula. The EFSA opinion (2006a) did not assign a BPA concentration to non-canned food.

2.19. "Composite food", non-canned

Concentration data in three non-canned "Composite foods" were available from the literature from Belgium (Geens et al., 2010). The BPA concentration in the vegetable soups ranged between 0.1 µg/kg and 0.4 µg/kg. The average BPA concentration was 0.3 µg/kg.

Concentration data for non-canned composite food were provided through the call for data by France (96 samples), Switzerland (seven samples), Ireland (two samples) and Norway (two samples) for a total of 107 samples. The samples were of different composite foods and dishes. The BPA concentration ranged from below the LOQ (10 %) to 25.8 µg/kg (sandwich, France). The average BPA concentration (MB) was 2.4 µg/kg.

When all European data on non-canned composite foods were pooled, average BPA concentration (MB) was 2.4 µg/kg.

Concentration values in samples from Japan (Sajiki et al., 2007) and Canada (Cao et al., 2011) were within the same range as the samples from Europe.

Neither the EFSA opinion (2006a) nor the FAO/WHO opinion (2011) assigned a BPA value to non-canned food.

2.20. "Snacks, desserts and other foods", non-canned

No BPA concentration data for non-canned "Snacks, desserts and other foods" were found in the European literature.

Concentration data for non-canned snacks, desserts and other foods were provided through the call for data by France (25 samples) and Ireland (six samples) for a total of 31 samples. The samples were of potato crisps and desserts. The BPA concentration ranged from below the LOD (68 %) to 0.4 µg/kg (potato crisps, France).

The average BPA concentration (MB) in non-canned snacks, desserts and other foods was 0.4 µg/kg.

Neither the EFSA opinion (2006a) nor the FAO/WHO opinion (2011) did assign a BPA value to non-canned food.

2.21. Foods in glass jars with metal lids

BPA can be used in the internal coating of metal lids for foods in glass jars, and residues of BPA in these coatings can migrate into foods, especially at elevated temperatures (Cao et al., 2009a). Migration of BPA from the coating on metal lids into foods is assumed to be low compared with canned foods (Cao et al., 2009a). There are not many data available on the BPA concentration in food from glass jars with metal lids.

However, baby foods in glass jars with metal lids are an important part of the diets of children aged six months and older. One Canadian study has determined the BPA concentration in 99 baby food products in glass jars (Cao et al., 2009a). The BPA levels in 15 % of the samples were lower than the average LOD, and 70 % had BPA levels of less than 1 µg/kg. The average BPA level was 1.1 µg/kg.

Concentration data for 10 samples of fruit, vegetables and anchovies in glass jars were available from the literature in the Netherlands (Geens et al., 2010). The average BPA level was 0.60 µg/kg, with a range from 0.10 µg/kg in red cabbage to 1.28 µg/kg in pineapple.

As expected, the concentrations observed in foods in glass jars with metal lids were in line with those of non-canned food and lower than those in canned food. Concentration data from foods in glass jars with metal lids from the European market were therefore categorised with those of non-canned foods in the exposure assessment.

2.22. Water from water pipes relined with epoxy resins

Data on BPA in drinking water were available from the literature. A survey performed in Sweden (KEMI, 2013) investigated whether any BPA could be released in drinking water from aged water pipes relined with epoxy resins. Two different techniques for relining were used in Sweden from 2006

to 2011, one so-called one-component method in which the composition of the material is prepared industrially and another so-called two-component method in which the components are mixed on the spot. Both hot and cold water were collected and analysed. The concentrations in 31 samples of hot water ranged from below the LOQ of 0.01 µg/L (19 %) to 60 µg/L. Mean BPA concentration (MB) was 6.2 µg/L, and the 95th percentile (MB) was 60 µg/L.

In general the levels were low in cold water. A total of 19 samples of cold water from water pipes relined with the two-component method were analysed for BPA concentration, and the range was from below the LOQ of 0.01 µg/L (66 %) to 1.1 µg/L. The average BPA concentration (MB) was 0.10 µg/L.

The ANSES opinion (2013) paid special attention to water networks renovated with epoxy resins. However, all 46 samples analysed had BPA concentrations below the LOQ of 0.025 µg/L.

Appendix D. Summary of the non-dietary sources

Table 39: Overview of the literature concerning non-food sources considered in the exposure assessment

Author	Country	Location	Unit	Min	Max	Mean	Median	95th percentile
Outdoor air								
Salapasidou et al., 2011	Greece	Urban traffic site	ng/m^3	0.06	18.6	6.78		
		Industrial site	ng/m^3	LOD	47.3	13.2		
Wilson et al., 2007	USA	North Carolina	ng/m^3	1.0	1.5			
		Ohio	ng/m^3	0.7	0.9			
Rudel et al., 2010	USA	California	ng/m^3		2.0		0.5	
Matsumoto et al., 2005	Japan	Urban ambient outdoor air	ng/m^3	0.02	1.92	0.51		
Fu and Kawamura, 2010	Worldwide		pg/m^3	1	17 400			
Surface water								
Klecka et al., 2007	North America		µg/L				0.08	
	Europe		µg/L				0.01	
Air								
ANSES, 2013	France	30 homes	ng/m^3		5.3	1.0	0.6	
Wilson et al., 2007	USA	257 US homes	ng/m^3	0.9	193		1.82	11.1
Rudel et al., 2010	USA	50 Californian houses	ng/m^3	0.5	20		0.5	
Dust								
Völkel et al., 2008	Germany	12 German homes	µg/kg	117	1 486		553	
Geens et al., 2009a	Belgium	18 Belgian homes	ng/g	535	9 729		1 461	
Geens et al., 2009a	Belgium	2 Belgian offices	ng/g	4 685	8 380			
ANSES, 2013	France	25 French homes	mg/kg		20	5.8	4.7	
Paper products								
Biedermann et al., 2010	Switzerland	Thermal papers	g/kg	8	17	13.3		
Östberg and Noaksson, 2010	Sweden	Receipts	g/kg	5	32			
Liao and Kannan, 2011a	USA	Thermal paper receipts	g/kg	0.000001	13.9			
Liao and Kannan, 2011b	USA	Paper currencies	mg/kg	0.001	82.7			
Gehring et al., 2004	Germany	Recycled toilet paper	mg/kg	3.2	46.1			
Toys								
Viñas et al., 2012	Spain	Toys and teats	µg/L	0.2	5.9			
KEMI, 2012	Sweden	Toys and teats	µg/L	< 0.1	2.1			

Author	Country	Location	Unit	Min	Max	Mean	Median	95th percentile
Lassen et al., 2011	Denmark	Pacifiers	ng/product		1 360	319		
Cosmetics								
Cacho et al., 2013	Spain	Various cosmetic products	µg/kg	< LOQ	88			
Dodson et al., 2012	USA	Various cosmetic products	mg/kg	1	100			
Dental sealants								
Sasaki et al., 2005	Japan	Saliva	µg/L		100			
Kang et al., 2011	South Korea	Saliva	µg/L		21	5		

Appendix E. Sources of FoodEx level 1

The chronic exposure was estimated by multiplying the average BPA concentration for each FoodEx level 1 food group(s) and type of packaging (canned or non-canned) with their respective consumption (amount per kg bw), separately for each individual in the database, calculating the sum of exposure for each survey day for the individual and then deriving the daily average for the survey period. The dietary surveys used, by age class, are given in the tables below.

Table 40: Number of dietary surveys according to the percentage of average dietary exposure to BPA per type of packaging (canned vs. not canned), FoodEx level 1 category and scenario—Toddlers (total number of surveys = 7)

Packaging type	FoodEx level 1 category	Number of dietary surveys (middle bound) (% average BPA contribution)											
		Scenario 1						Scenario 2					
		< 1 %	1–5 %	5–10 %	10–25 %	25–50 %	50–75 %	< 1 %	1–5 %	5 – 10 %	10–25 %	25–50 %	50–75 %
Canned	Alcoholic beverages	7	0	0	0	0	0	7	0	0	0	0	0
Canned	Animal and vegetable fats and oils	7	0	0	0	0	0	7	0	0	0	0	0
Canned	Composite food	5	1	1	0	0	0	0	3	1	2	1	0
Canned	Fish and other seafood	6	1	0	0	0	0	0	5	1	1	0	0
Canned	Fruit and fruit products	6	1	0	0	0	0	3	3	1	0	0	0
Canned	Fruit and vegetable juices	7	0	0	0	0	0	2	2	3	0	0	0
Canned	Grains and grain-based products	6	1	0	0	0	0	6	1	0	0	0	0
Canned	Herbs, spices and condiments	7	0	0	0	0	0	3	3	1	0	0	0
Canned	Legumes, nuts and oilseeds	5	1	1	0	0	0	0	4	2	1	0	0
Canned	Meat and meat products	6	1	0	0	0	0	0	0	2	5	0	0
Canned	Milk and dairy products	7	0	0	0	0	0	5	2	0	0	0	0
Canned	Non-alcoholic beverages	7	0	0	0	0	0	7	0	0	0	0	0
Canned	Products for special nutritional use	7	0	0	0	0	0	7	0	0	0	0	0
Canned	Snacks, desserts and other foods	7	0	0	0	0	0	3	1	0	2	1	0
Canned	Starchy roots and tubers	7	0	0	0	0	0	7	0	0	0	0	0
Canned	Sugar and confectionery	7	0	0	0	0	0	7	0	0	0	0	0
Canned	Vegetables and vegetable products	3	1	1	1	1	0	0	0	0	3	4	0

Packaging type	FoodEx level 1 category	Number of dietary surveys (middle bound) (% average BPA contribution)											
		Scenario 1						Scenario 2					
		< 1 %	1–5 %	5–10 %	10–25 %	25–50 %	50–75 %	< 1 %	1–5 %	5 – 10 %	10–25 %	25–50 %	50–75 %
Not canned	Alcoholic beverages	7	0	0	0	0	0	7	0	0	0	0	0
Not canned	Animal and vegetable fats and oils	7	0	0	0	0	0	7	0	0	0	0	0
Not canned	Composite food	2	4	0	1	0	0	6	1	0	0	0	0
Not canned	Drinking water	0	5	1	1	0	0	1	6	0	0	0	0
Not canned	Eggs and egg products	7	0	0	0	0	0	7	0	0	0	0	0
Not canned	Fish and other seafood	0	5	0	2	0	0	5	2	0	0	0	0
Not canned	Food for infants and small children	0	5	0	2	0	0	4	2	1	0	0	0
Not canned	Fruit and fruit products	0	7	0	0	0	0	7	0	0	0	0	0
Not canned	Fruit and vegetable juices	0	5	2	0	0	0	5	2	0	0	0	0
Not canned	Grains and grain-based products	0	1	6	0	0	0	0	7	0	0	0	0
Not canned	Herbs, spices and condiments	6	1	0	0	0	0	7	0	0	0	0	0
Not canned	Legumes, nuts and oilseeds	7	0	0	0	0	0	7	0	0	0	0	0
Not canned	Meat and meat products	0	0	0	2	5	0	0	2	4	1	0	0
Not canned	Milk and dairy products	0	1	5	1	0	0	0	7	0	0	0	0
Not canned	Non-alcoholic beverages	5	2	0	0	0	0	7	0	0	0	0	0
Not canned	Products for special nutritional use	7	0	0	0	0	0	7	0	0	0	0	0
Not canned	Snacks, desserts and other foods	6	1	0	0	0	0	7	0	0	0	0	0
Not canned	Starchy roots and tubers	1	6	0	0	0	0	6	1	0	0	0	0
Not canned	Sugar and confectionery	6	1	0	0	0	0	7	0	0	0	0	0
Not canned	Vegetables and vegetable products	0	4	3	0	0	0	7	0	0	0	0	0

Table 41: Number of dietary surveys according to the percentage of average dietary exposure to BPA per type of packaging (canned vs. not canned), FoodEx level 1 category and scenario—Children 3-10 years (total number of surveys = 15)

Packaging type	FoodEx level 1 category	Number of dietary surveys (middle bound) (% average BPA contribution)											
		Scenario 1						Scenario 2					
		< 1 %	1 –5 %	5 –10 %	10 –25 %	25 –50 %	50 –75 %	< 1 %	1 –5 %	5 –10 %	10 –25 %	25 –50 %	50 –75 %
Canned	Alcoholic beverages	15	0	0	0	0	0	15	0	0	0	0	0
Canned	Animal and vegetable fats and oils	15	0	0	0	0	0	15	0	0	0	0	0
Canned	Composite food	12	1	2	0	0	0	5	1	2	2	4	1
Canned	Fish and other seafood	9	5	1	0	0	0	0	6	8	1	0	0
Canned	Fruit and fruit products	11	4	0	0	0	0	3	8	4	0	0	0
Canned	Fruit and vegetable juices	12	2	1	0	0	0	3	7	5	0	0	0
Canned	Grains and grain-based products	14	1	0	0	0	0	8	6	1	0	0	0
Canned	Herbs, spices and condiments	15	0	0	0	0	0	6	5	3	1	0	0
Canned	Legumes, nuts and oilseeds	12	3	0	0	0	0	3	7	3	2	0	0
Canned	Meat and meat products	12	2	1	0	0	0	0	0	5	10	0	0
Canned	Milk and dairy products	14	0	0	0	1	0	9	5	1	0	0	0
Canned	Non-alcoholic beverages	15	0	0	0	0	0	15	0	0	0	0	0
Canned	Products for special nutritional use	15	0	0	0	0	0	15	0	0	0	0	0
Canned	Snacks, desserts and other foods	15	0	0	0	0	0	5	5	2	2	1	0
Canned	Starchy roots and tubers	15	0	0	0	0	0	13	2	0	0	0	0
Canned	Sugar and confectionery	15	0	0	0	0	0	15	0	0	0	0	0
Canned	Vegetables and vegetable products	8	3	2	1	1	0	0	0	2	7	6	0
Not canned	Alcoholic beverages	15	0	0	0	0	0	15	0	0	0	0	0
Not canned	Animal and vegetable fats and oils	15	0	0	0	0	0	15	0	0	0	0	0
Not canned	Composite food	6	3	1	4	1	0	9	6	0	0	0	0
Not canned	Drinking water	1	10	4	0	0	0	5	10	0	0	0	0
Not canned	Eggs and egg products	15	0	0	0	0	0	15	0	0	0	0	0
Not canned	Fish and other seafood	0	10	4	1	0	0	12	3	0	0	0	0
Not canned	Food for infants and small children	15	0	0	0	0	0	15	0	0	0	0	0
Not canned	Fruit and fruit products	1	14	0	0	0	0	15	0	0	0	0	0
Not canned	Fruit and vegetable juices	0	10	5	0	0	0	13	2	0	0	0	0
Not canned	Grains and grain-based products	0	0	13	2	0	0	0	15	0	0	0	0
Not canned	Herbs, spices and condiments	12	3	0	0	0	0	15	0	0	0	0	0

Packaging type	FoodEx level 1 category	Number of dietary surveys (middle bound) (% average BPA contribution)											
		Scenario 1						Scenario 2					
		< 1 %	1 –5 %	5 –10 %	10 –25 %	25 –50 %	50 –75 %	< 1 %	1 –5 %	5 –10 %	10 –25 %	25 –50 %	50 –75 %
Not canned	Legumes, nuts and oilseeds	15	0	0	0	0	0	15	0	0	0	0	0
Not canned	Meat and meat products	0	0	0	2	11	2	0	6	5	4	0	0
Not canned	Milk and dairy products	0	5	9	1	0	0	2	13	0	0	0	0
Not canned	Non-alcoholic beverages	7	8	0	0	0	0	15	0	0	0	0	0
Not canned	Products for special nutritional use	15	0	0	0	0	0	15	0	0	0	0	0
Not canned	Snacks, desserts and other foods	13	2	0	0	0	0	15	0	0	0	0	0
Not canned	Starchy roots and tubers	0	15	0	0	0	0	13	2	0	0	0	0
Not canned	Sugar and confectionery	10	5	0	0	0	0	15	0	0	0	0	0
Not canned	Vegetables and vegetable products	0	8	7	0	0	0	15	0	0	0	0	0

Table 42: Number of dietary surveys according to the percentage of average dietary exposure to BPA per type of packaging (canned vs. not canned), FoodEx level 1 category and scenario—Adolescents (total number of surveys = 12)

Packaging type	FoodEx LEVEL 1 category	Number of dietary surveys (middle bound) (% average BPA contribution)											
		Scenario 1						Scenario 2					
		< 1 %	1 –5 %	5 –10 %	10 –25 %	25 –50 %	50 –75 %	< 1 %	1 –5 %	5 –10 %	10 –25 %	25 –50 %	50 –75 %
Canned	Alcoholic beverages	12	0	0	0	0	0	12	0	0	0	0	0
Canned	Animal and vegetable fats and oils	12	0	0	0	0	0	12	0	0	0	0	0
Canned	Composite food	9	1	2	0	0	0	4	2	1	2	3	0
Canned	Fish and other seafood	4	4	4	0	0	0	0	3	7	2	0	0
Canned	Fruit and fruit products	11	1	0	0	0	0	1	11	0	0	0	0
Canned	Fruit and vegetable juices	8	2	1	1	0	0	4	6	1	1	0	0
Canned	Grains and grain-based products	12	0	0	0	0	0	7	5	0	0	0	0
Canned	Herbs, spices and condiments	11	1	0	0	0	0	5	2	4	1	0	0
Canned	Legumes, nuts and oilseeds	10	2	0	0	0	0	1	6	3	2	0	0
Canned	Meat and meat products	10	1	1	0	0	0	0	0	0	10	2	0
Canned	Milk and dairy products	12	0	0	0	0	0	11	1	0	0	0	0
Canned	Non-alcoholic beverages	12	0	0	0	0	0	12	0	0	0	0	0
Canned	Products for special nutritional use	12	0	0	0	0	0	12	0	0	0	0	0
Canned	Snacks, desserts and other foods	12	0	0	0	0	0	6	3	2	1	0	0
Canned	Starchy roots and tubers	12	0	0	0	0	0	10	2	0	0	0	0
Canned	Sugar and confectionery	12	0	0	0	0	0	12	0	0	0	0	0
Canned	Vegetables and vegetable products	5	2	2	2	1	0	0	0	1	7	4	0
Not canned	Alcoholic beverages	10	2	0	0	0	0	12	0	0	0	0	0
Not canned	Animal and vegetable fats and oils	12	0	0	0	0	0	12	0	0	0	0	0
Not canned	Composite food	3	3	3	2	1	0	7	5	0	0	0	0
Not canned	Drinking water	1	6	5	0	0	0	3	9	0	0	0	0
Not canned	Eggs and egg products	12	0	0	0	0	0	12	0	0	0	0	0
Not canned	Fish and other seafood	0	4	8	0	0	0	8	4	0	0	0	0
Not canned	Food for infants and small children	12	0	0	0	0	0	12	0	0	0	0	0
Not canned	Fruit and fruit products	2	10	0	0	0	0	12	0	0	0	0	0
Not canned	Fruit and vegetable juices	3	8	1	0	0	0	12	0	0	0	0	0
Not canned	Grains and grain-based products	0	0	10	2	0	0	0	12	0	0	0	0
Not canned	Herbs, spices and condiments	8	4	0	0	0	0	12	0	0	0	0	0

Packaging type	FoodEx LEVEL 1 category	Number of dietary surveys (middle bound) (% average BPA contribution)											
		Scenario 1						Scenario 2					
		< 1 %	1 –5 %	5 –10 %	10 –25 %	25 –50 %	50 –75 %	< 1 %	1 –5 %	5 –10 %	10 –25 %	25 –50 %	50 –75 %
Not canned	Legumes, nuts and oilseeds	12	0	0	0	0	0	12	0	0	0	0	0
Not canned	Meat and meat products	0	0	0	0	9	3	0	2	6	4	0	0
Not canned	Milk and dairy products	0	11	1	0	0	0	5	7	0	0	0	0
Not canned	Non-alcoholic beverages	4	8	0	0	0	0	12	0	0	0	0	0
Not canned	Products for special nutritional use	11	1	0	0	0	0	12	0	0	0	0	0
Not canned	Snacks, desserts and other foods	12	0	0	0	0	0	12	0	0	0	0	0
Not canned	Starchy roots and tubers	0	12	0	0	0	0	12	0	0	0	0	0
Not canned	Sugar and confectionery	12	0	0	0	0	0	12	0	0	0	0	0
Not canned	Vegetables and vegetable products	0	8	4	0	0	0	12	0	0	0	0	0

Table 43: Number of dietary surveys according to the percentage of average dietary exposure to BPA per type of packaging (canned vs. not canned), FoodEx level 1 category and scenario—Women (18–45 years) (total number of surveys = 15)

Packaging type	FoodEx level 1 category	Number of dietary surveys (middle bound) (% average BPA contribution)											
		Scenario 1						Scenario 2					
		< 1 %	1 –5 %	5 –10 %	10 –25 %	25 –50 %	50 –75 %	< 1 %	1 –5 %	5 –10 %	10 –25 %	25 –50 %	50 –75 %
Canned	Alcoholic beverages	14	1	0	0	0	0	15	0	0	0	0	0
Canned	Animal and vegetable fats and oils	15	0	0	0	0	0	15	0	0	0	0	0
Canned	Composite food	11	3	0	1	0	0	4	5	1	2	3	0
Canned	Fish and other seafood	5	4	5	1	0	0	0	4	8	3	0	0
Canned	Fruit and fruit products	10	5	0	0	0	0	0	15	0	0	0	0
Canned	Fruit and vegetable juices	12	2	1	0	0	0	3	11	1	0	0	0
Canned	Grains and grain-based products	12	3	0	0	0	0	8	7	0	0	0	0
Canned	Herbs, spices and condiments	13	2	0	0	0	0	4	8	3	0	0	0
Canned	Legumes, nuts and oilseeds	10	4	0	1	0	0	2	8	3	2	0	0
Canned	Meat and meat products	11	2	2	0	0	0	0	0	1	14	0	0
Canned	Milk and dairy products	15	0	0	0	0	0	12	3	0	0	0	0
Canned	Non-alcoholic beverages	14	1	0	0	0	0	15	0	0	0	0	0
Canned	Products for special nutritional use	15	0	0	0	0	0	15	0	0	0	0	0
Canned	Snacks, desserts and other foods	15	0	0	0	0	0	7	6	1	1	0	0
Canned	Starchy roots and tubers	15	0	0	0	0	0	14	1	0	0	0	0
Canned	Sugar and confectionery	15	0	0	0	0	0	15	0	0	0	0	0
Canned	Vegetables and vegetable products	5	2	4	4	0	0	0	0	0	5	10	0
Not canned	Alcoholic beverages	6	9	0	0	0	0	13	2	0	0	0	0
Not canned	Animal and vegetable fats and oils	15	0	0	0	0	0	15	0	0	0	0	0
Not canned	Composite food	5	5	2	2	1	0	13	2	0	0	0	0
Not canned	Drinking water	1	7	5	2	0	0	3	12	0	0	0	0
Not canned	Eggs and egg products	15	0	0	0	0	0	15	0	0	0	0	0
Not canned	Fish and other seafood	0	9	5	1	0	0	12	3	0	0	0	0
Not canned	Food for infants and small children	15	0	0	0	0	0	15	0	0	0	0	0
Not canned	Fruit and fruit products	3	12	0	0	0	0	15	0	0	0	0	0
Not canned	Fruit and vegetable juices	5	9	1	0	0	0	15	0	0	0	0	0
Not canned	Grains and grain-based products	0	2	12	1	0	0	0	15	0	0	0	0

Packaging type	FoodEx level 1 category	Number of dietary surveys (middle bound) (% average BPA contribution)											
		Scenario 1						Scenario 2					
		< 1 %	1 –5 %	5 –10 %	10 –25 %	25 –50 %	50 –75 %	< 1 %	1 –5 %	5 –10 %	10 –25 %	25 –50 %	50 –75 %
Not canned	Herbs, spices and condiments	9	6	0	0	0	0	15	0	0	0	0	0
Not canned	Legumes, nuts and oilseeds	15	0	0	0	0	0	15	0	0	0	0	0
Not canned	Meat and meat products	0	0	0	2	12	1	0	3	9	3	0	0
Not canned	Milk and dairy products	0	14	1	0	0	0	8	7	0	0	0	0
Not canned	Non-alcoholic beverages	4	10	1	0	0	0	8	7	0	0	0	0
Not canned	Products for special nutritional use	15	0	0	0	0	0	15	0	0	0	0	0
Not canned	Snacks, desserts and other foods	15	0	0	0	0	0	15	0	0	0	0	0
Not canned	Starchy roots and tubers	1	14	0	0	0	0	14	1	0	0	0	0
Not canned	Sugar and confectionery	15	0	0	0	0	0	15	0	0	0	0	0
Not canned	Vegetables and vegetable products	0	5	10	0	0	0	15	0	0	0	0	0

Table 44: Number of dietary surveys according to the percentage of average dietary exposure to BPA per type of packaging (canned vs. not canned), FoodEx level 1 category and scenario—Men 18–45 years (total number of surveys = 15)

Packaging type	FoodEx level 1 category	Number of dietary surveys (middle bound) (% average BPA contribution)											
		Scenario 1						Scenario 2					
		< 1 %	1 –5 %	5 –10 %	10 –25 %	25 –50 %	50 –75 %	< 1 %	1 –5 %	5 –10 %	10 –25 %	25 –50 %	50 –75 %
Canned	Alcoholic beverages	14	0	1	0	0	0	15	0	0	0	0	0
Canned	Animal and vegetable fats and oils	15	0	0	0	0	0	15	0	0	0	0	0
Canned	Composite food	10	3	2	0	0	0	5	4	1	2	3	0
Canned	Fish and other seafood	5	6	3	1	0	0	0	3	9	3	0	0
Canned	Fruit and fruit products	13	2	0	0	0	0	4	11	0	0	0	0
Canned	Fruit and vegetable juices	12	2	1	0	0	0	6	8	1	0	0	0
Canned	Grains and grain-based products	13	2	0	0	0	0	9	6	0	0	0	0
Canned	Herbs, spices and condiments	13	2	0	0	0	0	4	8	3	0	0	0
Canned	Legumes, nuts and oilseeds	9	4	1	1	0	0	1	8	4	2	0	0
Canned	Meat and meat products	10	3	2	0	0	0	0	0	0	13	2	0
Canned	Milk and dairy products	15	0	0	0	0	0	14	1	0	0	0	0
Canned	Non-alcoholic beverages	14	1	0	0	0	0	15	0	0	0	0	0
Canned	Products for special nutritional use	15	0	0	0	0	0	15	0	0	0	0	0
Canned	Snacks, desserts and other foods	15	0	0	0	0	0	8	5	1	1	0	0
Canned	Starchy roots and tubers	15	0	0	0	0	0	14	1	0	0	0	0
Canned	Sugar and confectionery	15	0	0	0	0	0	15	0	0	0	0	0
Canned	Vegetables and vegetable products	6	0	6	2	1	0	0	0	0	5	10	0
Not canned	Alcoholic beverages	1	11	3	0	0	0	6	9	0	0	0	0
Not canned	Animal and vegetable fats and oils	15	0	0	0	0	0	15	0	0	0	0	0
Not canned	Composite food	7	4	2	2	0	0	13	2	0	0	0	0
Not canned	Drinking water	2	9	4	0	0	0	5	10	0	0	0	0
Not canned	Eggs and egg products	15	0	0	0	0	0	15	0	0	0	0	0
Not canned	Fish and other seafood	0	9	5	1	0	0	13	2	0	0	0	0
Not canned	Food for infants and small children	15	0	0	0	0	0	15	0	0	0	0	0
Not canned	Fruit and fruit products	11	4	0	0	0	0	15	0	0	0	0	0
Not canned	Fruit and vegetable juices	8	6	1	0	0	0	14	1	0	0	0	0
Not canned	Grains and grain-based products	0	2	13	0	0	0	0	15	0	0	0	0

Packaging type	FoodEx level 1 category	Number of dietary surveys (middle bound) (% average BPA contribution)											
		Scenario 1						Scenario 2					
		< 1 %	1 –5 %	5 –10 %	10 –25 %	25 –50 %	50 –75 %	< 1 %	1 –5 %	5 –10 %	10 –25 %	25 –50 %	50 –75 %
Not canned	Herbs, spices and condiments	10	5	0	0	0	0	15	0	0	0	0	0
Not canned	Legumes, nuts and oilseeds	15	0	0	0	0	0	15	0	0	0	0	0
Not canned	Meat and meat products	0	0	0	1	10	4	0	1	7	7	0	0
Not canned	Milk and dairy products	0	14	1	0	0	0	10	5	0	0	0	0
Not canned	Non-alcoholic beverages	4	11	0	0	0	0	8	7	0	0	0	0
Not canned	Products for special nutritional use	15	0	0	0	0	0	15	0	0	0	0	0
Not canned	Snacks, desserts and other foods	15	0	0	0	0	0	15	0	0	0	0	0
Not canned	Starchy roots and tubers	2	13	0	0	0	0	14	1	0	0	0	0
Not canned	Sugar and confectionery	15	0	0	0	0	0	15	0	0	0	0	0
Not canned	Vegetables and vegetable products	0	10	5	0	0	0	15	0	0	0	0	0

Table 45: Number of dietary surveys according to the percentage of average dietary exposure to BPA per type of packaging (canned vs. not canned), FoodEx level 1 category and scenario—Other adults 45–65 years (total number of surveys = 14)

Packaging type	FoodEx level 1 category	Number of dietary surveys (middle bound) (% average BPA contribution)											
		Scenario 1						Scenario 2					
		< 1 %	1 –5 %	5 –10 %	10 –25 %	25 –50 %	50 –75 %	< 1 %	1 –5 %	5 –10 %	10 –25 %	25 –50 %	50 –75 %
Canned	Alcoholic beverages	13	1	0	0	0	0	14	0	0	0	0	0
Canned	Animal and vegetable fats and oils	14	0	0	0	0	0	14	0	0	0	0	0
Canned	Composite food	10	3	0	1	0	0	3	5	2	1	3	0
Canned	Fish and other seafood	5	5	3	1	0	0	0	1	6	7	0	0
Canned	Fruit and fruit products	10	4	0	0	0	0	1	13	0	0	0	0
Canned	Fruit and vegetable juices	12	2	0	0	0	0	8	6	0	0	0	0
Canned	Grains and grain-based products	12	2	0	0	0	0	8	6	0	0	0	0
Canned	Herbs, spices and condiments	14	0	0	0	0	0	7	7	0	0	0	0
Canned	Legumes, nuts and oilseeds	10	2	1	1	0	0	1	7	4	2	0	0
Canned	Meat and meat products	10	3	1	0	0	0	0	0	0	13	1	0
Canned	Milk and dairy products	14	0	0	0	0	0	12	2	0	0	0	0
Canned	Non-alcoholic beverages	14	0	0	0	0	0	14	0	0	0	0	0
Canned	Products for special nutritional use	14	0	0	0	0	0	14	0	0	0	0	0
Canned	Snacks, desserts and other foods	14	0	0	0	0	0	9	5	0	0	0	0
Canned	Starchy roots and tubers	14	0	0	0	0	0	13	1	0	0	0	0
Canned	Sugar and confectionery	14	0	0	0	0	0	14	0	0	0	0	0
Canned	Vegetables and vegetable products	6	0	7	1	0	0	0	0	0	4	10	0
Not canned	Alcoholic beverages	1	12	1	0	0	0	8	6	0	0	0	0
Not canned	Animal and vegetable fats and oils	14	0	0	0	0	0	14	0	0	0	0	0
Not canned	Composite food	7	3	1	3	0	0	12	2	0	0	0	0
Not canned	Drinking water	1	7	6	0	0	0	4	10	0	0	0	0
Not canned	Eggs and egg products	14	0	0	0	0	0	14	0	0	0	0	0

Packaging type	FoodEx level 1 category	Number of dietary surveys (middle bound) (% average BPA contribution)											
		Scenario 1						Scenario 2					
		< 1 %	1 –5 %	5 –10 %	10 –25 %	25 –50 %	50 –75 %	< 1 %	1 –5 %	5 –10 %	10 –25 %	25 –50 %	50 –75 %
Not canned	Fish and other seafood	0	5	6	3	0	0	11	3	0	0	0	0
Not canned	Food for infants and small children	14	0	0	0	0	0	14	0	0	0	0	0
Not canned	Fruit and fruit products	2	12	0	0	0	0	14	0	0	0	0	0
Not canned	Fruit and vegetable juices	8	6	0	0	0	0	14	0	0	0	0	0
Not canned	Grains and grain-based products	0	2	12	0	0	0	0	14	0	0	0	0
Not canned	Herbs, spices and condiments	12	2	0	0	0	0	14	0	0	0	0	0
Not canned	Legumes, nuts and oilseeds	14	0	0	0	0	0	14	0	0	0	0	0
Not canned	Meat and meat products	0	0	0	1	11	2	0	2	9	3	0	0
Not canned	Milk and dairy products	0	13	1	0	0	0	11	3	0	0	0	0
Not canned	Non-alcoholic beverages	4	9	1	0	0	0	8	6	0	0	0	0
Not canned	Products for special nutritional use	14	0	0	0	0	0	14	0	0	0	0	0
Not canned	Snacks, desserts and other foods	14	0	0	0	0	0	14	0	0	0	0	0
Not canned	Starchy roots and tubers	2	12	0	0	0	0	13	1	0	0	0	0
Not canned	Sugar and confectionery	14	0	0	0	0	0	14	0	0	0	0	0
Not canned	Vegetables and vegetable products	0	5	9	0	0	0	14	0	0	0	0	0

Table 46: Number of dietary surveys according to the percentage of average dietary exposure to BPA per type of packaging (canned vs. not canned) and scenario—Elderly and very elderly (total number of surveys = 7)

Packaging type	FoodEx level 1 category	Number of dietary surveys (middle bound) (% average BPA contribution)											
		Scenario 1						Scenario 2					
		< 1 %	1 –5 %	5 –10 %	10 –25 %	25 –50 %	50 –75 %	< 1 %	1 –5 %	5 –10 %	10 –25 %	25 –50 %	50 –75 %
Canned	Alcoholic beverages	7	0	0	0	0	0	7	0	0	0	0	0
Canned	Animal and vegetable fats and oils	7	0	0	0	0	0	7	0	0	0	0	0
Canned	Composite food	7	0	0	0	0	0	2	3	0	1	1	0
Canned	Fish and other seafood	4	2	0	1	0	0	0	1	3	3	0	0
Canned	Fruit and fruit products	6	1	0	0	0	0	1	3	3	0	0	0
Canned	Fruit and vegetable juices	6	1	0	0	0	0	5	2	0	0	0	0
Canned	Grains and grain-based products	7	0	0	0	0	0	5	2	0	0	0	0
Canned	Herbs, spices and condiments	7	0	0	0	0	0	5	2	0	0	0	0
Canned	Legumes, nuts and oilseeds	7	0	0	0	0	0	0	5	1	1	0	0
Canned	Meat and meat products	5	2	0	0	0	0	0	0	0	7	0	0
Canned	Milk and dairy products	7	0	0	0	0	0	4	3	0	0	0	0
Canned	Non-alcoholic beverages	7	0	0	0	0	0	7	0	0	0	0	0
Canned	Products for special nutritional use	7	0	0	0	0	0	7	0	0	0	0	0
Canned	Snacks, desserts and other foods	7	0	0	0	0	0	5	1	1	0	0	0
Canned	Starchy roots and tubers	7	0	0	0	0	0	6	1	0	0	0	0
Canned	Sugar and confectionery	7	0	0	0	0	0	7	0	0	0	0	0
Canned	Vegetables and vegetable products	3	0	3	0	1	0	0	0	0	2	5	0
Not canned	Alcoholic beverages	0	7	0	0	0	0	5	2	0	0	0	0
Not canned	Animal and vegetable fats and oils	7	0	0	0	0	0	7	0	0	0	0	0
Not canned	Composite food	5	0	1	1	0	0	7	0	0	0	0	0
Not canned	Drinking water	1	3	3	0	0	0	2	5	0	0	0	0
Not canned	Eggs and egg products	7	0	0	0	0	0	7	0	0	0	0	0
Not canned	Fish and other seafood	0	3	2	2	0	0	7	0	0	0	0	0
Not canned	Food for infants and small children	7	0	0	0	0	0	7	0	0	0	0	0
Not canned	Fruit and fruit products	0	7	0	0	0	0	7	0	0	0	0	0
Not canned	Fruit and vegetable juices	5	2	0	0	0	0	7	0	0	0	0	0
Not canned	Grains and grain-based products	0	0	7	0	0	0	0	7	0	0	0	0

Packaging type	FoodEx level 1 category	Number of dietary surveys (middle bound) (% average BPA contribution)											
		Scenario 1						Scenario 2					
		< 1 %	1 –5 %	5 –10 %	10 –25 %	25 –50 %	50 –75 %	< 1 %	1 –5 %	5 –10 %	10 –25 %	25 –50 %	50 –75 %
Not canned	Herbs, spices and condiments	6	1	0	0	0	0	7	0	0	0	0	0
Not canned	Legumes, nuts and oilseeds	7	0	0	0	0	0	7	0	0	0	0	0
Not canned	Meat and meat products	0	0	0	0	6	1	0	1	5	1	0	0
Not canned	Milk and dairy products	0	6	1	0	0	0	4	3	0	0	0	0
Not canned	Non-alcoholic beverages	1	6	0	0	0	0	4	3	0	0	0	0
Not canned	Products for special nutritional use	7	0	0	0	0	0	7	0	0	0	0	0
Not canned	Snacks, desserts and other foods	7	0	0	0	0	0	7	0	0	0	0	0
Not canned	Starchy roots and tubers	0	7	0	0	0	0	6	1	0	0	0	0
Not canned	Sugar and confectionery	7	0	0	0	0	0	7	0	0	0	0	0
Not canned	Vegetables and vegetable products	0	2	5	0	0	0	7	0	0	0	0	0

Appendix F. Equations and parameters used in the calculation of exposure from non-dietary sources

Table 47: Overview of the equations and parameters used for calculating exposure from non-food sources

Pathway/Source	Formula	Parameters
		General: *bw*: body weight (kg bw) E_{source}: exposure contribution of respective source (ng/kg bw per day)
Ingestion/dust	$E_{dust} = \frac{C_{dust} \times q_{dust}}{bw}$	C_{dust}: concentration in dust (median) (ng/mg) q_{dust}: dust ingestion (mg/day)
Ingestion/mouthing of toys Ingestion/mouthing of pacifiers	$E_{toy} = \frac{q_{product} \times f_{time} \times f_{surface}}{bw}$	$q_{product}$: total amount of BPA that migrated into artificial saliva (ng) f_{time}: correction factor sucking time per day/duration of migration experiment (1/day) $f_{surface}$: correction factor for contact surface (–)
Ingestion/thermal paper transfer to food	$E_{tp\text{-}food} = \frac{a_{finger} \times n_{finger} \times f_{avail} \times f_{trans} \times q_{handling}}{bw}$	a_{finger}: amount on finger after touching thermal paper (ng) n_{finger}: number of fingers touching thermal paper (–) f_{avail}: available fraction for transfer to food (–) f_{trans}: transfer fraction to food (–) $q_{handling}$: handling events with transfer (1/day)
Inhalation/air	$E_{air} = \frac{C_{air} \times q_{air}}{bw}$	C_{air}: concentration in air (ng/m^3) q_{air}: quantity of inhaled air per day (m^3/day)
Dermal uptake/thermal paper	$E_{tp\text{-}dermal} = \frac{a_{finger} \times n_{finger} \times q_{handling}}{bw}$	a_{finger}: amount on finger after touching thermal paper (ng) n_{finger}: number of fingers touching thermal paper (–) $q_{handling}$: handling events (1/day)
Dermal uptake/cosmetics	$E_{cosmetics} = \frac{C_{cosmetics} \times q_{cosmetics} \times f_{ret}}{bw}$	$C_{cosmetics}$: concentration in cosmetics (ng/mg) $q_{cosmetics}$: applied amount per day (mg/day) f_{ret}: retention factor (1 for leave-on) (–)

Appendix G. Biomonitoring: estimation of daily BPA intake from creatinine-based urinary concentration

For the estimation of daily BPA intake, volume-based BPA concentrations (µg BPA/L urine) are generally preferred over creatinine-based urinary concentrations (µg BPA/g creatinine) (Lakind and Naiman, 2008; Mahalingaiah et al., 2008; Geens et al., 2012a). The arguments against creatinine-based data are: (i) the larger variation range of > 1 000 % in urinary creatinine concentration compared with up to 300 % variation in daily urinary volume (Boeniger et al., 1993); and (ii) the differences in the physiological mode of urinary excretion (active secretion, filtration) between glucuronidated BPA and creatinine (Boeniger et al., 1993; Mahalingaiah et al., 2008). Although the large North American surveys (NHANES, CHMS) indicate an approximately 10-fold difference between the 5th and 95th percentiles in (spot urine) creatinine concentration (Health Canada, 2012), the comparison between (spot urine) creatinine concentration and daily urinary volume falls short, because in the latter the within-day variation is removed. Moreover, although one may expect an increase in variability by dividing one fluctuating variable (BPA concentration) by another (creatinine concentration), there is *de facto* no increase in the 95th percentile to 50th percentile ratio between volume-based BPA concentrations and creatinine-based urinary BPA concentrations. An additional argument for the use of creatinine-based concentrations instead of volume-based concentrations is the fact that the former is not dependent on drinking behaviour. An example of changing drinking behaviour is the retrospective study by Koch et al. (2012), who reported an increase in 24-hour urine volume from 1.6 to 2.1 L in German students between 1995 and 2009, which was associated with a decrease in mean urinary creatinine concentration from 1.2 to 0.8 g/L. The daily urinary excretion of creatinine, in contrast, depends primarily on the muscle mass of the individual. A man excretes 14–16 mg/kg bw per day, and a woman 11–20 mg/kg bw per day, but the amount is fairly consistent for a given individual (McClatchey, 2002).

Based on creatinine-based urinary concentration of total BPA X_{BPA} (µg/g creatinine), the daily BPA exposure $\dot{m}_{\mathrm{BPA}}$ (ng/kg bw per day) was calculated by:

$$\dot{m}_{\mathrm{BPA}} = \frac{X_{\mathrm{BPA}} \times \dot{m}_{\mathrm{creatinine}}}{W}$$

where $\dot{m}_{\mathrm{creatinine}}$ (g/day) is the creatinine excretion rate and W (kg) is the body weight (Lakind and Naiman, 2008; UBA, 2012). Depending on whether body weight is available from the studies, either study-specific individual or mean values or generic values derived by linear interpolation from body weight vs. age relationships taken from the literature were used. Age-specific generic values on daily creatinine excretion were taken from Valentin (2002), except for cases in which study-specific values from 24-hour urine sampling were available. Table 48 shows the body weight and creatinine excretion rate parameters that were used to translate creatinine-based BPA concentration into daily BPA exposure. Generic values for the creatinine excretion rate were taken from ICRP reference tables (Valentin, 2002).

Age-specific estimates were available only from a few European studies, and only for children, adolescents, adults and the (very) elderly. For the children, the creatinine-based BPA intakes tend to be lower than the volume-based BPA intakes (e.g. 44 vs. 53 ng/kg bw per day for the Duisburg birth cohort study). The same tendency applies for the adolescents and the adults except the German ESB study and the MoBa study (Figure 17). In the German ESB study, a significant difference is not to be expected because both (creatinine-based and volume-based) exposure estimates were derived from 24-hour urine and creatinine excretions of the study participants rather than from generic values from the literature. For the (very) elderly, the Liege HBM study indicates that the creatinine-based intake is somewhat higher than the volume-based intake (49 vs. 40 ng/kg bw per day).

The daily BPA intake, as estimated from creatinine-adjusted urinary BPA concentrations, is shown in Figure 17 (red symbols). For comparative purposes, estimates derived from volume-based urinary BPA concentrations (black symbols) are also shown.

Table 48: Body weight and creatinine excretion rate parameters for the considered European and North American studies. Given are the parameters for body weight (*W*), creatinine excretion rate ($\dot{m}_{creatinine}$), and the specific creatinine excretion rate (spec. $\dot{m}_{creatinine}$). Gender and age were taken into account when deriving generic parameter values from published parameter–age relationships by linear interpolation. Study-specific parameters are set in italic font. References from which these parameters were taken are: [1] Koch et al. (2012); [2] Bergmann and Mensink (1999); [3] Valentin (2002); [4] Stolzenberg et al. (2007); [5] Ye et al. (2009a); [6] CDC (2012); [7] Health Canada (2012); [8] Monika Kasper-Sonnenberg (Ruhr University Bochum, Germany, 2013, personal communication); [9] Elly Den Hond (Flemish Institute for Technological Research [VITO], Belgium, 2013, personal communication)

Study	Gender	Age (years)	Sampling	W (kg)	$\dot{m}_{creatinine}$ (mL/day)	spec. $\dot{m}_{creatinine}$ (mL/kg bw per day)	Reference
German ESB	MF	20–30	24hU	*72*	1 000	14	[1]
Duisburg BCS	F	29–49	MU	*71*	1 000	14	[8, 3]
Duisburg BCS	MF	6–8	MU	*24*	458	17	[8, 3]
Generation R	Pregnant F	18–41	SU	74	1 000	14	[5, 3]
MoBa	Pregnant F		SU	*74*	1 000	14	[5, 3]
Flemish HMB	MF	14–16	SU	*57*	1200	21	[9, 3]
Liege HMB	MF	7–11	MU	34	586	17	[2, 3]
Liege HMB	MF	12–19	MU	65	1 200	19	[2, 3]
Liege HMB	MF	20–39	MU	75	1 350	18	[2, 3]
Liege HMB	MF	40–59	MU	79	1 350	17	[2, 3]
Liege HMB	MF	60–75	MU	78	1 350	17	[2, 3]
NHANES	MF	6–>65	SU	*29–83*	490–1350	16–18	[6, 3]
CHMS	MF	6–79	SU	*33–80*	650–1 350	17–19	[7, 3]

M, male; F, female; 24hU, 24-hour urine; MU, morning urine; SU, spot urine, ?, not available.

The differences between creatinine-based and volume-based BPA exposure estimates among the European studies suggest that generic values for the daily urine volume overestimate the true daily urine volume in the children, adolescents and adults. In the (very) elderly, the situation seems to be reversed. This hypothesis is corroborated by North American surveys (NHANES, CHMS), for which explanatory information on urinary creatinine concentration is also available (Table 49). For the adolescents and adults in the NHANES survey, the actual creatinine concentrations are higher than the generic predictions (e.g. 1.33 vs. 0.92 g/L for the adolescents), which explains the lower creatinine-based BPA exposure estimates compared with the volume-based BPA exposure estimates (Figure 17). In other words, US adolescents and adults produce less urine than expected from data in the literature and produce, therefore, a more concentrated urine. Using volume-based urinary BPA concentrations in combination with generic values from the literature on daily urinary output will consequently overestimate the daily BPA exposures for US adolescents and adults. Explanations for differences among the US (very) elderly and among the Canadian population groups can be derived in a similar manner.

In conclusion, the estimation of daily BPA exposure from creatinine-based urinary BPA concentrations leads to slightly different values from those obtained from volume-based urinary BPA concentrations. For the few European studies (with the exception of the German ESB study), there is a tendency for lower BPA exposures in children, adolescents and adults, and a tendency for slightly higher BPA exposures for the (very) elderly. These differences are (at least partly) explainable by daily urinary outputs that deviate from the generic values taken from the literature. For the derivation

of reference values for the comparison with BPA uptake via food and non-food resources, the volume-based BPA intakes will be used because these are more conservative and better supported by a larger number of European studies.

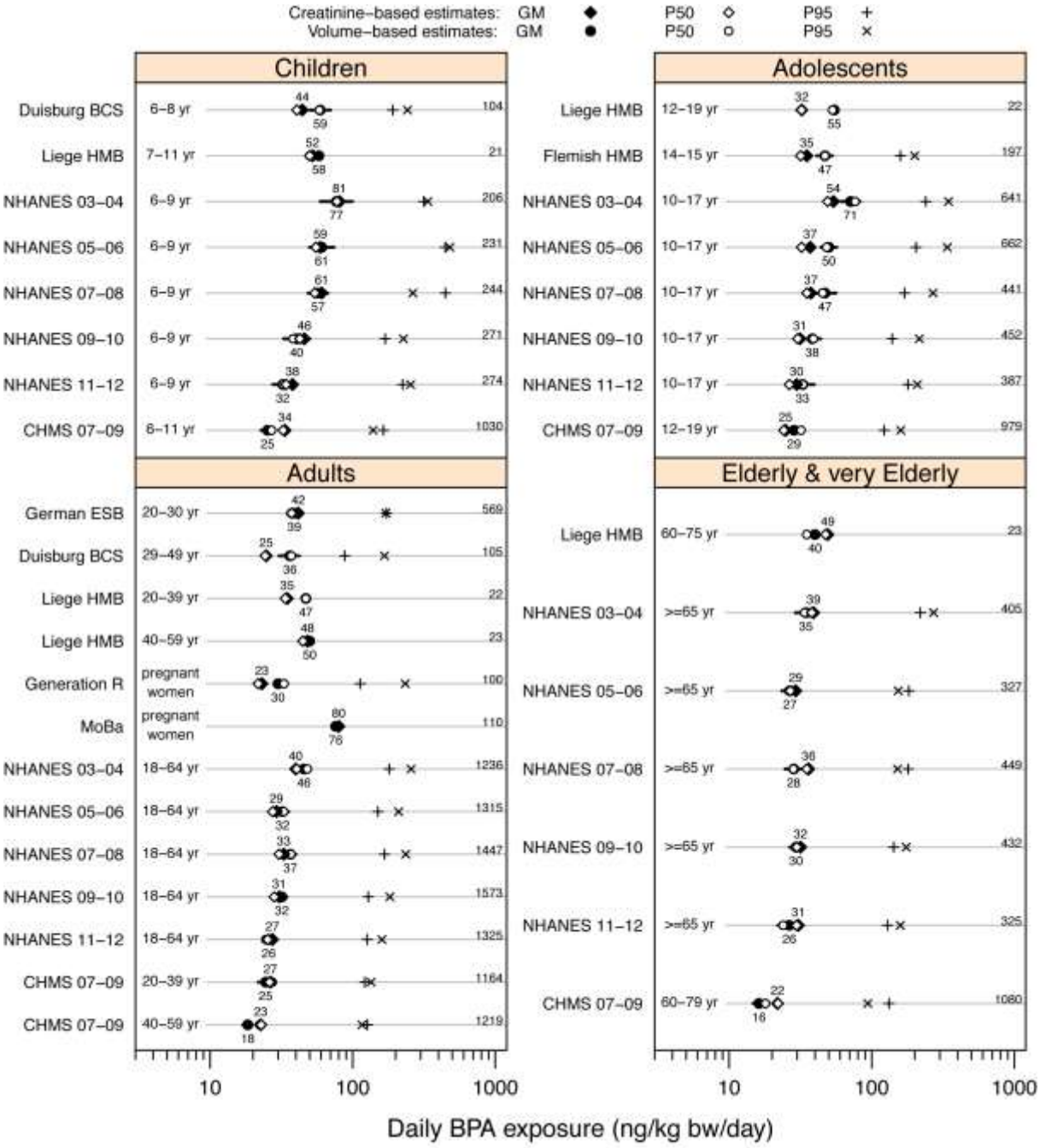

Figure 17: Daily BPA exposures as estimated from creatinine-based and volume-based urinary BPA concentrations. The age-specific estimates for daily BPA exposure from the different studies are grouped by the age classes defined in Section 4.5.1. Filled triangles and circles with associated numbers and error bars indicate the GMs and the 95 % confidence intervals for the creatinine-based and volume-based data. The medians (P50) are shown by open triangles and circles, and the 95th percentiles by plus signs and crosses. The number of subjects is given on the right. Age ranges and specific population groups (pregnant and parturient women) are indicated. The studies comprise the European studies and large-sized population-based surveys from North America (NHANES, CHMS).

Table 49: Comparison of study-specific and generic urinary creatinine concentrations. Given are the (average) median creatinine concentration for different age groups in the NHANES survey (2003–2004, 2005–2006, 2007–2008, 2009–2010) and the CHMS (2007–2009) survey. Also given are the generic values which were obtained from Valentin (2002) by dividing the (age-specific) creatinine excretion rate by urinary output rate

Age group	Urinary [Cr] (g/L)		Age group (years)	Urinary [Cr] (g/L)	
	NHANES	Valentin		CHMS	Valentin
Children	0.86	0.82	6–11	0.75	0.86
Adolescents	1.33	0.92	12–19	1.33	1.00
Adults	1.20	0.96	20–39	1.01	0.96
(Very) Elderly	0.91	0.96	40–59	0.87	0.96
			60–79	0.81	0.96

Appendix H. Evaluation of uncertainties in the exposure assessment through expert judgement

This appendix documents the approach taken to evaluating uncertainties affecting the CEF Panel's exposure assessment for BPA and presents the detailed results for different parts of the exposure assessment.

The general approach is adapted from the method for qualitative evaluation of uncertainty that was suggested in EFSA guidance on dealing with uncertainties in exposure assessment (EFSA, 2006b). The suggested approach comprised the following key steps:

- systematically examine every part of the assessment for potential sources of uncertainty;
- list the identified uncertainties in a table;
- evaluate the impact of each uncertainty on the outcome of the exposure assessment, using a suitable scale;
- evaluate the combined impact of all the uncertainties, considered together, on the outcome of the exposure assessment.

The evaluation of uncertainties is approximate, using expert judgement. EFSA guidance (2006b) suggested expressing the evaluation on a qualitative scale, provided the scale was defined, and showed an example where this was done with combinations of "+" and "–" symbols. Subsequently it was realised that while helpful in indicating the relative magnitudes of uncertainties, a qualitative scale does not give any indication how large they are in absolute terms, which is in principle needed for risk management. For example, if an exposure estimate is 10, its uncertainty is evaluated as "++" and the corresponding TDI is 20, then the risk manager needs to know whether "++" means the true exposure could be larger by a factor of 2 or more, because that would imply potential exceedance of the TDI. Therefore, some later EFSA opinions provided quantitative scales for the symbols, notably the guidance document of the EFSA Panel on Plant Protection Products and their Residues (PPR) on probabilistic modelling of dietary exposure (EFSA PPR Panel, 2012).

The general principles above have been applied to the exposure assessment, but the detailed methodology and format of the evaluation have been adapted to suit the differing needs of different parts of the assessment, as described below.

The following sections assess uncertainty for each of the individual sources of exposure, and for both average and high estimates of exposure, as both are used in risk characterisation (Section 5.1- Part II-Toxicological assessment and risk characterisation). . Uncertainties associated with the biomonitoring data on BPA in urine are also assessed below, so that they can be taken into account when comparing forward modelling estimates of exposure with estimates derived from biomonitoring (section 4.7.2). How the uncertainties for different sources of exposure combine is considered in Sections 5.1 in Part II-Toxicological assessment and risk characterisation and in Section 4.7.2 of the main opinion, in order to reach a conclusion on the overall uncertainty associated with the assessment of aggregate exposure.

Uncertainties affecting the estimation of exposures were evaluated using a tabular format similar to the original suggestions of EFSA (EFSA, 2006b). The CEF Panel's assessment of the impact of each uncertainty was expressed using symbols whose meaning is defined on a quantitative scale (Figure 14). Plus symbols mean that the true value of the exposure could be higher than the estimate; minus symbols mean that the true value could be lower; a dot (●) means that the impact of the uncertainty is less than +/–20 %. As the evaluation is approximate, each symbol represents a range of possible values; for example, "++" means that the true exposure is judged to be between two and five times the estimate. Pairs of symbols are used where the uncertainty spans a larger range; for example "–/++" would mean that the true value exposure is judged to be between half and five times the estimate. However, the relative likelihood of different values within the range was not assessed.

It is emphasised that all the evaluations are approximate expert judgements and should not be interpreted as precise estimates.

1. Uncertainties in the assessment of dietary exposure (excluding breastfed infants)

Uncertainties affecting the estimation of high dietary exposures were evaluated by adding two extra columns to the tabular format suggested by EFSA (EFSA, 2006b) (Table 51). The left-hand column in Table 51 lists the sources of uncertainty identified, and the right-hand column gives the CEF Panel's evaluation of the impact of those uncertainties on its estimates of high exposure, using symbols from the scale in Figure 14. The two additional columns, in the centre of the table, identify the variable that is affected by each uncertainty, and the value(s) used for that variable in the CEF Panel's calculation of high exposure.

The scale in Figure 14 was also used to evaluate the combined impact of all the uncertainties on the assessment of high dietary exposures, which is shown in the bottom row of Table 50 together with a short explanation of how it was derived.

Table 50: Evaluation of uncertainties affecting the assessment of high dietary exposure**.** The evaluations are approximate expert judgements and should not be interpreted as precise estimates. See Figure 14 for key to symbols

Source of uncertainty (high scenario)	Parameter affected	Value used in assessment		Impact on high exposure estimate
The Comprehensive Database includes nine surveys for toddlers, 17 surveys for children (3-10 years), 12 surveys for adolescents, 15 surveys for adults, seven surveys for elderly and six surveys for very elderly Consumption patterns in other Member States can be different	Food consumption	Individual consumption data	food	–/+
Food consumption data for women aged from 18 to 45 years from 15 different surveys have been used as a proxy for women of childbearing age Younger and older women can still be considered in childbearing age Women can change their consumption patterns when pregnant: it is possible that consumption of foods with higher BPA content (e.g. canned) might change by more than 20 % but not as high as double	Food consumption	Individual consumption data	food	–/+
Dietary data in the Comprehensive Database have been collected by means of different study designs, methodologies and protocols that could bias their results in a different way for each survey In particular, the following parameters may affect the level of detail and the accuracy of the collected data: the dietary assessment method used; the description and codification of the food consumed; the number of days per subject; the sampling design and size; the management of under-reporters; the quantification of portion sizes; the software applications used; and the non-dietary information collected. Furthermore, in some of the countries, data provided to EFSA came from relatively old national dietary surveys	Food consumption	Individual consumption data	food	–/+

Source of uncertainty (high scenario)	Parameter affected	Value used in assessment	Impact on high exposure estimate
Increasing the number of survey days (for both recalls and records) has the advantage of reducing the effect of study subjects' day-to-day variation, thus leading to an improved estimation of consumption variability. As survey duration increases, high percentile consumption decreases. This might be particularly important for episodically consumed foods, as some kind of canned foods could be Only food consumption data collected on more than one day per subject have been used to assess chronic exposure. The number of days per subject ranged from two to three in toddlers and from two to seven in women aged from 18 to 45 years	Food consumption	Individual food consumption data	–/●
Only a limited number of dietary surveys included in the Comprehensive Database presented information on the type of packaging (canned or non-canned, in particular). Two scenarios were therefore considered: (i) only foods specifically codified as canned were considered as such; and (ii) at FoodEx level 4, any food that has been codified as canned in at least one survey is always considered to be consumed as canned in all dietary surveys included in the Comprehensive Database The ratio between the 95th percentiles calculated under scenario 2 and scenario 1 ranged from 4 to 4.8 in toddlers and from 2.1 to 6.8 among women aged from 18 to 45 years	Food consumption	Individual food consumption data	–/● (scenario 2)
Different methods of analysis have been used to quantify BPA in food and beverages, all presenting an uncertainty. Occurrence data are from different origins, total diet studies (TDS), monitoring and literature Data on occurrence of BPA in food retrieved from scientific journals can be biased towards positive results as negative results are not always published Data from TDS can be biased owing to pooling of the food samples Data from the literature represent 22 % of the samples. It is therefore expected that this bias produces limited effects	BPA occurrence levels	Average BPA concentration assessed by merging data from different sources or publications	●

Source of uncertainty (high scenario)	Parameter affected	Value used in assessment	Impact on high exposure estimate
Food samples below the limit of quantification or reporting were handled through the substitution method: the lower bound (LB) value was obtained by assigning a value of zero to all the samples reported as less than the left-censoring limit, the middle bound (MB) value by assigning half of the left-censoring limit, and the upper bound (UB) by assigning the left-censored limit as the sample result At the 95th percentile, MB exposure estimates were 4 –20 % (scenario 1) and 2–9 % (scenario 2) higher than those calculated using the LB method and 2–20 % (scenario 1) and 2–8 % (scenario 2) lower than those calculated using the UB method	BPA occurrence levels	Average BPA occurrence for LB, MB and UB have been calculated	●
Bias could have been introduced by the limited number of samples for some of the categories and owing to the large food categories, specific foods could present lower or higher levels In particular, relatively high levels of BPA in non-canned meat and fish have been identified in many samples from France and one from Ireland. These are difficult to explain, more samples from different countries would have been useful. However, the relatively low impact of non-canned food to the 95th percentile exposure in scenario 2 makes it unlikely this would change exposure by more (or even as much as) double	BPA occurrence levels	Average BPA occurrence for each FoodEx level 1 food group and type of packaging (canned or non-canned)	–/+
Bias could have been introduced owing to the limited number of samples and Member States represented. Data from France are, for example, predominant for non-canned food and beverages. BPA levels could be lower or higher in some of the Member States On average, specific population groups could be exposed to systematically lower or higher levels than those calculated at EU level, e.g. through the consumption of specific brands	BPA occurrence levels	Average BPA occurrence has been calculated at EU level	–/+
In general, analytical determination performed in food was aimed at quantifying unconjugated BPA and would not allow the detection or quantification of conjugated BPA (sulphated, glucuronidated). Based on ANSES specific analysis, conjugated BPA represents a very minor fraction of total BPA. This uncertainty is therefore likely to have a minor impact on the estimate of high exposure	BPA occurrence levels	Total BPA	●
Data on body weight at subject level was used. Direct measurements were taken in some of the surveys, while, in the remaining, self-reported measures were used	Body weight	Individual body weights	●

Source of uncertainty (high scenario)	Parameter affected	Value used in assessment	Impact on high exposure estimate
Toddlers High levels of exposure have been estimated by means of the 95th percentile for the total population. A limited number of subjects were available for some of the age classes. In particular, in the case of toddlers the 95th percentile was assessed only for four surveys presenting at least 60 subjects per study.	BPA exposure	Highest 95th percentile among toddlers from four different dietary surveys	–/+
Women aged 18–45 High levels of exposure have been estimated by means of the 95th percentile for the total population. A limited number of subjects was available for some of the age classes. In particular, in the case of women aged from 18 to 45 years the 95th percentile was assessed for 15 surveys	BPA exposure	Highest 95th percentile among women aged from 18 to 45 years old from 15 different dietary surveys	–/●
Overall assessment – high dietary exposure The main source of uncertainty in the assessment of dietary exposure to BPA is the result of limitations in the representativity of the available information on food consumption and BPA occurrence in food. In the case of toddlers, the age group presenting the highest exposure estimates, only for four surveys was it possible to calculate the 95th percentile of exposure, whereas this was possible for 15 dietary surveys in the case of women aged 18–45 years. Uncertainty for other adults and for children aged 3-10 years and adolescents is considered to be in the same range as for women aged 18-45 years. Also noteworthy is the fact that food consumption data from different surveys presents different levels of bias owing to the different study designs, methodologies and protocols used. Exposure could also have been under- or overestimated owing to the limited number of analytical BPA samples, mainly available for specific food categories and from a scarce number of Member States. A clear overestimation has been introduced in the assessment of dietary exposure to BPA by not correcting for usual intake and by assuming (scenario 2) that any food that has been codified as canned in at least one survey is always consumed as canned in all dietary surveys.			–/+ In toddlers –/● In men and women aged from 18 to 45 years old, children aged 3-10 years, adolescents and the elderly.
Overall assessment – average dietary exposure The same uncertainties listed above for high dietary exposure apply also to the assessment of average dietary exposure except the overestimation of high exposure when assessed from short-term surveys, due to day-to-day variation. Uncertainty is therefore reduced for the average exposure estimates, but not by enough to bring it within +/-20%, The overall uncertainty evaluations for average dietary exposure are therefore the same as those given above for high exposure estimates, for all age groups.			As for high dietary exposure (above)

2. Uncertainties in the assessment of exposure for breastfed infants

Exposure of breastfed infants is assessed separately from the rest of the population and involves only two variables: (i) the concentration of BPA in human breast milk; and (ii) the consumption of breast milk by infants (expressed per kg body weight). Uncertainties affecting this assessment are evaluated in Table 52.

Table 51: Evaluation of uncertainties affecting the estimation of high exposure of breastfed infants to BPA in human breast milk. The evaluations are approximate expert judgements and should not be interpreted as precise estimates. See Figure 14 for key to symbols

Source of uncertainty	Parameter affected	Impact of uncertainty on high exposure estimate
Analytical uncertainty for concentrations above LOD	BPA concentration in breast milk	
Recovery: Not a problem in studies (7 of 8) using isotope-dilution mass spectrometry owing to the implicit recovery correction		●
Repeatability: Intra- and inter-day CV < 15 % for MS-based methods		●
Accuracy: < ±10 % (intra- and inter-day)		●
Contamination of breast milk samples Only three out of eight studies (all from the same lab) measured both unconjugated and total BPA. The median proportion of unconjugated BPA ranged from < 30 % to 76 %. It is unclear whether the variable proportion in unconjugated BPA arises from contamination and/or from enzymatic deconjugation by a breast milk β-glucuronidase during sample collection and storage	BPA concentration in breast milk	–/●
Sampling uncertainty Number of subjects ranges from n = 3–4 in method development studies to n = 20–100 in other studies. The relatively low number of subjects per study and the non-representative sampling may result in a sampling bias. This affects the study estimates for the central tendency and the variability, which both enter into the calculation of the high BPA concentration	BPA concentration in breast milk	–/+
Uncertainty about the variability of the population means The number of studies (n = 8) is low, and only four studies (the moderately sized ones) were finally considered for the estimation of average and high concentrations of unconjugated and total BPA. The estimate for the average concentration of total BPA in initial breast milk (colostrum) is based on the sample mean of one study only. For mature breast milk, the estimate is based on taking the average of the sample means of three studies only. Based on this low number of studies, there is practically no information on variability of the sample means across different populations or countries. Information on this inter-country variability is especially relevant for the calculation of the high BPA concentration in order to capture high levels of exposure that may occur in specific geographic areas. The absence of this information leads to an uncertainty that is judged to be greater than 20 % but lower than 200 %	BPA concentration in breast milk	●/+
Distribution uncertainty There are generally not enough data per study to directly get a reliable empirical (non-parametric) estimate of the 95th percentile. However, the available raw data for the moderately sized (n ≥ 20) studies suggest a log-normal distribution so that a parametric estimation of the 95th percentile appears feasible. Based on two studies on BPA in mature milk, a standard deviation was derived which was then used (together with a mean value) to estimate the 95 % percentile as a measure for the high BPA concentration. In principle, this estimate is conservative, as the calculated standard deviation reflects not only the between-individual variability but also the within-individual variability, which would average out in the long term. (Repeated/serial milk collections are unfortunately not available to estimate the relative contributions of these two variabilities)	BPA concentration in breast milk	–/●

Source of uncertainty	Parameter affected	Impact of uncertainty on high exposure estimate
Uncertainty about regional differences In the breast milk database, the European countries are, in essence, not covered. However, based on the urinary BPA concentrations, there is no reason to assume a considerably different (or higher) BPA exposure of European mothers in comparison with the USA, for which five studies on breast milk are available, and which have the main impact on the calculation of estimates for average and high BPA concentrations in breast milk	BPA concentration in breast milk	–/+
Measurement of breast milk consumption Different methods of measurement have been used to quantify human milk consumption, all presenting an uncertainty. The uncertainties are expected to be relatively small and tend to average out when the number of observations increase	Breast milk consumption	●
Variation between individuals The average breast milk volume is given per kilogram body weight and thereby takes into account the size of the baby. However, after correction for body weight there will be some residual variation between children in their average consumption per day of colostrum and breast milk. EFSA (EFSA CONTAM Panel, 2012) has previously used 800 mL as an estimate of average intake of breast milk for three-month-olds with a body weight 6.1 kg, and 1 200 mL for high intake, suggesting that variation of up to 50 % is considered possible	Breast milk consumption	–/+
Variation of consumption in the first days of life The volumes consumed increases approximately linearly from a few grams on day 1 to around 500 g on day 5. Considering an average consumption of 250 g over the first five days, and assuming an average body weight for a newborn infant of 3.25 kg, an average consumption rate of 75 g/kg bw per day (rounded by 5-g steps) is obtained. Because of the transitional character in the milk production and consumption rate, this estimate is associated with an uncertainty that is judged to be larger than ± 20 % but smaller than ± 200 %		–/+
Variation of consumption of breast milk in months 0–6 An estimated value of 150 g/kg bw per day already used in previous EFSA opinion has been used. The energy requirement and thereby the human milk consumption per kg body weight decreases steadily from month 1 to month 6 in exclusively breastfed children. The standard breast milk volume can be an underestimate the first months and an overestimate when the child reaches six months of age		–/+
Overall assessment—mature breast milk There is no reason to assume all the individual uncertainties to be correlated. It is expected that the unidirectional but oppositely directed uncertainties on sample contamination and population means variability would cancel out. The other bidirectional uncertainties add up and increase the overall uncertainty in both directions. However, the upwards uncertainties are countered by the uncertainty relating to the question of whether the proportion of conjugated BPA in breast milk becomes systemically available. As a result, it is expected that overall, the true exposures will lie between 20 % and 120 % of the estimate		– –/● (Mature breast milk)

Source of uncertainty	Parameter affected	Impact of uncertainty on high exposure estimate
Overall assessment—initial breast milk (colostrum) The above assessment is valid for mature breast milk, for which the estimate is supported by several small to medium-sized studies. For initial breast milk (colostrum), a reliable estimate could not be derived because of the discrepancies between the three available studies and the low sample sizes in some of the studies. The uncertainty for initial breast milk is further increased by the fact that milk production during the first five days is of a transitional character with changes in milk production rate and milk composition (protein and fat content). Last but not least, there is the possibility of an exposure from medical devices of mothers staying in the hospital for a few days after delivery		– –/+ (Initial breast milk/colostrum)

3. Uncertainties in the assessment of exposure in formula-fed infants

Table 52: Evaluation of uncertainties affecting the estimation of high dietary exposure (95th percentile) of 80 ng/kg bw per day in formula-fed infants. The evaluations are approximate expert judgements and should not be interpreted as precise estimates. See Figure 14 for key to symbols

Source of uncertainty (high scenario)	Parameter affected	Value used in assessment	Impact on high exposure estimate
The assumed consumption value of ready-to-eat infant formula (independently of being prepared from a powder or liquid) is based on water consumption of 150 g/kg bw per day (WHO, 2003), leading to formula consumption of 171 g/kg bw per day. Variability in the consumption between individuals is expected to be low. In its assessment of BPA, WHO used as 95th percentile of consumption of infant formula in infants 174 mL/kg bw (WHO, 2011a)	Consumption of water/kg bw	150 g/kg bw per day	●
Method of analysis—analytical determination CV ≤ 15 %	BPA occurrence levels	0	●
Sampling: Estimates were based on data from the literature and only a small number of samples were available (10 for canned powder). The values ranged from < LOD/LOQ to 2.7 µg/kg for canned formula; 47 % of the samples were below LOQ	BPA occurrence levels	95th of BPA concentration (MB) was 2.2 µg/kg	–/+
Sampling: Estimates were based on data from the literature and only one sample of non-canned formula below the LOD/LOQ, with an MB of 0.9 µg/kg.	BPA occurrence levels	LB, MB and UB for average and 95th percentile	–/+
Uncertainty owing to deconjugation of conjugated BPA: In general, analytical determinations performed in food aimed at quantifying unconjugated BPA and would not allow the detection or quantification of glucuronated BPA. However, according to ANSES data, the proportion of conjugated BPA in formula was not significant	BPA occurrence levels	Total BPA is assumed	●

Source of uncertainty (high scenario)	Parameter affected	Value used in assessment	Impact on high exposure estimate
BPA level in water: The water used to reconstitute infant formula from powder was assumed to contain 0.2 µg/kg of BPA (MB of all data on non-canned water), leading to an estimated exposure of 30 ng/kg bw per day from water. However, the formula could be reconstituted systematically with water containing significantly more BPA in infants living in flats where old waterpipes have been lined with epoxy resins (high exposure from water would then be 165 ng/kg bw per day. If the percentage of infants in this situation was more than 5 % in one of the EU countries, this would lead to a real highest 95th percentile in the EU more than twice the estimate of 80 ng/kg bw per day. Other cases such as water warmed in a PC kettle or water filtered with a PC filter would lead to very little additional exposure (see Table 24 in paragraph 4.5.3.4)	BPA occurrence levels	0.2 µg/kg (background level water)	●/++
A dilution factor in powder formula preparation of 7 is assumed. This can vary depending on the instruction of preparation.	BPA occurrence levels	1/7	●
The value used in the exposure assessment covers the most common types of packaging (powder or non-canned liquid infant formula) and baby bottles not releasing any BPA, whereas other cases can occur leading to a higher exposure Old PC bottles may still in use and can yield a high exposure of 684 ng/kg bw day. If the percentage of infants in this situation was more than 5 % in one of the EU countries, this would lead to a real highest 95th percentile eight times higher than the estimate of 80 ng/kg bw per day.	BPA occurrence levels		●/++
Overall assessment The main sources of uncertainty in the high level of exposure from infant formula are related to the lack of knowledge on the percentage of infants for whom more BPA is present in the water used to reconstitute infant formula, for whom old PC bottles bought before the 2011 ban would be used. This percentage could be higher than 5 % in some countries, leading to significantly higher 95th percentile			–/+++

4. Uncertainties in the assessment of (average and high) non-dietary exposure

Some sources of exposure were considered to be negligible or zero for toddlers and infants and were therefore not included in the exposure assessment. For both infants and toddlers, exposure from thermal paper was excluded. For infants in the first five days of life, exposure via toys, cosmetics and dust were also excluded. There is high confidence in these assumptions, so their uncertainty is not considered further.

The uncertainty evaluations below relate to the assessments of external non-dietary exposure, prior to absorption into the body. Uncertainties associated with assessing the fraction absorbed into the body are addressed separately (see Appendix D in Part II-Toxicological assessment and risk characterisation).

4.1. Assessment of average non-dietary exposure

The estimates of average exposure from non-dietary sources is intended to have the same level of conservativeness as the estimate of dietary exposure performed under scenario 2. Thus, in scenario 2 for dietary exposure all foods that may be canned are considered to be canned. To correspond with

this, all thermal paper is assumed to contain BPA. The effect of this on the exposure estimates is considered below.

Table 53: Evaluation of variability and uncertainties affecting the assessment of average external BPA exposure of dust ingestion for all age groups. See Figure 14 for key to symbols

Source of variability or uncertainty (average scenario)	Parameter affected	Value used in assessment	Impact on average exposure estimate
In order not to multiply too many worst case parameters (so as to achieve a realistic worst case) for this parameter an average (mean) value was used. Concentrations in dust are assessed in three European studies. The median value was used from the study that had the middle median value of all considered studies.	C_{dust}	1.461 mg/kg	+
Method of analysis: trace analytics +/- 15 %	C_{dust}	1.461 mg/kg	•
Dust ingestion rates in general are very uncertain. They are derived from soil ingestion studies. No specific dust ingestion studies are available to date. In this assessment values from the exposure factors handbook (EPA, 2011) were used. They are considered conservative estimates.	q_{dust}	30 mg/d (infants) 60 mg/d (toddlers) 60 mg/d (children 3-10 years) 60 mg/d (adolescents) 30 mg/d (adults)	- - - (infants) - - (toddlers) - - (children 3-10 years) - - (adolescents) - - (adults)
For infant body weight a value for 1-3 months old infants was used (EFSA Scientific Committee, 2012). For toddlers also a value on the conservative side was used. For children 3-10 years the average bodyweight for 9 years (RIVM) was used as a conservative value. For adolescents the average bodyweight for 15 year old adolescents was used, which is a less conservative value. Adult female body weights vary: about 70 % are below the EFSA default value of 70 kg. (EFSA Scientific Committee, 2012)	body weight	5 kg (infants) 12 kg (toddlers) 30 kg (children 3-10 years) 44 kg (adolescents) 70 kg (adults)	- (infants) - (toddlers) - -/+ (children 3-10 years) -/+ (adolescents) -/+ (adults)
Overall assessment Conservative dust ingestion rates have been used for the average exposure due to a lack of more refined data. Therefore, the average exposure is expected to be largely overestimated.			- - - / • (infants) - - / • (toddlers) - - / • (children 3-10 years) - - / • (adolescents) - - / • (adults)

Table 54: Evaluation of variability and uncertainties affecting the assessment of average external BPA BPA exposure from toys in infants and toddlers. See Figure 14 for key to symbols

Source of variability or uncertainty (average scenario)	Parameter affected	Value used in assessment	Impact on average exposure estimate
This average amount of leaching from toys was derived from one migration study with toys bought in Sweden. Toys will vary largely, so this value may not be representative. However, toys made of PC are not frequent on the market, so the true average value is likely to be closer to 0	q_{toy}	141 ng	– –
Method of analysis: trace analytics ± 15 %	q_{toy}	141 ng	●
The time fraction that the toy is sucked per day will be highest for continuous sucking (1) and lowest for not sucking. Average sucking times have been used that were observed in children of different age classes	f_{time}	0.012/day (infants) 0.001/day (toddlers)	●
The fraction of surface in contact with the mouth zone of the baby will be variable depending on the toy. Many different sizes of toys are available. Here, as an example a rattle was assessed: for a rattle approximately 0.5 of the rattle will be in contact with saliva. It is assumed that all of that saliva is subsequently ingested. This may not be true—saliva not ingested may reduce the effective surface up to five times. For some toys, the fraction could exceed 0.6, hence +.	$f_{surface}$	0.5	– –/+
For infant body weight a value for infants one to three months old was used (EFSA Scientific Committee, 2012). For toddlers too a value on the conservative side was used	Body weight	5 kg (infants) 12 kg	– (infants) – (toddlers)
Overall assessment Because of the small fraction of PC toys on the market this value may be an overestimation for average exposure			– –-/+

Table 55: Evaluation of variability and uncertainties affecting the assessment of average external BPA exposure from air inhalation forall age groups. See Figure 14 for key to symbols.

Source of variability or uncertainty (average scenario)	Parameter affected	Value used in assessment	Impact on average exposure estimate
Concentrations of BPA in indoor air are only available for France in a limited study. It is not clear whether levels of BPA in indoor air will vary between countries in Europe. For this assessment it was assumed that people spend 100 % of their time indoors. Since outdoor levels of BPA seem to be slightly lower, this may result in a slight overestimation (not much, because on average people in industrialized countries spend 90 % of their time indoors). However, in one study for Greece levels in outdoor air were as high as 6 ng/m^3. People in Greece, however, may spend more time outdoors than people in Northern Europe. Taking into account the high levels in outdoor air in Greece (which were not used in the assessment), there may be an underestimation for Greece and other Southern countries.	C_{air}	1.0 ng/m^3	- / ++
Method of analysis and sampling together can affect the measurement so that the variation may be +/- 100 %	C_{air}	1.0 ng/m^3	-/+
Inhalation rates vary with the activity profile. Therefore, the highest uncertainty is associated with the mix of activities during the day. Here, average values proposed by EPA, 2011 were used for the different consumer groups.	q_{air}	3.6 m^3/d (infants) 8.9 m^3/d (toddlers) 12 m^3/d (Children 3-10 years) 16.3 m^3/d (adolescents) 16.0 m^3/d (adults)	-/+ (infants) -/+ (toddlers) -/+ (children 3-10 years) -/+ (adolescents) -/+ (adults)
For infant body weight a value for 1-3 months old infants was used (EFSA Scientific Committee, 2012). For toddlers also a value on the conservative side was used. For children 3-10 years the average bodyweight for 9 years (RIVM) was used as a conservative value. For adolescents the average bodyweight for 15 year old adolescents was used, which is a less conservative value. Adult female body weights vary: about 70 % are below the EFSA default value of 70 kg. (EFSA Scientific Committee, 2012)	body weight	5 kg (infants) 12 kg (toddlers) 30 kg (children 3-10 years) 44 kg (adolescents) 70 kg (adults)	- (infants) - (toddlers) - -/+ (children 3-10 years) -/+ (adolescents) -/+ (adults)
Overall assessment. The activity profile will be very different for different subpopulations and different cultures. Also levels in indoor air are only available for one country in Europe and may be different in other countries.			- - / ++ (infants) - / ++ (all other age groups)

The estimates of average exposure from non-dietary sources is intended to have the same level of conservativeness as the estimate of dietary exposure performed under scenario 2. Therefore, all thermal paper is estimated to contain BPA.

Table 56: Evaluation of variability and uncertainties affecting the assessment of average level external dermal exposure to BPA from thermal paper for children (3-10 years), adolescents and adults. See Figure 14 for key to symbols

Source of variability or uncertainty (average scenario)	Parameter affected	Value used in assessment	Impact on average exposure estimate
The amount left on the fingers after handling thermal papers depends on the wetness and greasiness of the touching skin. If the paper is handled very shortly, not pressed and the fingers are dry it can be assumed that no BPA is transferred at all. The highest amount transferred was observed for wet fingers (Lassen et al, 2011). The average value presumably is on the conservative side, since it was derived by pressing hardly a thermal paper during 10 s (with dry fingers).	q_{finger}	1.4 µg	- / +
Method of analysis – analytical determination CV ≤ 15%	q_{finger}	1.4 µg	•
Maximum is 10. Normally people grasp paper with thumb and 1 or 2 finger tips. More contact can occur for those who fold their tickets, but the two little fingers are not involved. Based on the limited data available, 3 fingers per handling event is thought to be a average case.	n_{finger}	3	- / +
This value is based on the number of credit card receipts/person/year in Denmark.	$q_{handling}$	0.5 (children 3-10 years) 1 (adolescents) 1 per day (adults)	- - / + - - / ++ - - / ++
Not all thermal papers contain BPA. Presumably today around 80 % thermal papers contain BPA and the percentage may be declining due to public debate.	Occurrence of BPA in thermal paper	100 % (Upper bound)	-
For children 3-10 years the average bodyweight for 9 years (RIVM) was used as a conservative value. For adolescents the average bodyweight for 15 year old adolescents was used, which is a less conservative value. Adult female body weights vary: about 70 % are below the EFSA default value of 70 kg. (EFSA Scientific Committee, 2012)	body weight	30 kg (children 3-10 years) 44 kg (adolescents) 70 kg (adults)	- -/+ (children 3-10 years) -/+ (adolescents) -/+ (adults)
Overall assessment For n_{finger} and $q_{handling}$ data are lacking, which is why the assessment is highly uncertain. It is not clear, in which direction the true value may lie.			- - -/++ all age groups

Table 57: Evaluation of variability and uncertainties affecting the assessment of average level of external BPA exposure from cosmetics from all age groups. See Figure 14 for key to symbols

Source of variability or uncertainty (average scenario)	Parameter affected	Value used in assessment	Impact on average exposure estimate
Only one analytical study on 30 products is available to date, from which 6 contained BPA. No information was given, whether children's products were included. This data is not representative for cosmetic products in the EU. The range of possible concentrations of BPA in the EU therefore is not known. The highest boundary may be 10 ppm, since this is an acceptable level for impurities in a product. One product concentration was chosen for an exemplary worst case assessment: a face cream as a proxy for body lotion.	$C_{cosmetics}$	0.031 µg/g	--/++
Method of analysis: trace analytics +/- 15 %	$C_{cosmetics}$	0.031 µg/g	•
Application rates of body lotion have been assessed in a large study on the European level for adults. Data is considered as robust. For infants , children and adolescents, however, use data had to be extrapolated from adult data.	$q_{cosmetics}$	0.77 g/d (infants) 1.1 g/d (toddlers) 2.1 g/d (children 3-10 years) 3.5 g/d (adolescents) 4.6 g/d (adults)	- /+ (infants, toddlers, children 3-10 years, adolescents) • (adults)
It was assumed that only one cosmetic was used (a worst case body lotion). In reality, some individuals using body lotion will also use other cosmetics leading to some additional BPA exposure.	$q_{cosmetics}$		+
For infant body weight a value for 1-3 months old infants was used (EFSA Scientific Committee, 2012). For toddlers also a value on the conservative side was used. For children 3-10 years the average bodyweight for 9 years (RIVM) was used as a conservative value. For adolescents the average bodyweight for 15 year old adolescents was used, which is a less conservative value. Adult female body weights vary: about 70 % are below the EFSA default value of 70 kg. (EFSA Scientific Committee, 2012)	body weight	5 kg (infants) 12 kg (toddlers) 30 kg (children 3-10 years) 44 kg (adolescents) 70 kg (adults)	- (infants) - (toddlers) - -/+ (children 3-10 years) -/+ (adolescents) -/+ (adults)
Overall assessment A large uncertainty is associated with the occurrence of BPA in cosmetics. It is not clear whether the study on 30 products is representative for the European market, nor is it clear how BPA enters the products (during production or from packaging).			--/++ (all age groups)

4.2. Assessment of high non-dietary exposure

Table 58: Evaluation of variability and uncertainties affecting the assessment of external exposure from thermal paper for children (3-10 years), adolescents and adults. Note that evaluations in columns 4 and 5 of the table are approximate expert judgements and should not be interpreted as precise estimates. See Figure 14 for key to symbols

Source of variability or uncertainty (high scenario)	Parameter affected	Value used in assessment	Impact on high exposure estimate
The approximation of a 95th percentile was performed by combining two average parameter values (q_{finger} and bodyweight) with approximate 75th percentile values for two other parameters and an upper bound for another (BPA occurrence). It is uncertain whether this approach leads to the true 95th percentile. The more parameters introduced as the 75th percentile, the higher will be the percentile. For two 75th percentile and two average parameters the 95th percentile is more likely to be slightly underestimated than overestimated.	(all)		●/+
The amount left on the fingers after handling thermal papers depends on the wetness and greasiness of the touching skin. If the paper is handled very shortly, not pressed and the fingers are dry it can be assumed that no BPA is transferred from the paper to the fingers at all. The highest amount of 30 µg transferred was observed for wet fingers (Lassen et al, 2011). In order not to multiply too many worst-case parameters (so as to achieve a realistic worst case) for this parameter an average value was used. However, this average presumably is on the conservative side, since it was derived by pressing hard on a thermal paper for 10 s (with dry fingers), which is not always done when handling receipts.	q_{finger} quantity on the finger	1.4 µg (Average value)	- -/++
Method of analysis – analytical determination CV ≤ 15%	q_{finger}	1.4 µg	●
Maximum is 10. Normally people grasp paper with thumb and 1 or 2 finger tips. More contact can occur for those who fold their tickets, but the two little fingers are not involved. Based on the limited data available, 6 fingers per handling event is thought to be an approximate 75th percentile and suitable for making an estimate of high exposure when combined with the other input variables.	n_{finger} number of fingers	6 (Approx. 75th percentile)	●
The used value was determined as a worst case by Lassen et al, 2011 from a use study with shopping receipts (3.6/day) and added safety value for unknown papers, e.g. bus tickets. The frequency of handling may occasionally and for special people be much higher, but presumably not more than 10 events (7 shopping, 2 bus, 1 canteen ticket) on a regular basis.	$f_{handling}$ frequency of handling	2 / day children 3-10 years) 4.6 / day (adolescents) 4.6 / day (adults)	-/+ (all age groups)

Source of variability or uncertainty (high scenario)	Parameter affected	Value used in assessment	Impact on high exposure estimate
For children 3-10 years the average bodyweight for 9 years (RIVM) was used as a conservative value. For adolescents the average bodyweight for 15 year old adolescents was used, which is a less conservative value. Adult female body weights vary: about 70 % are below the EFSA default value of 70 kg. (EFSA Scientific Committee, 2012)	body weight	30 kg (children 3-10 years) 44 kg (adolescents) 70 kg (adults)	- -/+ (children 3-10 years) -/+ (adolescents) -/+ (adults)
Not all thermal papers contain BPA. Presumably today around 80 % thermal papers contain BPA and the percentage may be declining due to public debate.	Occurrence of BPA in thermal paper	100 % (Upper bound)	-
Overall assessment. The largest uncertainty arises from the variability of people's skin wetness and greasiness, and behavioural factors. From the combination of a conservative average for the amount on the fingers and approximate 75th percentiles for the both use parameters, a 95th percentile was targeted. In order to roughly check the assumptions to achieve a P95, a Monte Carlo simulation was performed by applying the full parameter range given above. In this Monte Carlo simulation the 95th percentile was estimated to be about 400 ng/kg bw /d in comparison to 163 ng/kg bw /d for the deterministic evaluation, meaning that there is the possibility of underestimating the 95th percentile. However, the assumption that the controlled experiment mimics worst-case touching of thermal paper, may have led to overestimation. Overall, it is estimated that the true 95th percentile may be between 2-5 times lower and 2-5 times higher than the estimated 95th percentile.			--/++

Table 59: Evaluation of variability and uncertainties affecting the assessment of high external exposure from cosmetics in all age groups. See Figure 14 for key to symbols

Source of variability or uncertainty (average scenario)	Parameter affected	Value used in assessment	Impact on average exposure estimate
The approximation of a 95th percentile was performed by combining two average parameter values ($C_{cosmetics}$ and bodyweight) with an approximate 95th percentile value for one other parameter ($q_{cosmetics}$). A further implicit upper bound parameter is the occurrence: it is assumed that all people use a BPA-containing body lotion on the whole body. However, more cosmetics than just body lotion may contain BPA, but since most of the other will result in much smaller exposure (due to amount applied) their contribution will be relatively low. It is uncertain whether this approach leads to the true 95th percentile. For this combination it is more likely to be overestimated than underestimated.	(all)		-/●

Source of variability or uncertainty (average scenario)	Parameter affected	Value used in assessment	Impact on average exposure estimate
Only one analytical study on 30 products is available to date, from which 6 contained BPA. No information was given, whether children's products were included. This data is not representative for cosmetic products in the EU. The range of possible concentrations of BPA in the EU therefore is not known. The highest boundary may be 10 ppm, since this is an acceptable level for impurities in a product. One product concentration was chosen for an exemplary worst case assessment: a face cream as a proxy for body lotion.	$C_{cosmetics}$	0.031 µg/g	--/++
Method of analysis: trace analytics +/- 15 %	$C_{cosmetics}$	0.031 µg/g	•
Application rates of body lotion have been assessed in a large study on the European level for adults. Data is considered as robust. For infants and children, however, use data had to be extrapolated from adult data by using surface ratios.	$q_{cosmetics}$	1.5 g/d (infants) 2.1 g/d toddlers) 4.1 g/d children 3-10 years) 6.8 g/d (adolescents) 9.0 g/d (adults)	- /+ (infants, toddlers, children 3-10 years, adolescents) • (adults)
For infant body weight a value for 1-3 months old infants was used (EFSA Scientific Committee, 2012). For toddlers also a value on the conservative side was used. For children 3-10 years the average bodyweight for 9 years (RIVM) was used as a conservative value. For adolescents the average bodyweight for 15 year old adolescents was used, which is a less conservative value. Adult female body weights vary: about 70 % are below the EFSA default value of 70 kg. (EFSA Scientific Committee, 2012)	body weight	5 kg (infants) 12 kg (toddlers) 30 kg (children 3-10 years) 44 kg (adolescents) 70 kg (adults)	- (infants) - (toddlers) - -/+ (children 3-10 years) -/+ (adolescents) -/+ (adults)
Overall assessment A large uncertainty is associated with the occurrence of BPA in cosmetics. It is not clear whether the study on 30 products is representative for the European market, nor is it clear how BPA enters the products (during production or from packaging).			--/++

Table 60: Evaluation of variability and uncertainties affecting the assessment of high external exposure from dust ingestion in all age groups. See Figure 14 for key to symbols

Source of variability or uncertainty (high scenario)	Parameter affected	Value used in assessment	Impact on high exposure estimate
The approximation of the 95th percentile was performed by combining two average parameter values ($C_{dust,}$ bodyweight) with higher percentile values for two other parameters. Supposed that these parameters would be 75th percentiles the approach would likely lead to a 95th percentile.			●/+

Source of variability or uncertainty (high scenario)	Parameter affected	Value used in assessment	Impact on high exposure estimate
Concentrations in dust are assessed in three European studies. Here the median value from the study with the middle median values was used.	C_{dust}	1.461 mg/kg (Average value)	-/+
Method of analysis: trace analytics +/- 15 %	C_{dust}	1.461 mg/kg	●
Dust ingestion rates are very uncertain. They are derived from soil ingestion studies. No specific dust ingestion studies are available to date. It is assumed that the true value for dust ingestion is lower, because pika behavior contributes large amounts of data for toddlers. In this assessment the rates suggested by Oomen et al, 2008 were used.	q_{dust}	50 mg/d (infants) 100 mg/d (toddlers) 100 mg/d (children 3-10 years) 100 mg/d (adolescents) 50 mg/d (adults)	- - - / - - (infants) - - / + (toddlers) - - / + (children 3-10 years) - - / + (adolescents) - - / + (adults)
For infant body weight a value for 1-3 months old infants was used (EFSA Scientific Committee, 2012). For toddlers also a value on the conservative side was used. For children 3-10 years the average bodyweight for 9 years (RIVM) was used as a conservative value. For adolescents the average bodyweight for 15 year old adolescents was used, which is a less conservative value. Adult female body weights vary: about 70 % are below the EFSA default value of 70 kg. (EFSA Scientific Committee, 2012)	body weight	5 kg (infants) 12 kg (toddlers) 30 kg (children 3-10 years) 44 kg (adolescents) 70 kg (adults)	- (infants) - (toddlers) - -/+ (children 3-10 years) -/+ (adolescents) -/+ (adults)
Overall assessment. Because of the very uncertain dust ingestion rates, the true value for the 95th percentile may be below the calculated values. However, since dust concentrations were shown to be higher e.g. for France both uncertainties may level out.			- - - / +

Table 61: Evaluation of variability and uncertainties affecting the assessment of high external exposure from air inhalation by infants, toddlers and adults. See Figure 14 for key to symbols

Source of variability or uncertainty (average scenario)	Parameter affected	Value used in assessment	Impact on average exposure estimate
The approximation of a 95th percentile was performed by combining two average parameter values (C_{air}, bodyweight) with the 95th percentile values for q_{air}. It is uncertain whether this approach leads to the true 95th percentile.	(all)		- /+
Concentrations of BPA in indoor air are only available for France in a limited study. It is not clear whether levels of BPA in indoor air will vary between countries in Europe. For this assessment it was assumed that people spend 100 % of their time indoors. Since outdoor levels of BPA seem to be slightly lower, this may result in a slight overestimation (not much, because on average people in industrialized countries spend 90 % of	C_{air}	1.0 ng/m^3	- / +++

Source of variability or uncertainty (average scenario)	Parameter affected	Value used in assessment	Impact on average exposure estimate
their time indoors). However, in one study for Greece levels in outdoor air were as high as 6 ng/m^3. People in Greece, however, may spend more time outdoors than people in Northern Europe. Taking into account the high levels in outdoor air in Greece (which were not used in the assessment), there may be an underestimation for Greece and other Southern countries.			
Method of analysis and sampling together can affect the measurement so that the variation may be +/- 100 %	C_{air}	1.0 ng/m^3	-/+
Inhalation rates vary with the activity profile. Therefore, the highest uncertainty is associated with the mix of activities during the day. Here, P95 values proposed by EPA, 2011 were used for the different consumer groups.	q_{air}	7.1 m^3/d (infants) 13.7 m^3/d (toddlers) 16.6 m^3/d (children 3-10 years) 24.6 m^3/d (adolescents) 21.4 m^3/d (adults)	-/+ (all age groups)
For infant body weight a value for 1-3 months old infants was used (EFSA Scientific Committee, 2012). For toddlers also a value on the conservative side was used. For children 3-10 years the average bodyweight for 9 years (RIVM) was used as a conservative value. For adolescents the average bodyweight for 15 year old adolescents was used, which is a less conservative value. Adult female body weights vary: about 70 % are below the EFSA default value of 70 kg. (EFSA Scientific Committee, 2012)	body weight	5 kg (infants) 12 kg (toddlers) 30 kg (children 3-10 years) 44 kg (adolescents) 70 kg (adults)	- (infants) - (toddlers) - -/+ (children 3-10 years) -/+ (adolescents) -/+ (adults)
Overall assessment. The activity profile will be very different for different subpopulations and different cultures. Also levels in indoor air are only available for one country in Europe and may be different in other countries.			- / ++ (all age groups)

5. Evaluation of uncertainties affecting the assessment of high total exposure based on biomonitoring data on total BPA concentration in urine

In this assessment, data for three- to five-year-old children were taken as a surrogate, as no biomonitoring data are available for one- to three-year-old toddlers. For women of childbearing age, data for mothers, pregnant and parturient women were used. The evaluations are approximate expert judgements and should not be interpreted as precise estimates.

Table 62: Evaluation of uncertainties affecting the assessment of high total exposure in women (W) of childbearing age, toddlers (T), and infants (I) based on biomonitoring data on total BPA concentration in urine. See Figure 14 for key to symbols

Source of uncertainty	Parameter affected	Value used in assessment	Impact on high exposure estimate
Analytical uncertainty for urinary BPA concentrations above LOD Recovery: Not a problem as all studies use isotope-dilution mass spectrometry with recovery correction Repeatability: Intra- and inter-day CV < 21 % Accuracy: < ±20 % (intra- and inter-day). Taken together, the overall analytical uncertainty is regarded as being within ± 20 %	BPA concentration in urine, C_{BPA} (µg/L)	Range of 95th percentiles: W: 5–12 µg/L T: 23 µg/L I: 2.2–3.4 µg/L	W: ● T: ● I: ●
Contamination of urine samples Most studies report only total BPA concentration in urine, but only a few studies also report the concentration of unconjugated BPA. It can, however, be expected that contamination of urine samples during collection and storage is generally under control. A small proportion of total BPA might be from contamination, which would then result in a slight overestimation, so it tends to be conservative	BPA concentration in urine, C_{BPA} (µg/L)	Range of 95th percentiles: W: 5–12 µg/L T: 23 µg/L I: 2.2–3.4 µg/L	W: ● T: ● I: ●
Sampling uncertainty Number of subjects per study is 60–164 (women), 30–137 (toddlers), and 46 (infants). The relatively low number of subjects in some studies may result in a sampling bias. Moreover, only a few European studies (GerES IV, INMA) can be assumed to be representative for a specific age class and geographical region. The database contains 10 studies for women from 10 different European countries (but only six have reported a 95th percentile), two European studies for "toddlers" (but only one has reported a 95th percentile), and one European study for infants. Biomonitoring studies may, therefore, not have captured high levels of exposure that may occur in specific geographic areas or specific population groups	BPA concentration in urine, C_{BPA} (µg/L)	Range of 95th percentiles: W: 5–12 µg/L T: 23 µg/L I: 2.2–3.4 µg/L	W: ●/+ T: ●/+ I: ●/++
Distribution uncertainty Most studies provide the 95th percentile (P95) of the distribution of the BPA concentration in individual urinary samples. The P95 is used to obtain estimates for high BPA exposures. Many studies report data for spot urine samples, for which the P95 relates to the 95 % probability that a single, randomly collected sample from a randomly selected subject has an urinary BPA concentration not exceeding the P95. This is important as urinary BPA concentrations of repeated urine collections from individuals may vary by up to two orders of magnitude. Some studies exist that indicate that the total variance can be broken down into 70 % within-day variability, 21 % between-day variability, and 9 % between-person variability. Thus, taking the P95 of the reported values will overestimate the P95 of long-term average values (true value will be lower)	BPA concentration in urine, C_{BPA} (µg/L)	Range of 95th percentiles: W: 5–12 µg/L T: 23 µg/L I: 2.2–3.4 µg/L	W: –/● T: –/● I: –/●

Source of uncertainty	Parameter affected	Value used in assessment	Impact on high exposure estimate
Uncertainty in specific urinary output rate The specific urinary output rate (mL/kg bw per day) is the urinary output rate (mL/day) divided by body weight (kg) For the *urinary output rate*, generic values were generally used to estimate the average urinary output rate per population subgroup. These generic values were derived by linear interpolation from urinary output vs. age relationships taken from the literature. Some studies, however, collected 24-hour urine samples and provided individual data for daily urinary output. The average of these experimental data can be compared with generic values to obtain a measure of possible bias. For example, the German ESB study (Koch et al., 2012) analysed historical 24-hour urine samples of 20- to 30-year-old male and female students and reported an increase in urinary output rate from 1 500 mL/day in 1995 to 2 000 mL/day in 2009. The generic value for adults (averaged over males and females) is 1 400 mL/day. In this particular case, the deviation of the average experimental values from the generic value is + 7 % and + 42 %. For *body weight*, too, generic values were generally used to estimate the average body weight per population subgroup. These generic values were derived by linear interpolation from body vs. age relationships taken from the literature. Some studies, however, measured the individual body weights. The average of these experimental data can be compared with generic values to obtain a measure of possible bias. The available data suggest the uncertainty to be within ± 20 %. Taking both parameters together, the range of values for the specific urinary output rate for women is 17–27 mL/kg bw per day. For studies for which the upper value was taken, the true value could be lower by a factor of 1.6. For studies for which the lower value was taken, the true value could be higher by a factor of 1.6.	Specific urinary output rate, spec. $\dot{V}_{\text{urine}}$ (mL/kg bw per day)	Range of values: W: 17–27 mL/kg bw per day T: 30 mL/kg bw per day I: 48 mL/kg bw per day	W: –/+ T: –/+ I: –/+
Uncertainty about time trends in exposure Urinary samples were collected in different time periods, i.e. in 2004–2012 (women), 2003–2006 ("toddlers") and 2008 (infants). There could be changes in exposure over the years in exposure. A retrospective study using historical samples of students from the German ESB study indicated a gradual decline in the 95th percentiles from 1995 to 2001/2003, which, however, did not continue from 2003 on and seemed to be reversed to some extent from 2003 on (Koch et al., 2012). The results of US NHANES suggests a slight decline in the 95th percentiles of 257 ng/kg bw per day to 183 ng/kg bw per day for adults over the period from 2003–2004 to 2009–2010	Daily BPA exposure, $\dot{m}_{\text{BPA}}$ (ng/kw bw per day)	Range of 95th percentiles: W: 85–234 ng/kg bw per day T: 676 ng/kg bw per day I: 161 ng/kg bw per day	W: ● T: ● I: ●

Source of uncertainty	Parameter affected	Value used in assessment	Impact on high exposure estimate
Uncertainty in extrapolating from children to toddlers There is no indication that the exposure of three- to five-year-old children, which was taken as a surrogate for the exposure of one- to three-year-old toddlers, is substantially different from that of toddlers. The first line of evidence from the biomonitoring study GerES IV is that three- to five-year-old children have a higher exposure than six- to eight-year-old children (Becker et al., 2009). Other biomonitoring studies on four-year-old children (INMA) and older children (Duisburg BCS, Liege HBM, DEMOCOPHES) provide additional support for this age dependency. The second line of evidence is that the modelling approach did not indicate substantial differences in the high total exposure between toddlers and the age class of 3- to 10-year-old children. This provides an indirect indication for similar exposures between the toddlers and the surrogate group of three- to five-year-old children, because this group can be expected to be in the upper tail of the modelled exposure distribution of the 3- to 10-year-old children	Daily BPA exposure, $\dot{m}_{BPA}$ (ng/kw bw per day)	Range of 95th percentiles: T: 676 ng/kg bw per day	T: ●
Overall assessment The main sources of uncertainty in the estimation of high total exposure based on biomonitoring data are the *sampling uncertainty* owing to limitations in the representativity of the available information on total BPA concentration in urine, the *distribution uncertainty* in the 95th percentile, and the *uncertainty in the specific urinary output rate*. The last uncertainty is two-sided. The distribution uncertainty in the 95th percentile is one-sided so that the true value for high total exposure is likely to be lower than the estimate. The sampling uncertainty is also one-sided but orientated in the opposite direction so that the true value for high total exposure is likely to be higher than the estimate. Overall, the two uncertainties in opposite directions may cancel out to some extent, but the outcome could be positive or negative depending on their true magnitudes. Hence, the overall assessment is that the true value could be either lower or higher than the estimate The estimates for high total exposure are 234 ng/kg bw per day for women (W) of childbearing age, 676 ng/kg bw per day for "toddlers" (T) and 161 ng/kg bw per day for infants (I) As a control check for the high total exposure estimate for women (which was derived from the highest 95th percentile of six studies), a parametric statistic was calculated from the $\log_{10}$-transformed individual P95 values and, based on that, the value $10^{(\text{average} + 1.64 \times \text{sigma})}$ was then used as a proxy for a hypothetical European country with the highest P95. This control check yielded a value of 296 µg/L, which is 26 % higher than the chosen value of 234 µg/L for women. No such control checking is possible for "toddlers" and infants. However, compared with the infant study (n = 46), the study for "toddlers" is a large-sized (n = 137) representative study (GerES IV), which results in different uncertainty ratings			W: –/+ T: –/+ I: –/++

Appendix I. Literature quality tables

Table 63: Literature quality table—occurrence in food

Title **Authors** **Journal. Year. Volume:Issue, Page number** **DOI**	**Country of origin of samples**	**Sample description**	**Method description and quality parameters**	**Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning**
Determination of bisphenol A in US infant formulas: updated methods and concentrations. Ackerman, L. K., Noonan, G. O., Heiserman, W. M., Roach, J. A, Limm, W. and Begley, T. H. Journal of Agricultural and Food Chemistry. 2010. 58:4, 2307-2313. 10.1021/jf903959u	United States of America	Not considered	Not considered	Excluded – samples from USA (i.e. did not meet geographical origin criteria)
Comparison of Single-walled Carbon Nanotubes, Multi-walled Carbon Nanotubes and C18 as Adsorbents for the Solid Phase Extraction of Bisphenol A and Bisphenol F in Canned Food. Ahmadkhaniha, R., Salimi, M. and Rastkari, N. Fullerenes, Nanotubes and Carbon Nanostructures. 2013. 21, 604-616. 10.1080/1536383x.2011.643430	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Analytical methods for the determination of bisphenol A in food. Ballesteros-Gomez, A. Rubio, S. and Perez-Bendito, D. Journal of Chromatography A. 2009. 1216:3, 449-460. 10.1016/j.chroma.2008.06.037	Not considered	Not considered	Not considered	Excluded - analytical method review paper - no relevant data reported for calculation of exposure from food
Migration of cyclo-diBA from coatings into canned food: Method of analysis, concentration determined in a survey	Not considered	Not considered	Not considered	Excluded – paper published after

[24] For inclusion/exlusion criteria see Appendix A.

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning
and in silico hazard profiling. Biedermann, S., Zurfluh, M., Grob, K., Vedani, A. and Brüschweiler, B. J. Food and Chemical Toxicology. 2013. 58, 107-115. 10.1016/j.fct.2013.04.004				December 2012 (i.e. did not meet publication period criteria)
Determination of bisphenol A in wine by sol-gel immunoaffinity chromatography, HPLC and fluorescence detection. Brenn-Struckhofova, Z. and Cichna-Markl, M. Food Additives and Contaminants. 2006. 23:11, 1227–1235. 10.1080/02652030600654382	Austria	46 white and 13 red wine samples of which 10 were taken directly from the wine vats, 21 had been filled into glass bottles and 28 were purchased from supermarkets (packaged in glass bottles (n=17) or tetra-brik (n=11))	Filtered samples were cleaned-up by sol-gel immunoaffinity chromatography, using polyclonal BPA rabbit antibodies. Analysis was carried out by HPLC-FLD. LOD (3x Signal:Noise ratio (S:N)) = 0.1 µg/L LOQ (6x S:N) = 0.2 µg/L Recovery = 74 - 81 % (average of three spiking levels: 0.4, 0.8 and 1.2 µg/L) Repeatability = not given Calibration = external standards 0.3 to 100 µg/L in mobile phase Measures taken to reduce contamination: No information on prevention of contamination or blanks.	Included NOTE: although no measures were described to reduce background contamination the paper described concentration data for wine which was not available elsewhere and so was included
Stir bar sorptive extraction coupled to gas chromatography-mass spectrometry for the determination of bisphenols in canned beverages and filling liquids of canned vegetables. Cacho, J. I., Campillo, N., Viñas, P. and Hernández-Córdoba, M.	Samples were purchased in Spain	Beverages and filling liquids of vegetables (canned) 10 canned beverages, and 10 filling	Following degassing and dilution with water the BPA was derivatised in situ with acetic anhydride, extracted using stir bar sorptive extraction, and analysed by thermal desorption GC-MS.	Included

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning
Journal of Chromatography A. 2012. 1247, 146-153. 10.1016/j.chroma.2012.05.064		liquids of vegetables	LOD = 2.5 ng/L in solution (3x st dev of the procedural blank) equates to 12.5 ng/L in sample (sample was diluted x5 with water prior to analysis) LOQ = 8.4 ng/L (10x st dev of the procedural blank) equates to 42 ng/L in sample (sample was diluted x5 with water prior to analysis) Recovery = 86-122 % at 0.1 µg/L and 97-105 % at 1 µg/L Repeatability = 1.9 % intraday and 3.1 % interday for water spiked with BPA at 0.5 µg/L. < 10 % in matrix (recovery study) Calibration = external standards 0.02 to 2.5 µg/L in water Measures taken to reduce contamination: Reported repeatable trace background levels of BPA of 10 ng/L - background concentration was subtracted from reported values.	
Levels of bisphenol A in canned liquid infant formula products in Canada and dietary intake estimates. Cao, X. L., Dufresne, G., Belisle, S., Clement, G., Falicki, M., Beraldin, F. and Rulibikiye, A. Journal of Agricultural and Food Chemistry. 2008. 56, 7919-7924. 10.1021/jf8008712	Canada	Not considered	Not considered	Excluded - samples from Canada (i.e. did not meet geographical origin criteria)
Migration of bisphenol A from can coatings to liquid infant formula during storage at room temperature. Cao, X. L., Corriveau, J., Popovic, S. Journal of Food Protection. 2009. 72:12, 2571-2574.	Canada	Not considered	Not considered	Excluded - samples from Canada (i.e. did not meet geographical origin criteria)

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning
DOI not given				
Levels of bisphenol A in canned soft drink products in Canadian markets. Cao, X. L., Corriveau, J., Popovic, S. Journal of Agricultural and Food Chemistry. 2009. 57, 1307-1311. 10.1021/jf803213g	Canada	Not considered	Not considered	Excluded - samples from Canada (i.e. did not meet geographical origin criteria)
Bisphenol A in baby food products in glass jars with metal lids from Canadian markets. Cao, X. L., Corriveau, J., Popovic, S., Clement, G., Beraldin, F. and Dufresne, G. Journal of Agricultural and Food Chemistry. 2009. 57:12, 5345-5351. 10.1021/jf9006888	Canada	Not considered	Not considered	Excluded - samples from Canada (i.e. did not meet geographical origin criteria)
Bisphenol A in canned food products from Canadian markets. Cao, X. L., Corriveau, J., Popovic, S. Journal of Food Protection. 2010. 73, 1085-1089. DOI not given	Canada	Not considered	Not considered	Excluded - samples from Canada (i.e. did not meet geographical origin criteria)
Sources of low concentrations of bisphenol A in canned beverage products. Cao, X. L., Corriveau, J., Popovic, S. Journal of Food Protection. 2010. 73, 1548-1551. DOI not given	Canada	Not considered	Not considered	Excluded - samples from Canada (i.e. did not meet geographical origin criteria)
Concentrations of bisphenol A in the composite food samples from the 2008 Canadian total diet study in	Canada	Not considered	Not considered	Excluded - samples from Canada (i.e. did not meet geographical origin

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning
Quebec City and dietary intake estimates. Cao, X. L., Perez-Locas, C., Dufresne, G., Clement, G., Popovic, S., Beraldin, F., Dabeka, R. W. and Feeley, M. Food Additives and Contaminants Part A. 2011. 28:6, 791-798. 10.1080/19440049.2010.513015				criteria)
The contribution of diet to total bisphenol A body burden in humans: Results of a 48 hour fasting study. Christensen, K. L., Lorber, M., Koslitz, S., Bruning, T. and Koch, H. M. Environment International. 2012. 50, 7-14. 10.1016/j.envint.2012.09.002	Not considered	Not considered	Not considered	Excluded - biomonitoring data only - no relevant data for calculation of exposure from food NOTE: paper considered in the scope of the biomonitoring assessment
Simultaneous determination of bisphenol A and bisphenol B in beverages and powdered infant formula by dispersive liquid–liquid micro-extraction and heartcutting multidimensional gas chromatography-mass spectrometry. Cunha, S. C., Almeida, C., Mendes, E. and Fernandes, J. O. Food Additives and Contaminants. 2011. 28:4, 513-526. 10.1080/19440049.2010.542551	Samples purchased in Portugal (randomly purchased in local supermarkets)	22 canned soft drinks, 8 canned beers, 7 canned infant formula (infant formula was reconstituted with water following on-pack instructions prior to analysis)	BPA was extracted from the samples using disperse liquid-liquid micro-extraction with simultaneous derivatisation with acetic anhydride. Analysis was carried out by two-dimensional GC-MS. LOD = 0.005 µg/L in canned beverages and 0.06 µg/L in reconstituted powdered infant formula (3x S:N) LOQ = 0.01 µg/L in canned beverages and 0.20 µg/L in reconstituted powdered infant formula (10x S:N) Recovery = 83 % for beverage spiked at	Included

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning
			0.05 µg/L, 93 % for beverage spiked at 0.2 µg/L; 114 % for powdered infant formula spiked at 0.05 µg/L, 93 % for powdered infant formula spiked at 0.2 µg/L (six replicates of each) Repeatability = 8 % for beverage spiked at 0.05 µg/L, 8 % for beverage spiked at 0.2 µg/L; 15 % for powdered infant formula spiked at 0.05 µg/L, 7 % for powdered infant formula spiked at 0.2 µg/L (six spiked replicates) Calibration = Matrix matched - 0.02-10 µg/L for beverages and 0.5-10 µg/L for infant formula Measures taken to reduce contamination: BPA free bottled beverages and milk samples used as method blanks to check for background contamination.	
Determination of bisphenol A and bisphenol B in canned seafood combining QuEChERS extraction with dispersive liquid-liquid microextraction followed by gas chromatography-mass spectrometry. Cunha, S. C., Cunha, C., Ferreira, A. R. and Fernandes, J. O. Analytical and Bioanalytical Chemistry. 2012. 404, 2453-2463. 10.1007/s00216-012-6389-5	Samples purchased in Portugal (randomly purchased in local supermarkets)	47 canned seafood samples (23 canned tunas, 10 canned sardines, 3 canned mackerels, 3 canned squid, 3 canned octopuses, 2 canned mussels, 1 canned eel, 1 canned	BPA was extracted from the fish samples using acetonitrile with QuEChERS and DLLME clean-up. The extracted BPA was derivatised using acetic anhydride and the derivative analysed by GC-MS. LOD = 0.2 µg/kg in the foodstuff (3x S:N) LOQ = 1 µg/kg in the foodstuff (corresponding to the lowest calibration standard) Recovery = 68-104 % for tuna, 71-104 % for sardines in sauce (spike levels = 1, 5 and 20 µg/kg) Repeatability = 8-21 % for tuna, 11-19 % for sardines in sauce (spike levels = 1, 5 and	Included

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning
		anchovy, 1 canned codfish)	20 µg/kg) Calibration = matrix matched standards in the range 1 to 150 µg/kg Measures taken to reduce contamination: Muffled glassware was used - no plasticware - to minimise contamination. Method blanks were prepared periodically to check for background contamination	
Assessment of bisphenol A and bisphenol B in canned vegetables and fruits by gas chromatography-mass spectrometry after QuEChERS and dispersive liquid-liquid microextraction. Cunha, S. C. and Fernandes, J. O. Food Control. 2013. 33, 549-555. 10.1016/j.foodcont.2013.03.028	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Endocrine disrupting chemicals in fish bile: A rapid method of analysis using English sole (Parophrys vetulus) from Puget Sound, WA, USA. da Silva, D. A. M., J. Buzitis, J., Reichert, W. L., West, J. E., O'Neill, S. M., Johnson, L. L., Collier, T. K. and Ylitalo, G. M. Chemosphere. 2013. 92, 1550-1556. 10.1016/j.chemosphere.2013.04.027	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Uptake and accumulation of four PPCP/EDCs in two leafy vegetables. Dodgen, L. K., Li, J., Parker, D. and Gan, J. J. Environmental Pollution. 2013. 182, 150-156. 10.1016/j.envpol.2013.06.038	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning
The investigation of bisphenol A presence in canned tuna fish using high-performance-liquid chromatography method. Er, B. and Sarimehmetoğlu, B. Journal of Animal and Veterinary Advances. 2011. 10, 2859-2862. DOI not given	Samples purchased in Turkey	160 canned tuna fish samples	Solvent extracted samples were cleaned-up by SPE. Analysis was carried out by HPLC-FLD LOD = 1.96 µg/L in solution LOQ = Not given Recovery = Not given Repeatability = Not given Calibration = Not specified Measures taken to reduce contamination: No information on prevention of contamination or blanks	Excluded - method performance criteria not defined and so method quality criteria could not be confirmed to have been met
Simultaneous determination of bisphenol A, octylphenol, and nonylphenol by pressurised liquid extraction and liquid chromatography–tandem mass spectrometry in powdered milk and infant formulas. Ferrer, E., Santoni, E., Vittori, S., Font, G., Manes, J. and Sagratini, G. Food Chemistry. 2011. 126, 360-367. 10.1016/j.foodchem.2010.10.098	Samples purchased in Spain and Italy (5 samples purchased from each)	2 samples of powdered skimmed milk and 8 powdered infant formula	BPA was extracted using pressurised liquid extraction with a C18 dispersant. Analysis was carried out by LC-MS/MS. LOD (3x S:N) = 5 µg/kg LOQ (10x S;N) = 16 µg/kg Recovery = 89-92 % for five replicates of infant formula and powdered skimmed milk spiked at 50 µg/kg and 500 µg/kg Repeatability = 12 to 14 % or five replicates of infant formula and powdered skimmed milk spiked at 50 µg/kg and 500 µg/kg Calibration = Matrix matched - concentration range 3 orders of LOQ Measures taken to reduce contamination: No measures against contamination reported	Excluded - the reported concentrations were described as comparable to others in the literature however the values given in this paper were several orders of magnitude greater than the supposedly comparable values

Title **Authors** **Journal. Year. Volume:Issue, Page number** **DOI**	**Country of origin of samples**	**Sample description**	**Method description and quality parameters**	**Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning**
Determination of bisphenol A in foods as 2,2-bis-(4-(isopropoxycarbonyloxy)phenyl)propane by gas chromatography/mass spectrometry. Feshin, D. B., Fimushkin, P. V., Brodskii, E. S., Shelepchikov, A. A., Mir-Kadyrova, E. Y. and Kalinkevich, G. A. Journal of Analytical Chemistry. 2012. 67:5, 460-466. DOI not given	Samples purchased in Russia	One sample of each of: an energetic beverage, infant meat puree, infant formula feed, canned meat and canned vegetables	Aqueous samples derivatised directly in the matrix with isopropyl chloroformate, other foods solvent extracts were derivatised following sample clean-up by SPE for fat containing samples. Analysis was carried out by GC-MS. LOD < 0.05 µg/kg for energetic beverage, < 0.1 µg/kg for infant meat puree, infant formula feed, canned meat and canned vegetables LOQ = not given Recovery = 103 % when 300 ng added - average of triplicate results, 104 % when 600 ng added (BPA spiked into apple juice mass of apple juice not given) Repeatability = 0.005 % given in paper - actually 3.8 % using data given (triplicate extracts of a meat puree sample at 1.33 µg/kg) Calibration = 5 to 1200 ng (in 20 mL water) Measures taken to reduce contamination: A method blank was prepared in each batch to check for contamination	Included
Field-amplified sample injection-micellar electrokinetic capillary chromatography for the analysis of bisphenol A, bisphenol F, and their diglycidyl ethers and derivatives in canned soft drinks. Gallart-Ayala, H., Nunez, O., Moyano, E. and Galceran, M. T.	Not considered	Not considered	Not considered	Excluded - analytical method paper - no relevant data reported for calculation of exposure from food

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning
Electrophoresis. 2010. 31:9, 1550-1559. 10.1002/elps.200900606				
Analysis of bisphenols in soft drinks by on-line solid phase extraction fast liquid chromatography-tandem mass spectrometry. Gallart-Ayala, H., Moyano, E. and Galceran, M. T. Analytica Chimica Acta. 2011. 683, 227-233. 10.1016/j.aca.2010.10.034	Samples purchased in Spain	Eleven beverages (cola, soda, beer, tea and energy drinks)	Beverage samples were analysed directly. BPA was concentrated using on-line SPE. Analysis was carried out by LC-MS. LOD = 0.025 µg/L in the cola, 0.015 µg/L in the lemon soda and 0.025 µg/L in the tonic water (3x S:N) LOQ = 0.085 µg/L in the cola, 0.050 µg/L in the lemon soda and 0.085 µg/L in the tonic water (10x S:N) Recovery = 98 % in the cola, 97 % in the lemon soda and 97 % in the tonic spiked at 0.5 µg/L, 98 % in the cola, 96 % in the lemon soda and 94 % in the tonic spiked at 0.2 µg/L (five replicates of each) Repeatability = 2.5 % in the cola, 4 % in the lemon soda and 3.5 % in the tonic spiked at 0.5 µg/L, 3 % in the cola, 5 % in the lemon soda and 5 % in the tonic spiked at 0.2 µg/L (five replicates of each) Calibration = 0.05 to 10 µg/L Measures taken to reduce contamination: Avoided the use of plastic-ware with on-line SPE. Water blank samples were injected between sample batches to control carry-over and background contamination.	Included
Decanoic acid reverse micelle-based coacervates for the microextraction of bisphenol A from canned vegetables	Samples purchased in	1 can of each of red peppers,	BPA was extracted from the foods using coacervative microextraction. Analysis was	Included

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning
and fruits. García-Prieto, L., Lunar, L., Rubio, S. and Pérez-Bendito, D. Analytica Chimica Acta. 2008. 617, 51-58. 10.1016/j.aca.2008.01.061	Spain	sweetcorn, green beans, peas, fruit salad, peaches in syrup - all from Spain and 1 can of mango slices from Thailand	carried out by LC-FLD LOD = 1.3 µg/kg peas (3x S:N) LOQ = 9.3 µg/kg (not stated how determined) Recovery = 86 % for six replicates of peas spiked at 200 µg/kg Repeatability = 2.8 % for six replicates of peas spiked at 200 µg/kg Calibration = 0.14 to 20 ng BPA in acetonitrile (not expressed as a concentration) Measures taken to reduce contamination: No measures against contamination reported	
Intake of bisphenol A from canned beverages and foods on the Belgian market. Geens, T., Zipora Apelbaum, T., Goeyens, L., Neels, H. and Covaci, A. Food Additives and Contaminants. 2010. 27:11, 1627-1637. 10.1080/19440049.2010.508183	Samples purchased in Belgium	50 beverages (45 canned, 4 in PET and 1 in Tetra Pak) and 44 foods including fruits, vegetables, soups, fish and meat (27 canned, 1 in paper, 2 in Tetra Pak, 10 in glass and 4 in plastic containers)	After degassing BPA was extracted from the beverage sample using SPE. BPA was extracted from solid content of canned foods using solvent. The liquid content of canned food was filtered. Analysis was carried out by GC-MS after derivatisation with pentafluorobenzoylchloride. LOD = not given LOQ = 0.02 µg/kg for beverages, 0.10 µg/kg for food (calculated from 3x st dev of the procedural blanks) Recovery = 95 % for beverages spiked at 4.4 µg/L, 93 % for foods spiked at 10.5 µg/kg Repeatability = within day = 0.8 - 5.5 % for beverages spiked at 4.4 µg/L and 2.8 % for foods spiked at 10.5 µg/kg; between day =	Included

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning
			3.0 % for beverages spiked at 4.4 µg/L and 2.8 % for foods spiked at 10.5 µg/kg Calibration = not given Measures taken to reduce contamination: Method blank prepared to determine any contamination through the procedure	
A review of dietary and non-dietary exposure to bisphenol-A. Geens, T., Aerts, D., Berthot, C., Bourguignon, J. P., Goeyens, L., Lecomte, P., Maghuin-Rogister, G., Pironnet, A. M., Pussemier, L., Scippo, M. L., Van Loco, J. and Covaci, A. Food and Chemical Toxicology. 2012. 50, 3725-3740. 10.1016/j.fct.2012.07.059	Not considered	Not considered	Not considered	Excluded - review paper - no relevant data for calculation of exposure from food
Determination of bisphenol A and bisphenol B residues in canned peeled tomatoes by reversed-phase liquid chromatography. Grumetto, L., Montesano, D., Seccia, S., Albrizio, S. and Barbato, F. Journal of Agricultural and Food Chemistry. 2008. 56, 10633-10637. 10.1021/jf802297z	Samples purchased in Italy	42 canned tomato samples (38 from Italy, 4 from China). 26 samples had packaging coated with epoxyphenolic lacquer and 16 with low BADGE enamel	BPA was extracted from the samples with solvent, concentrated and the solvent extracts passed down the SPE cartridges. Analysis was carried out by LC-UV and LC-FLD (fractions were collected and infused into an MS source for confirmation) LOD = 1.1 µg/kg (calculated as 3x st dev of the noise) LOQ = 3.7 µg/kg (calculated as 10x st dev of the noise) Recovery = 94.3 % BPA spiked at 100, 200, 300 and 500 µg/kg into blank tomatoes Repeatability = 2.63 % BPA spiked at 100, 200, 300 and 500 µg/kg into blank tomatoes	Included

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning
			Calibration = External calibration 50 to 1000 µg/L Measures taken to reduce contamination: Control (previously verified as BPA free) tomato samples used as method blank matrices to determine any contamination through the procedure. No plastic ware was used in the laboratory	
Determination of five bisphenols in commercial milk samples by liquid chromatography coupled to fluorescence detection. Grumetto, L., Gennari, O., Montesano, D., Ferracane, R., Ritieni, A., Albrizio, S. and Barbato, F. Journal of Food Protection. 2013. 76:9, 1590-1596. 10.4315/0362-028X.JFP-13-054	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
4-Nonylphenol and bisphenol A in Swedish food and exposure in Swedish nursing women. Gyllenhammar, I., Glynn, A., Darnerud, P. O., Lignell, S., van Delft, R. and Aune, M. Environment International. 2012. 43, 21-29. 10.1016/j.envint.2012.02.010	Samples were purchased in Sweden	Samples tested were composites of food groups	Not considered	Excluded – the samples were market basket with wide pooled samples. Some of the pooled samples also had canned and non-canned food together (i.e. did not meet the sample type criteria)
Determination of bisphenol A in Iranian packaged milk by solid-phase extraction and HPLC. Hadjmohammadi, M. R. and Saeidi, I. Monatshefte für Chemie. 2010. 141:5, 501-506. 10.1007/s00706-010-0297-1	Iran	Not considered	Not considered	Excluded - samples from Iran (i.e. did not meet geographical origin criteria)

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning
Development of a liquid chromatography-tandem mass spectrometry procedure for determination of endocrine disrupting compounds in fish from Mediterranean rivers. Jakimska, A., Huerta, B., Barganska, Z., Kot-Wasik, A., Rodriguez-Mozaz, S. and Barcelo, D. Journal of Chromatography A. 2013. 1306, 44-58. 10.1016/j.chroma.2013.07.050	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Human exposure to bisphenol A. Kang, J. H., Kondo, F. and Katayama, Y. Toxicology. 2006. 226:2-3, 79-89. 10.1016/j.tox.2006.06.009	Not considered	Not considered	Not considered	Excluded - review paper from Japan - no relevant data for calculation of exposure from food
Optimized extraction method for LC–MS determination of bisphenol A, melamine and di(2-ethylhexyl) phthalate in selected soft drinks, syringes, and milk powder. Khedr, A. Journal of Chromatography B. 2013. 930, 98-103. 10.1016/j.jchromb.2013.04.040	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Determination of bisphenol-A, 2,4-dichlorophenol, bisphenol-AF and tetrabromobisphenol-A in liquid foods and their packaging materials by vortex-assisted supramolecular solvent microextraction/high-performance liquid chromatography. Li, Y., Jiao, Y., Guo, Y. and Yang, Y. Analytical Methods. 2013. 5:19, 5037-5043. 10.1039/c3ay40586a	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Determination of Bisphenol A and Alkylphenols in Soft Drinks by High-Performance Liquid Chromatography	Not considered	Not considered	Not considered	Excluded – paper published after

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning
with Fluorescence Detection. Li, Y., Zhang, S., Song, C. and You, J. Food Analytical Methods. 2013. 6:5,: 1284-1290. 10.1007/s12161-012-9541-0				December 2012 (i.e. did not meet publication period criteria)
Concentrations and profiles of bisphenol A and other bisphenol analogues in foodstuffs from the United States and their implications for human exposure. Liao, C. and Kannan, K. Journal of Agricultural and Food Chemistry. 2013. 61:19, 4655-4662. 10.1021/jf400445n	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Risk assessment of bisphenol A migrated from canned foods in Korea. Lim, D. S., Kwack, S. J., Kim, K. B., Kim, H. S. and Lee, B. M. Journal of Toxicology and Environmental Health. Part A. 2009. 72:21-22, 1327-1335. 10.1080/15287390903212444	Korea	Not considered	Not considered	Excluded - samples from Korea (i.e. did not meet geographical origin criteria)
On-line precolumn enrichment of bisphenol A using boronate column in microcolumn liquid chromatography. Lim, L. W. and Takeuchi, T. Journal of Chromatography A. 2006. 1106:1-2, 139-145. 10.1016/j.chroma.2005.09.003	Not considered	Not considered	Not considered	Excluded - analytical method paper - no relevant data for calculation of exposure from food
Elimination of matrix effects in the determination of bisphenol A in milk by solid-phase microextraction-high-performance liquid chromatography. Liu, X., Ji, Y., Zhang, H. and Liu, M.	China	Not considered	Not considered	Excluded - samples from China (i.e. did not meet geographical origin criteria)

Title **Authors** **Journal. Year. Volume:Issue, Page number** **DOI**	**Country of origin of samples**	**Sample description**	**Method description and quality parameters**	**Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning**
Food Additives and Contaminants. 2008. 25:6, 772-778. 10.1080/02652030701713921				
Development and comparison of two dispersive liquid–liquid microextraction techniques coupled to high performance liquid chromatography for the rapid analysis of bisphenol A in edible oils. Liu, S., Xie, Q., Chen, J., Sun, J., He, H. and Zhang, X. Journal of Chromatography A. 2013. 1295, 16-23. 10.1016/j.chroma.2013.04.054	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Isotope dilution-gas chromatography/mass spectrometry method for the analysis of alkylphenols, bisphenol A, and estrogens in food crops. Lu, J., Wu, J., Stoffella, P. J. and Wilson, P. C. Journal of Chromatography A. 2012. 1258, 128-135. 10.1016/j.chroma.2012.08.033	United States of America	Not considered	Not considered	Excluded - samples from USA (i.e. did not meet geographical origin criteria)
Determination of bisphenol A in milk by solid phase extraction and liquid chromatography–mass spectrometry, Maragou, N.C., Lampi, E. N., Thomaidis, N. S. and Koupparis, M. A. Journal of Chromatography A. 2006. 1129, 165-173. 10.1016/j.chroma.2006.06.103	Samples purchased in Greece	8 canned condensed milk and 1 canned powdered infant formula sample	BPA was extracted from the milk samples using solid phase extraction. Analysis was carried out by LC-ESI-MS LOD = 1.7 µg/kg milk (3.3×SDn=10)/b) where SD is the st dev of the response of 10 replicate milk samples spiked at 5 µg/kg, b is the slope of the calibration line from 5 to 200 µg/L LOQ = 5.1 µg/kg milk ((10×SDn=10)/b) Recovery = 83 % for milk spiked at 5 µg/kg, 101 % for milk spiked at 50 µg/kg and 106 % for milk spiked at 500 µg/kg (intra-day, n=6); 97 % for milk spiked at 5 µg/kg, 97 % for milk	Included

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning
			spiked at 50 µg/kg and 104 % for milk spiked at 500 µg/kg (inter-day, n=6) Repeatability = 12.5 % for milk spiked at 5 µg/kg, 5.0 % for milk spiked at 50 µg/kg and 2.1 % for milk spiked at 500 µg/kg (intra-day, n=6); 17.6 % for milk spiked at 5 µg/kg, 5.8 % for milk spiked at 50 µg/kg and 5.2 % for milk spiked at 500 µg/kg (inter-day, n=6) Calibration = External calibration 5 to 700 µg/L Measures taken to reduce contamination: Water and milk blanks were analysed in each batch to check for contamination	
Dietary exposure assessment of pregnant women to bisphenol-A from cans and microwave containers in Southern Spain. Mariscal-Arcas, M., Rivas, A., Granada, A., Monteagudo, C., Murcia, M. A. and Olea-Serrano, F. Food and Chemical Toxicology. 2009. 47, 506-510. 10.1016/j.fct.2008.12.011	Not considered	Not considered	Not considered	Excluded - no relevant data for calculation of exposure from food
Selective Molecularly Imprinted Polymer Obtained from a Combinatorial Library for the Extraction of Bisphenol A. Martin-Esteban, A. and Tadeo, J. L. Combinatorial Chemistry and High Throughput Screening. 2006. 9, 747-751. DOI not given	Not considered	Not considered	Not considered	Excluded - analytical method paper - no relevant data for calculation of exposure from food
Bisphenol A content in fish caught in two different sites of the Tyrrhenian Sea (Italy). Mita, L., Bianco, M., Viggiano, E., Zollo, F., Bencivenga,	Samples obtained from two coastal regions of	Dorsal muscular tissue and liver samples	Solvent extracted samples were cleaned-up by SPE. Analysis was carried out by HPLC-UV or FLD and in some cases were validated by GC-	Excluded - method performance criteria not defined and so method quality criteria could not

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning
U., Sica, V., Monaco, G., Portaccio, M., Diano, N., Colonna, A., Lepore, M., Canciglia, P. and Mita, D. G. Chemosphere. 2011. 82, 405-410. 10.1016/j.chemosphere.2010.09.071	Italy	of mullet, salpa, white bream, bass and ombrine	MS LOD = not given LOQ = not given Recovery = not given Repeatability = not given Calibration = not given Measures taken to reduce contamination: Samples stored in glass containers but no other measures described to reduce background contamination	be confirmed to have been met
Analysis of bisphenol A in milk by using a multicommuted fluorimetric sensor. Molina-García, L., Fernández-de Córdova, M. L. and Ruiz-Medina, A. Talanta. 2012. 96, 195-201. 10.1016/j.talanta.2012.02.021	Samples purchased in Spain	3 x Powdered milk, 2 x powdered infant formula, 3 x liquid infant formula and 6 x liquid milk	Following precipitation of the protein the BPA was extracted from the sample using SPE. Analysis was carried out using a multicommuted fluorimetric sensor LOD = 0.06 µg/L (paper doesn't describe how it was determined) LOQ = 0.2 µg/L (0.19 µg/kg) (not described how determined) Recovery = 93-106 % for four samples spiked at 0.5, 2.0 and 5.0 µg/L Repeatability = Intra-day = 3.4 % at 4 µg/L. Inter-day = 5.7 % at 4 µg/L Calibration = 0.2 to 5.0 µg/L Measures taken to reduce contamination: No measures against contamination reported	Included
Development of monoclonal antibody-based	Not	Not	Not considered	Excluded - analytical

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning
immunoassays for the analysis of bisphenol A in canned vegetables. Moreno, M. J., D'Arienzo, P., Manclus, J. J. and Montoya, A. Journal of Environmental Science and Health B. 2011. 46:6, 509-517. 10.1080/03601234.2011.583871	considered	considered		method paper - no relevant data for calculation of exposure from food
Assessing the quantitative relationships between preschool children's exposures to bisphenol A by route and urinary biomonitoring. Morgan, M. K., Jones, P. A., Calafat, A. M., Ye, X., Croghan, C. W., Chuang, J. C., Wilson, N. K., Clifton, M. S., Figueroa, Z. and Sheldon, L. S. Environmental Science and Technology. 2011. 45:12, 5309-5316. 10.1021/es200537u	Not considered	Not considered	Not considered	Excluded - biomonitoring data only - no relevant data for calculation of exposure from food NOTE: paper considered in the scope of the biomonitoring assessment
Occurrence of endocrine disruption chemicals (Bisphenol A, 4-nonylphenol, and Octylphenol) in muscle and liver of, Cyprinus Carpino Common, from Anzali wetland, Iran. Mortazavi, S., Bakhtiari, A. R., Sari, A. E., Bahramifar, N. and Rahbarizadeh, F. Bulletin of Environmental Contamination and Toxicology. 2013. 90:5, 578-584. 10.1007/s00128-013-0964-0	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Development of a multiresidue method for the determination of endocrine disrupters in fish fillet using gas chromatography–triple quadrupole tandem mass	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning
spectrometry. Munaretto, J. S., Ferronato, G., Ribeiro, L, C., Martins, M. L., Adaime, M. B. and Zanella, R. Talanta. 2013. 116, 827-834. 10.1016/j.talanta.2013.07.047				not meet publication period criteria)
Simultaneous determination of bisphenol A and alkylphenol in plant oil by gel permeation chromatography and isotopic dilution liquid chromatography-tandem mass spectrometry. Niu, Y., Zhang, J., Wu, Y. and Shao, B. Journal of Chromatography A. 2011. 1218:31, 5248-5253. 10.1016/j.chroma.2011.06.005	Not considered	Not considered	Not considered	Excluded - analytical method paper - no relevant data for calculation of exposure from food
Analysis of bisphenol A and alkylphenols in cereals by automated on-line solid-phase extraction and liquid chromatography tandem mass spectrometry Niu, Y., Zhang, J., Wu, Y. and Shao, B. Journal of Agricultural and Food Chemistry. 2012. 60:24, 6116-6122. 10.1021/jf301401k	China	Not considered	Not considered	Excluded - samples from China (i.e. did not meet geographical origin criteria)
Concentration of bisphenol A in highly consumed canned foods on the US market. Noonan, G. O., Ackerman, L. K. and Begley, T. H. Journal of Agricultural and Food Chemistry. 2011. 59:13, 7178-7185. 10.1021/jf201076f	United States of America	Not considered	Not considered	Excluded - samples from USA (i.e. did not meet geographical origin criteria)
Design and implementation of an imprinted material for the extraction of the endocrine disruptor bisphenol A from	Not considered	Not considered	Not considered	Excluded – paper published after

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning
milk. O'Mahony, J., Moloney, M., McCormack, M., Nicholls, I. A., Mizaikoff, B. and Danaher, M. Journal of Chromatography B. 2013. 931, 164-169. 10.1016/j.jchromb.2013.05.025				December 2012 (i.e. did not meet publication period criteria)
Assessment of PCDD/F, PCB, OCP and BPA dietary exposure of non-breast-fed European infants. Pandelova, M., Piccinelli, R., Levy Lopez, W., Henkelmann, B., Molina-Molina, J. M., Arrebola, J. P., Olea, N., Leclercq, C. and Schramm, K.-W. Food Additives and Contaminants: Part A. 2011. 28:8, 1110-1122. 10.1080/19440049.2011.583281	Samples purchased in seven EU countries (Germany, UK, France, Sweden, Italy, Portugal, Slovak Republic)	6 pooled samples of infant formula and 5 pooled samples of baby food representing the diet of babies aged 5 to 9 months of age (including jarred foods)	BPA was extracted from the infant formula samples using acetonitrile. BPA was extracted from the freeze-dried solid food samples using hexane and acetonitrile. Following solid phase extraction the extracts were evaporated to dryness and derivatised using BSTFA. Analysis was carried out by GC-MS. Chlorinated BPA determined as well as BPA LOD = 0.8 to 1.7 µg/kg for BPA and it's chlorinated derivatives in the infant formula and 1.5 to 3.3 µg/kg for BPA and it's chlorinated derivatives in the solid foods and beverages (the paper doesn't describe how these were determined) LOQ = 2.6 to 5.8 µg/kg for BPA and it's chlorinated derivatives in the infant formula and 4.9 to 10.9 µg/kg for BPA and it's chlorinated derivatives in the solid foods and beverages (the paper doesn't describe how these were determined) Recovery = average recoveries were: 99.0 % (BPA), 101.2 % (ClBPA), 92.9 %, (Cl2BPA), 93.3 % (Cl3BPA) and 93.5 % (Cl4BPA) Repeatability = not given	Excluded - method performance criteria not well defined and so method quality criteria could not be confirmed to have been met

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning
			Calibration = not given Measures taken to reduce contamination: No measures against contamination reported	
Determination of bisphenol A in canned fatty foods by coacervative microextraction, liquid chromatography and fluorimetry. Pérez Bendito, M. D., Rubio Bravo, S., Lunar Reyes, M. L. and García Prieto, A. Food Additives and Contaminants: Part A. 2009. 26:2, 265-274. 10.1080/02652030802368740	Samples purchased in Spain	1 can of each of tuna in oil, mackerel in vegetable oil, sardines in olive oil, mussels in pickled sauce, meatballs and luncheon meat	BPA was extracted from the solid portion of the foods (the liquid portion was discarded) using coacervative microextraction. Analysis was carried out by LC-FLD LOD = 9 µg/kg (3x S:N) LOQ = depends on sample mass taken for 200 mg sample method quantification limit is 29 µg/kg for tuna in oil; for 400 mg sample method quantification limit is 14 µg/kg for tuna in oil Recovery = 90-99 % for overspiked food samples spiked with 50 ng BPA with a mass of food of either 200 mg or 400 mg Repeatability = 6 % for tuna spiked with BPA at concentrations between 0.05 and 1.5 µg/kg Calibration = 0.2 to 60 ng BPA in acetonitrile (not expressed as a concentration) Measures taken to reduce contamination: No measures against contamination reported	Included
Determination of bisphenol A in canned fish by sol–gel immunoaffinity chromatography, HPLC and fluorescence detection. Podlipna, D. and Cichna-Markl, M. European Food Research and Technology. 2007. 224, 629-634.	Samples purchased in Austria	7 tuna in brine, 5 tuna in oil, 5 sardines in oil, 1 mackerel in brine and 1	Solvent extracted samples were cleaned-up by sol-gel immunoaffinity chromatography, using polyclonal BPA rabbit antibodies. Analysis was carried out by HPLC-FLD LOD = 0.4 µg/L in solution, 0.4 µg/kg in tuna,	Excluded. NOTE: The highest BPA concentration value was obtained by analysing a sample after its best before date

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning
10.1007/s00217-006-0350-9		mackerel in oil	0.2 µg/kg in sardines, 0.2 µg/kg in mackerel, 0.9 µg/L in brine, 1.8 µg/L in oil (all 3x S:N) LOQ = 0.74 µg/L in solution, 0.8 µg/kg in tuna, 0.4 µg/kg in sardines, 0.4 µg/kg in mackerel, 1.9 µ/L in brine, 3.8 µg/L in oil (all 6x S:N) Recovery = 45 % in tuna, 97 % in sardines, 83 % in mackerel, 61 % in brine, 31 % in oil Repeatability = Standard deviation of the recovery was 5 % in tuna, 12 % in sardines, 26 % in mackerel, 12 % in brine, 9 % in oil Calibration = External calibration 0.5 to 100 µg/L Measures taken to reduce contamination: No measures against contamination reported	
Determination and occurrence of bisphenol A, bisphenol A diglycidyl ether, and bisphenol F diglycidyl ether, including their derivatives, in canned foodstuffs' from the Czech retail market. Poustka, J., Dunovská, L., Hajšlová, J., Holadová, K. and Poustková, I. Czech Journal of Food Sciences. 2007. 25:4, 221-229. Not given	Samples purchased in Czech Republic	1 can of each of sardines in oil, mackerel in oil, tuna fish, cod liver, luncheon meat and pate (pork)	Solvent extracted samples were cleaned-up by gel permeation chromatography. Analysis was carried out by HPLC-FLD LOD = 3 µg/kg luncheon meat LOQ = 10 µg/kg luncheon meat Recovery = 83 % in pork luncheon meat spiked at 100 µg/kg Repeatability = Coefficient of variation = 3.0 % for pork luncheon meat spiked at 100 µg/kg Calibration = External calibration 2 to 100 µg/L Measures taken to reduce contamination: No measures against contamination reported	Included
Levels Of bisphenol A and bisphenol F In canned foods in	Iran	Not	Not considered	Excluded - samples from

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning
Iranian markets. Rastkari, N., Yunesian, M. and Ahmadkhaniha, R. Iranian Journal of Environmental Health Science and Engineering. 2011. 8, 95-100. DOI not given		considered		Iran (i.e. did not meet geographical origin criteria)
Properties, threats, and methods of analysis of bisphenol a and its derivatives. Rykowska I. and Wasiak W. Acta Chromatographica. 2006. 16, 7-27. DOI not given	Not considered	Not considered	Not considered	Excluded - analytical method paper - no relevant data for calculation of exposure from food
Bisphenol A (BPA) and its source in foods in Japanese markets. Sajiki, J., Miyamoto, F., Fukata, H., Mori, C., Yonekubo, J. and Hayakawa, K. Food Additives and Contaminants. 2007. 24:1, 103-112. 10.1080/02652030600936383	Japan	Not considered	Not considered	Excluded - samples from Japan (i.e. did not meet geographical origin criteria)
Fast and selective pressurized liquid extraction with simultaneous in cell clean up for the analysis of alkylphenols and bisphenol A in bivalve molluscs Salgueiro-Gonzalez, N., Turnes-Carou, I., Muniategui-Lorenzo, S., Lopez-Mahia, P. and Prada-Rodriguez, D. Journal of Chromatography A. 2012. 1270, 80-87. 10.1016/j.chroma.2012.11.014	Samples obtained from Spain	6 samples of molluscs	BPA was extracted using selective pressurised liquid extraction with a simultaneous in cell clean up with analysis by LC-MS/MS LOD = 0.9 µg/kg in the foodstuff (average of procedural blanks + 3 x st dev of 10 procedural blanks) LOQ = 3.3 µg/kg in the foodstuff (average of procedural blanks + 10 x st dev of 10 procedural blanks) Recovery = 93-99 % (BPA spike levels into the mussels = 5, 50 and 500 µg/kg, seven replicates	Included

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning
			at each level) Repeatability = 3-8 % (BPA spike levels into the mussels = 5, 50 and 500 µg/kg, seven replicates at each level) Calibration = Quantification was achieved by standard addition. Linearity was demonstrated between 0.001 and 10,000 µg/kg Measures taken to reduce contamination: Filters and sorbents were rinsed with solvent prior to use. Procedural blanks were included to ensure background levels were low.	
Simultaneous determination of organochlorine pesticides and bisphenol A in edible marine biota by GC-MS. Santhi, V. A., Hairin, T. and Mustafa, A. M. Chemosphere. 2012. 86:10, 1066-1071. 10.1016/j.chemosphere.2011.11.063	Malaysia	Not considered	Not considered	Excluded - samples from Malaysia (i.e. did not meet geographical origin criteria)
Analysis of alkylphenol and bisphenol A in meat by accelerated solvent extraction and liquid chromatography with tandem mass spectrometry. Shao, B., Han, H., Li, D., Ma, Y., Tu, X. and Wu, Y. Food Chemistry. 2007. 105:3, 1236-1241. 10.1016/j.foodchem.2007.02.040	China	Not considered	Not considered	Excluded - samples from China (i.e. did not meet geographical origin criteria)
Analysis of alkylphenol and bisphenol A in eggs and milk by matrix solid phase dispersion extraction and liquid chromatography with tandem mass spectrometry. Shao, B., Han, H., Tu, X. and Huang, L. Journal of Chromatography B. 2007. 850:1-2, 412-416. 10.1016/j.jchromb.2006.12.033	China	Not considered	Not considered	Excluded - samples from China (i.e. did not meet geographical origin criteria)

Title **Authors** **Journal. Year. Volume:Issue, Page number** **DOI**	**Country of origin of samples**	**Sample description**	**Method description and quality parameters**	**Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning**
Single laboratory validation of a method for the determination of bisphenol A, bisphenol A diglycidyl ether and its derivatives in canned foods by reversed-phase liquid chromatography. Sun, C., Leong, L. P., Barlow, P. J., Chan, S. H. and Bloodworth, B. C. Journal of Chromatography A. 2006. 1129:1, 145-148. 10.1016/j.chroma.2006.08.018	Not considered	Not considered	Not considered	Excluded - review paper from Japan - no relevant data for calculation of exposure from food
Determinatıon of bisphenol a migrating from canned food and beverages in markets. Sungur, Ş., Köroğlu, M. and Özkan, A. Food Chemistry. 2014. 142, 87-91. 10.1016/j.foodchem.2013.07.034	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Determination of bisphenol A in water and milk by micellar liquid chromatography. Szymański, A., Rykowska, I, and Wasiak, W. Acta Chromatographica. 2006. 17, 161-172. DOI not given	Samples obtained from Poland	Powdered milk and mineral water in PC bottles	BPA was extracted from the water and reconstituted powdered milk samples using solid phase extraction. Analysis was carried out by micellar LC-UV LOD = 0.3 µg/L (3x S:N) LOQ = 1.0 µg/L (10x S:N) Recovery = 92.3 % for BPA spiked into water at 1 µg/L (after the SPE step?) six replicates. No recovery data for the matrix. Repeatability = 3.97 % for BPA spiked into water at 1 µg/L (after the SPE step?) six replicates. No repeatability data for the matrix. Calibration = External calibration 0.5 to 100 µg/L	Excluded - method performance criteria not well defined and so method quality criteria could not be confirmed to have been met

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning
			Measures taken to reduce contamination: No measures against contamination reported	
Human exposure to bisphenol A (BPA). Vandenberg, L. N., Hauser, R., Marcus, M., Olea, N. and Welshons, W. V. Reproductive Toxicology.2007. 24:2, 139-177. 10.1016/j.reprotox.2007.07.010	Not considered	Not considered	Not considered	Excluded - review paper - no relevant data for calculation of exposure from food
Comparison of two derivatization-based methods for solid-phase microextraction-gas chromatography-mass spectrometric determination of bisphenol A, bisphenol S and biphenol migrated from food cans. Viñas, P., Campillo, N., Martinez-Castillo, N. and Hernandez-Cordoba, M. Analytical and Bioanalytical Chemistry. 2010. 397:1, 115-125. 10.1007/s00216-010-3464-7	Samples obtained from Spain	9 canned food samples (peas, peas with carrots, sweet corn, artichoke, mushroom, bean shoot and mixed vegetables). Both the supernatant liquid contained in the can and the solid food were analysed (separately)	BPA was extracted from the supernatant and food samples following dilution/slurrying with water using solid phase microextraction. Derivatisation with acetic anhydride and BSTFA were compared. Analysis was carried out by GC-MS LOD = 0.016 µg/L (derivatisation using acetic anhydride), 0.025 µg/L (derivatisation using BSTFA) - 3 x S:N of solvent standards (no data presented for the matrix) LOQ = 0.055 µg/L (derivatisation using acetic anhydride), 0.083 µg/L (derivatisation using BSTFA) - 10 x S:N of solvent standards (no data presented for the matrix) Recovery = 84-112 % for BPA spiked into supernatant at 0.5 and 5 µg/L six replicates Repeatability = 5.12 % (derivatisation using BSTFA) and 5.43 % (derivatisation using acetic anhydride) - for solvent standards (no data presented for the matrix) Calibration = External calibration - working	Excluded - method performance criteria not well defined and so method quality criteria could not be confirmed to have been met

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning
			range described as 0.05 to 10 µg/L (derivatisation with acetic anhydride) and 0.1 to 10 µg/L (derivatisation with BSTFA) - reported concentrations were outside this range Measures taken to reduce contamination: No measures against contamination reported	
Bisphenol A: how the most relevant exposure sources contribute to total consumer exposure. von Goetz, N., Wormuth, M., Scheringer, M. and Hungerbuhler, K. Risk Analysis. 2010. 30:3, 473-487. 10.1111/j.1539-6924.2009.01345.x	Not considered	Not considered	Not considered	Excluded - exposure paper - no relevant data for calculation of exposure from food
Enhanced screening efficiency for endocrine-disrupting chemicals in milk and powdered milk using UPLC/QTOF-MS by the introduction of dansyl chloride derivatisation. Wang, H. X., Zhou, Y. and Jiang, Q. W. Food Addit Contam 30(1): 166-180. 10.1080/19440049.2012.720036	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Urinary bisphenol a concentration and thyroid function in Chinese adults. Wang, T., Lu, J., Xu, M., Xu, Y., Li, M., Liu, Y., Tian, X., Chen, Y., Dai, M., Wang, W., Lai, S., Bi, Y. and Ning, G. Epidemiology. 2013. 24:2, 295-302. 10.1097/EDE.0b013e318280e02f	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Assessment of risk to humans of bisphenol A in marine and freshwater fish from Pearl River Delta, China. Wei, X., Huang, Y., Wong, M. H., Giesy, J. P. and Wong,	China	Not considered	Not considered	Excluded - samples from China (i.e. did not meet geographical origin criteria)

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning
C. K. Chemosphere. 2011. 85:1, 122-128. 10.1016/j.chemosphere.2011.05.038				
Molecularly Imprinted Nanosilica Solid-Phase Extraction for Bisphenol A in Fish Samples. Wei, F., Liu, X., Zhai, M., Cai, Z., Xu, G., Yang, J., Du, S. and Hu, Q. Food Analytical Methods. 2013. 6:2, 415-420. 10.1007/s12161-012-9455-x	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
An observational study of the potential exposures of preschool children to pentachlorophenol, bisphenol-A, and nonylphenol at home and daycare. Wilson, N. K., Chuang, J. C., Morgan, M. K., Lordo, R. A. and Sheldon, L. S. Environmental Research. 2007. 103:1, 9-20. 10.1016/j.envres.2006.04.006	Not considered	Not considered	Not considered	Excluded - no relevant data for calculation of exposure from food
Endocrine disrupting chemicals: human exposure and health risks. Yang, M., Park, M. S. and Lee, H. S. Journal of Environmental Science and Health. Part C. 2006. 24:2, 183-224. 10.1080/10590500600936474	Not considered	Not considered	Not considered	Excluded - review paper - no relevant data for calculation of exposure from food
Single-step extraction and cleanup of bisphenol A in soft drinks by hemimicellar magnetic SPE prior to liquid chromatography/tandem mass spectrometry. Yazdinezhad, S. R., Ballesteros-Gómez, A., Lunar, L. and Rubio, S.	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning
Analytica Chimica Acta. 2013. 778, 31-37. 10.1016/j.aca.2013.03.025				
Simultaneous determination of steroidal and phenolic endocrine disrupting chemicals in fish by ultra-high-performance liquid chromatography-mass spectrometry/mass spectrometry. Ye, A., Yang, Y., Zhang, J., Liu, M., Hou, L. and Zhou, J. L. Journal of Chromatography A. 2013. 1278, 126-132. 10.1016/j.chroma.2013.01.008	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Concentrations of bisphenol A, bisphenol A diglycidyl ether, and their derivatives in canned foods in Japanese markets. Yonekubo, J., Hayakawa, K. and Sajiki, J. Journal of Agricultural and Food Chemistry. 2008. 56, 2041-2047. 10.1021/jf073106n	Japan	Not considered	Not considered	Excluded - samples from Japan (i.e. did not meet geographical origin criteria)
Sensitive gas chromatographic-mass spectrometric (GC-MS) method for the determination of bisphenol A in rice-prepared dishes. Zafra-Gómez, A., Morales, J. C., Ballesteros, O. and Navalón, A. Food Additives and Contaminants. 2009. 26:8, 1209-1216. 10.1080/02652030902939663	Not considered	Not considered	Not considered	Excluded - analytical method paper - no relevant data for calculation of exposure from food
Analysis of estrogenic compounds in environmental and biological samples by liquid chromatography-tandem mass spectrometry with stable isotope-coded ionization-enhancing reagent.	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[24] and reasoning
Zhang, S., You, J., Ning, S., Song, C. and Suo, Y. R. Journal of Chromatography A. 2013. 1280, 84-91. 10.1016/j.chroma.2013.01.045				period criteria)

Table 64: Literature quality table—occurrence in drinking water

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[25] and reasoning
Alkylphenols and phthalates in bottled waters. Amiridou, D. and Voutsa, D. Journal of Hazardous Materials. 2011. 185:1, 281-286. 10.1016/j.jhazmat.2010.09.031	Greece	Bottled waters	BPA was extracted from the water samples using dichloromethane, dried and evaporated to dryness. The extracts were derivatised using BSTFA. Analysis was carried out by GC-MS LOD = range of 2-30 ng/L reported for all analytes tested LOQ = Not given Recovery = 77-92 % (for alkylphenols spiked at 20, 50 and 100 ng/L) Repeatability = Not given Calibration = 10 to 200 ng/L (seven levels) Measures taken to reduce contamination: Glassware, solvents and samples were handled carefully to avoid contamination. Method blank prepared to determine any contamination through the procedure. Results were corrected for blank values.	Excluded – measurable BPA for PC water coolers only which were considered in the migration from food contact materials section. Method performance was assessed at concentrations below which BPA was measured in bottled water
Relevance of drinking water as a source of human exposure to bisphenol A. Arnold, S. M., Clark, K. E., Staples, C. A., Klecka, G. M., Dimond, S. S., Caspers, N. and Hentges, S. G. Journal of Exposure Science and Environmental Epidemiology. 2013. 23;2, 137-144. 10.1038/jes.2012.66	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)

[25] For inclusion/exlusion criteria see Appendix A.

Title **Authors** **Journal. Year. Volume:Issue, Page number** **DOI**	**Country of origin of samples**	**Sample description**	**Method description and quality parameters**	**Reported data included or excluded from the calculation of the exposure to bisphenol A[25] and reasoning**
Chemical compounds and toxicological assessments of drinking water stored in polyethylene terephthalate (PET) bottles: A source of controversy reviewed. Bach, C., Dauchy, X., Chagnon, M. C. and Etienne, S. Water Research. 2012. 46:3,: 571-583. 10.1016/j.watres.2011.11.062	Not considered	Not considered	Not considered	Excluded – review paper - no relevant data for calculation of exposure from drinking water
Survey of phthalates, alkylphenols, bisphenol A and herbicides in Spanish source waters intended for bottling. Bono-Blay, F., Guart, A., de la Fuente, B., Pedemonte, M., Cinta Pastor, M., Borrell, A. and Lacorte, S. Environmental Science and Pollution Research. 2012. 19, 3339–3349. 10.1007/s11356-012-0851-y	Source waters located throughout Spain	131 water sources intended for drinking	BPA was extracted from the water samples using solid phase extraction. Analysis was carried out by GC-MS LOD = 0.009 µg/L in the water (3x S:N) LOQ = 0.029 µg/L in the water (10x S:N) Recovery = 89 % at 1 µg/L, 93 % at 0.1 µg/L (HPLC water spiked with BPA) Repeatability = 5.4 % (HPLC water spiked with BPA at 0.01 µg/L, 93 % at 0.1 µg/L) Calibration = External calibration 5 to 1000 µg/L (samples enriched during the procedure to be in this range) Measures taken to reduce contamination: Method blank prepared to determine any contamination through the procedure	Included
Survey of bisphenol A in bottled water products in Canada. Cao, X-L and Corriveau, J. Food Additives and Contaminants Part B. 2008. 1:2, 161-164. 10.1080/02652030802563290	Canada	Not considered	Not considered	Excluded - samples from Canada (i.e. did not meet geographical origin criteria)

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[25] and reasoning
Determination of bisphenol A in water via inhibition of silver nanoparticles-enhanced chemiluminescence. Chen, X., Wang, C., Tan, X. and Wang, J. Analytica Chimica Acta. 2011. 689:1, 92-96. 10.1016/j.aca.2011.01.031	China	Not considered	Not considered	Excluded - samples from China (i.e. did not meet geographical origin criteria)
Occurrence and assessment of treatment efficiency of nonylphenol, octylphenol and bisphenol-A in drinking water in Taiwan. Chen, H. W., Liang, C. H., Wu, Z. M., Chang, E. E., Lin, T. F., Chiang, P. C. and Wang, G. S. The Science of the Total Environment. 2013. 449, 20-28. 10.1016/j.scitotenv.2013.01.038	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Ultra-trace analysis of hormones, pharmaceutical substances, alkylphenols and phthalates in two French natural mineral waters. Devier, M. H., Le Menach, K., Viglino, L., Di Gioia, L., Lachassagne, P. and Budzinski, H. The Science of the Total Environment. 2013. 443, 621-632. 10.1016/j.scitotenv.2012.10.015	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Factors affecting the quality of bottled water. Diduch, M., Polkowska, Z. and Namiesnik, J. Journal of Exposure Science and Environmental Epidemiology. 2013. 23(2): 111-119. 10.1038/jes.2012.101	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Quantification of bisphenol A, 353-nonylphenol and their chlorinated derivatives in drinking water treatment plants.	France	8 Drinking water samples	BPA was extracted from the water samples using solid phase extraction. Analysis was	Excluded – method performance was assessed

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[25] and reasoning
Dupuis, A., Migeot, V., Cariot, A., Albouy-Llaty, M., Legube, B. and Rabouan, S. Environmental Science and Pollution Research International. 2012. 19:9, 4193-4205. 10.1007/s11356-012-0972-3		collected at the outlet of the 8 different drinking water treatment plants	carried out by LC-MS/MS. LOD = 0.5 ng/L (3x S:N– corrected for recovery) LOQ = 1.5 ng/L (10x S:N– corrected for recovery) Recovery = 108 % for blank samples spiked at 20 and 40 ng/L Repeatability = 7 % intra-day RSD, 18 % inter-day RSD Calibration = 2 to 40 ng/L (five levels) Measures taken to reduce contamination: Glassware was baked, high quality solvents and teflon seals were used to minimise contamination. Method blanks were prepared to determine any contamination through the procedure.	at concentrations below which BPA was measured in treated water
Bisphenol A Detection in Various Brands of Drinking Bottled Water in Riyadh, Saudi Arabia Using Gas Chromatography/Mass Spectrometer. Elobeid, M. A., Almarhoon, Z. M., Virk, P., Hassan, Z. K., Omer, S. A., El Amin, M., Daghestani, M. H. and Al Olayan, E. M. Tropical Journal of Pharmaceutical Research. 2012. 13, 455-459. 10.4314/tjpr.v11i3.15	Saudi Arabia	Not considered	Not considered	Excluded - samples from Saudi Arabia (i.e. did not meet geographical origin criteria)
Detection and occurrence of chlorinated byproducts of bisphenol a, nonylphenol, and estrogens in drinking water of china: comparison to the parent compounds.	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did

Title **Authors** **Journal. Year. Volume:Issue, Page number** **DOI**	**Country of origin of samples**	**Sample description**	**Method description and quality parameters**	**Reported data included or excluded from the calculation of the exposure to bisphenol A[25] and reasoning**
Fan, Z., Hu, J., An, W. and Yang, M. Environmental Science and Technology. 2013. 47:19, 10841-10850. 10.1021/es401504a				not meet publication period criteria)
The occurrence and distribution of a group of organic micropollutants in Mexico City's water sources. Felix-Canedo, T. E., Duran-Alvarez, J. C. and Jimenez-Cisneros, B. Sci Total Environ. 2013. 454-455, 109-118. 10.1016/j.scitotenv.2013.02.088	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Migration of plasticizers phthalates, bisphenol A and alkylphenols from plastic containers and evaluation of risk. Guart, A., Bono-Blay, F., Borrell, A. and Lacorte, S. Food Additives and Contaminants Part A. 2011. 28, 676-685. 10.1080/19440049.2011.555845	No details are provided on the place of purchase or sampling but the authors are from Spain	Bottled water packed in 10 in PET bottles, 10 in PC coolers and 7 in HDPE bottles	BPA was extracted from the water samples using solid phase extraction. Analysis was carried out by GC-MS LOD = 0.009 µg/L (3x standard deviation of the blank samples, n=5) LOQ = not given Recovery = 97 % for HPLC water spiked at 1 µg/L Repeatability = not given Calibration = 10 to 10000 µg/L Measures taken to reduce contamination: Method blank prepared to determine any contamination through the procedure	Included
Migration of plasticizers from TritanTM and polycarbonate bottles and toxicological evaluation. Guart, A., Wagner, M., Mezquida, A., Lacorte, S., Oehlmann, J. and Borrell, A.	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[25] and reasoning
Food Chemistry. 2013. 141, 373-380. 10.1016/j.foodchem.2013.02.129				
Surface plasmon resonance sensor for detection of bisphenol A in drinking water. Hegnerová, K. and Homola, J Sensors and Actuators B. 2010. 151:1, 177-179. 10.1016/j.snb.2010.09.025	Not considered	Not considered	Not considered	Excluded - analytical method review paper - no relevant data for calculation of exposure from drinking water
Sol-gel coated polydimethylsiloxane/beta-cyclodextrin as novel stationary phase for stir bar sorptive extraction and its application to analysis of estrogens and bisphenol A. Hu, Y., Zheng, Y., Zhu, F. and Li, G. Journal of Chromatography A. 2007. 1148:1, 16-22. 10.1016/j.chroma.2007.02.101	China	Not considered	Not considered	Excluded - samples from China (i.e. did not meet geographical origin criteria)
BPA and environmental estrogen in potable water sources in Enugu municipality, South-East, Nigeria. Ignatius, C. M., Francis, E. E., Emeka, E. N., Elvis, N. S. and Ebele, J. I. Bulletin of Environmental Contamination and Toxicology. 2010. 85:5, 534-537. 10.1007/s00128-010-0111-0	Nigeria	Not considered	Not considered	Excluded - samples from Nigeria (i.e. did not meet geographical origin criteria)
Direct enrichment and high performance liquid chromatography analysis of ultra-trace Bisphenol A in water samples with narrowly dispersible Bisphenol A imprinted polymeric microspheres column. Jiang, M., Zhang, J. H., Mei, S. R., Shi, Y., Zou, L. J., Zhu, Y. X., Dai, K. and Lu, B. Journal of Chromatography A. 2006. 1110:1-2, 27-34.	China	Not considered	Not considered	Excluded - samples from China (i.e. did not meet geographical origin criteria)

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[25] and reasoning
10.1016/j.chroma.2006.01.051				
A novel sol-gel-material prepared by a surface imprinting technique for the selective solid-phase extraction of bisphenol A. Jiang, X., Tian, W., Zhao, C., Zhang, H. and Liu, M. Talanta. 2007. 72:1, 119-125. 10.1016/j.talanta.2006.10.006	China	Not considered	Not considered	Excluded - samples from China (i.e. did not meet geographical origin criteria)
Determination of bisphenol A, bisphenol F and their diglycidyl ethers in environmental water by solid phase extraction using magnetic multiwalled carbon nanotubes followed by GC-MS/MS. Jiao, Y, Ding, L, Fu, S., Zhu, S., Li, H. and Wang, L. Analytical Methods. 2012. 4:1, 291-298. 10.1039/c1ay05433c	CHina	Not considered	Not considered	Excluded - samples from China (i.e. did not meet geographical origin criteria)
Exposure to bisphenol A from bis-glycidyl dimethacrylate–based dental sealants. Joskow, R., Boyd Barr, D., Barr, J. R., Calafat, A. M., Needham, L. L. and Rubin, C. Journal of the American Dental Association. 2006. 137, 253-262. DOI not given	Not considered	Not considered	Not considered	Excluded – dental sealants data only - no relevant data for calculation of exposure from drinking water
Liquid phase microextraction with in situ derivatization for measurement of bisphenol A in river water sample by gas chromatography-mass spectrometry. Kawaguchi, M., Ito, R., Endo, N., Okanouchi, N., Sakui, N., Saito, K. and Nakazawa, H. Journal of Chromatography A. 2006. 1110:1-2, 1-5.	Japan	Not considered	Not considered	Excluded - samples from Japan (i.e. did not meet geographical origin criteria)

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[25] and reasoning
10.1016/j.chroma.2006.01.061				
Simultaneous determination and assessment of 4-nonylphenol, bisphenol A and triclosan in tap water, bottled water and baby bottles. Li, X., Ying, G. G., Su, H. C., Yang, X. B. and Wang, L. Environment International. 2010. 36:6, 557-562. 10.1016/j.envint.2010.04.009	China	Not considered	Not considered	Excluded - samples from China (i.e. did not meet geographical origin criteria)
Screening of endocrine-disrupting phenols, herbicides, steroid estrogens, and estrogenicity in drinking water from the waterworks of 35 Italian cities and from PET-bottled mineral water. Maggioni, S., Balaguer, P., Chiozzotto, C. and Benfenati, E. Environmental Science and Pollution Research International. 2013. 20:3, 1649-1660. 10.1007/s11356-012-1075-x	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Association between water consumption from polycarbonate containers and bisphenol A intake during harsh environmental conditions in summer. Makris, K. C., Andra, S. S., Jia, A., Herrick, L., Christophi, C. A., Snyder, S. A. and Hauser, R. Environmental Science and Technology. 2013. 47:7, 3333-3343. 10.1021/es304038k	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
One-step signal amplified lateral flow strip biosensor for ultrasensitive and on-site detection of bisphenol A (BPA) in aqueous samples. Mei, Z., Qu, W., Deng, Y., Chu, H., Cao, J., Xue, F.,	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[25] and reasoning
Zheng, L., El-Nezamic, H. S., Wu, Y. and Chen, W. Biosensors and Bioelectronics. 2013. 49, 457-461. 10.1016/j.bios.2013.06.006				period criteria)
Online in-tube microextractor coupled with UV-Vis spectrophotometer for bisphenol A detection. Poorahong, S., Thammakhet, C., Thavarungkul, P. and Kanatharana, P. Journal of Environmental Science and Health. Part A. 2013. 48:3, 242-250. 10.1080/10934529.2013.726592	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Properties, threats, and methods of analysis of bisphenol a and its derivatives. Rykowska I. and Wasiak W. Acta Chromatographica. 2006. 16, 7-27. DOI: not given	Not considered	Not considered	Not considered	Excluded - review paper - no relevant data for calculation of exposure from drinking water
Occurrence of bisphenol A in surface water, drinking water and plasma from Malaysia with exposure assessment from consumption of drinking water. Santhi, V. A., Sakai, N., Ahmad, E. D. and Mustafa, A. M. The Science of the Total Environment. 2012. 427-428, 332-338. 10.1016/j.scitotenv.2012.04.041	Malaysia	Not considered	Not considered	Excluded - samples from Malaysia (i.e. did not meet geographical origin criteria)
Dummy molecularly imprinted polymers as the coating of stir bar for sorptive extraction of bisphenol A in tap water. Sheng, N., Wei, F., Zhan, W., Cai, Z., Du, S., Zhou, X., Li, F. and Hu, Q. Journal of Separation Science. 2012. 35:5-6, 707-712.	China	Not considered	Not considered	Excluded - samples from China (i.e. did not meet geographical origin criteria)

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[25] and reasoning
10.1002/jssc.201100883				
Occurrence and distribution of steroids, hormones and selected pharmaceuticals in South Florida coastal environments. Singh, S. P., Azua, A., Chaudhary, A., Khan, S., Willett, K. L. and Gardinali, P. R. Ecotoxicology. 2010, 19:2, 338-350. 10.1007/s10646-009-0416-0	United States of America	Not considered	Not considered	Excluded - samples from USA (i.e. did not meet geographical origin criteria)
Efficiency of conventional drinking-water-treatment processes in removal of pharmaceuticals and other organic compounds. Stackelberg, P. E., Gibs, J., Furlong, E. T., Meyer, M. T., Zaugg, S. D. and Lippincott, R. L. The Science of the Total Environment. 2007. 377:2-3, 255-272. 10.1016/j.scitotenv.2007.01.095	United States of America	Not considered	Not considered	Excluded - samples from USA (i.e. did not meet geographical origin criteria)
Human exposure to bisphenol A (BPA). Vandenberg, L. N., Hauser, R., Marcus, M., Olea, N. and Welshons, W. V. Reproductive Toxicology. 2007. 24:2, 139-177. 10.1016/j.reprotox.2007.07.010	Not considered	Not considered	Not considered	Excluded - review paper - no relevant data for calculation of exposure from drinking water
Rapid determination of bisphenol A in drinking water using dispersive liquid-phase microextraction with in situ derivatization prior to GC-MS. Wang, X., Diao, C. P. and Zhao, R. S. Journal of Separation Science. 2009. 32:1, 154-159. 10.1002/jssc.200800436	China	Not considered	Not considered	Excluded - samples from China (i.e. did not meet geographical origin criteria)

Title Authors Journal. Year. Volume:Issue, Page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[25] and reasoning
Contaminant Migration From Polymeric Pipes Used in Buried Potable Water Distribution Systems: A Review. Whelton, A. J. and Nguyen, T. Critical Reviews in Environmental Science and Technology. 2013. 43:7, 679-751. 10.1080/10643389.2011.627005	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Determination of Bisphenol A in Plastic Bottled Drinking Water by High Performance Liquid Chromatography with Solid-membrane Extraction Based on Electrospun Nylon 6 Nanofibrous Membrane. Wu S. Y., Xu, Q, Chen, T. S., Wang, M., Yin, X. Y., Zhang, N. P., Shen, Y. Y., Wen, Z. Y. and Gu Z. Z. Chinese Journal of Analytical Chemistry. 2010. 38:4, 503-507. 10.1016/s1872-2040(09)60035-9	China	Not considered	Not considered	Excluded - samples from China (i.e. did not meet geographical origin criteria)
Electrochemical aptasensor for the determination of bisphenol A in drinking water. Xue, F., Wu, J., Chu, H., Mei, Z., Ye, Y., Liu, J., Zhang, R., Peng, C., Zheng, L. and Chen, W. Microchimica Acta. 2013. 180:1-2, 109-115. 10.1007/s00604-012-0909-z	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Endocrine disrupting chemicals: human exposure and health risks. Yang, M., Park, M. S. and Lee, H. S. Journal of Environmental Science and Health. Part C. 2006. 24:2, 183-224. 10.1080/10590500600936474	Not considered	Not considered	Not considered	Excluded - review paper - no relevant data for calculation of exposure from drinking water

Table 65: Literature quality table – occurrence in food contact materials

Title **Authors** **Journal. Year. Volume: issue, page number** **DOI**	**Country of origin of samples**	**Sample description**	**Method description and quality parameters**	**Reported data included or excluded from the calculation of the exposure to bisphenol A[26] and reasoning**
Migration from polycarbonate packaging to food simulants during microwave heating. Alin, L. and Hakkarainen, M. Polymer Degradation and Stability. 2012. 97:8, 1387-1395. 10.1016/j.polymdegradstab.2012.05.017	Not considered	Not considered	Not considered	Excluded - migration data rather than occurrence data was used for the determination of the exposure from food contact materials
The BIOSAFEPAPER project for in vitro toxicity assessments: preparation, detailed chemical characterisation and testing of extracts from paper and board samples Bradley, E. L., Honkalampi-Hamalainen, U., Weber, A., Andersson, M. A., Bertaud, F., Castle, L., Dahlman, O., Hakulinen, P., Hoornstra, D., Lhuguenot, J. C., Maki-Paakkanen, J., Salkinoja-Salonen, M., Speck, D. R., Severin, I., Stammati, A., Turco, L., Zucco, F. and von Wright, A. Food and Chemical Toxicology. 2008. 46:7, 2498-2509. 10.1016/j.fct.2008.04.017	Not considered	Not considered	Not considered	Excluded - migration data rather than occurrence data was used for the determination of the exposure from food contact materials
Investigation into the migration potential of coating materials from cookware products. Bradley, E. L., Read, W. A. and Castle, L. Food Additives and Contaminants. 2007. 24:3, 326-335. 10.1080/02652030601013711	Not considered	Not considered	Not considered	Excluded - migration data rather than occurrence data was used for the determination of the exposure from food contact materials
Migration and sensory properties of plastics-based nets	Not	Not	Not considered	Excluded - migration data

[26] For inclusion/exlusion criteria see Appendix A.

Title Authors Journal. Year. Volume: issue, page number DOI	Country of origin of samples	Sample description	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[26] and reasoning
used as food-contacting materials under ambient and high temperature heating conditions. Kontominas, M. G., Goulas, A. E., Badeka, A. V. and Nerantzaki, A. Food Additives and Contaminants. 2006. 23:6, 634-641. 10.1080/02652030600643369	considered	considered		rather than occurrence data was used for the determination of the exposure from food contact materials
Oestrogenicity of paper and cardboard extracts used as food containers. Lopez-Espinosa, M. J., Granada, A., Araque, P., Molina-Molina, J. M., Puertollano, M. C., Rivas, A., Fernandez, M., Cerrillo, I., Olea-Serrano, M. F., Lopez, C. and Olea, N. Food Additives and Contaminants. 2007. 24:1, 95-102. 10.1080/02652030600936375	Not considered	Not considered	Not considered	Excluded - migration data rather than occurrence data was used for the determination of the exposure from food contact materials
Physicochemical processes involved in migration of bisphenol A from polycarbonate. Mercea, P. Journal of Applied Polymer Science. 2009. 112:2, 579-593. 10.1002/app.29421	Not considered	Not considered	Not considered	Excluded - migration data rather than occurrence data was used for the determination of the exposure from food contact materials
Bisphenol A (BPA) and its source in foods in Japanese markets Sajiki, J., Miyamoto, F., Fukata, H., Mori, C., Yonekubo, J. and Hayakawa, K. Food Additives and Contaminants. 2007. 24:1, 103-112. 10.1080/02652030600936383	Not considered	Not considered	Not considered	Excluded - migration data rather than occurrence data was used for the determination of the exposure from food contact materials

Table 66: Literature quality table – migration from food contact materials

Title Authors Journal. Year. Volume: Issue, Page number DOI	Country of origin of samples	Sample description	Migration test conditions	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
Migration from polycarbonate packaging to food simulants during microwave heating. Alin, J. and Hakkarainen, M. Polymer Degradation and Stability. 2012. 97:8, 1387-1395. 10.1016/j.polymdegradstab.2012.05.017	Not considered	Not considered	Not considered	Not considered	Excluded - no relevant data for calculation of exposure of specific populations from food contact materials
Alkylphenols and phthalates in bottled waters. Amiridou, D. and Voutsa, D. Journal of Hazardous Materials. 2011. 185:1, 281-286. 10.1016/j.jhazmat.2010.09.031	Not considered	Not considered	Not considered	Not considered	Excluded – not relevant - occurrence in drinking water rather than migration data reported NOTE: paper also considered in the scope of the drinking water exposure assessment
Release of bisphenol A from polycarbonate baby bottles: mechanisms of formation and investigation of worst case scenarios. Biedermann-Brem, S., Grob, K. and Fjeldal, P. European Food Research and Technology. 2008. 227:4, 1053-1060. 10.1007/s00217-008-0819-9	Not considered	Not considered	Not considered	Not considered	Excluded – no relevant data for calculation of exposure of specific populations from food contact materials. Model studies determining the worst case migration rather than migration under actual conditions of use
Release of bisphenol A from polycarbonate baby bottles: water hardness as the most relevant factor. Biedermann-Brem, S., Grob, K. European Food Research and Technology. 2009	Samples were produced in USA and UK	PC baby bottles from two producers	Different conditions, use of tap water	BPA was determined in the exposed water samples by direct analysis using LC-FLD	Included NOTE: although method performance data was not

Title Authors Journal. Year. Volume: Issue, Page number DOI	Country of origin of samples	Sample description	Migration test conditions	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
228:679–684 DOI 10.1007/s00217-008-0978-8 NOTE: Not identified by contractor as a migration from food contact materials paper				LOD = 0.5 µg/L (5 x S:N) LOQ = Not given Recovery = Not given Repeatability = Not given Calibration = Not given Measurement uncertainty quoted as 20 % but no indication is given as to how this was calculated Measures taken to reduce contamination: No information on prevention of contamination or blanks	well described the paper provided migration data not available elsewhere
How Should the Release of Bisphenol A from Baby Bottles be Determined? Biedermann-Brem, S. and Grob, K. Chimia. 2009. 63:10, 694-694. 10.2533/chimia.2009.694	Not considered	Not considered	Not considered	Not considered	Excluded - review paper - no relevant data for calculation of exposure of specific populations from food contact materials
Investigation into the migration potential of coating materials from cookware products. Bradley, E. L., Read, W. A. and Castle, L. Food Additives and Contaminants. 2007. 24:3, 326-335. 10.1080/02652030601013711	Samples were purchased in the UK	26 non-stick coated cookware products , 5 tested for the migration of BPA	Olive oil: 175ºC for 1 hour; 95 % ethanol: 60ºC for 6 hours; Acetic acid: 100ºC for 1 hour	BPA was determined in the exposed 10 % ethanol and 3 % acetic acid simulants by HPLC-FLD. The exposed olive oil was diluted with heptane and extracted with acetonitrile which was analysed by HPLC-FLD LOD = Not given for all simulants/products - 0.026 mg/dm^2 in acetic acid for one product tested	Included NOTE: although method performance data was not well described the paper provided migration data not available elsewhere

Title Authors Journal. Year. Volume: Issue, Page number DOI	Country of origin of samples	Sample description	Migration test conditions	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
				LOQ = Not given Recovery = Not given Repeatability = Not given Calibration = Not given Measures taken to reduce contamination: No information on prevention of contamination or blanks	
Identification of Potential Migrants in Epoxy Phenolic Can Coatings. Bradley, E. L., Driffield, M., Harmer, N., Oldring, P. K. T. and Castle, L. International Journal of Polymer Analysis and Characterisation. 2008. 13:3, 200-223. 10.1080/10236660802070512	Not considered	Not considered	Not considered	Not considered	Excluded - migration data for can coatings was not used in the exposure assessment. Occurrence in canned food data was used to determine exposure from this source
Determination of bisphenol A in wine by sol-gel immunoaffinity chromatography, HPLC and fluorescence detection. Brenn-Struckhofova, Z. and Cichna-Markl, M. Food Additives and Contaminants. 2006. 23:11, 1227–1235. 10.1080/02652030600654382	Not considered	Not considered	Not considered	Not considered	Excluded – occurrence in food data only - no relevant data for calculation of exposure from food contact materials NOTE: paper considered in the scope of the food exposure assessment
Migration of Bisphenol A from Polycarbonate Baby and Water Bottles into Water under Severe Conditions.	Samples were purchased in Canada	5 polycarbonate baby bottles	70ºC for 2 hours	Following the addition of sodium chloride the BPA was extracted from the sample using SPME. Analysis was carried out by GC-	Included NOTE: although the samples

Title Authors Journal. Year. Volume: Issue, Page number DOI	Country of origin of samples	Sample description	Migration test conditions	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
Cao, X.-L. and Corriveau, J. Journal of Agricultural and Food Chemistry. 2008. 56, 6378–6381. 10.1021/jf800870b				MS LOD = 0.5 µg/L LOQ = Not given Recovery = Not given Repeatability = Not given Calibration = 5 to 600 µg/L Measures taken to reduce contamination: Method blanks were prepared to determine any contamination through the procedure. Blank levels detected were subtracted from the reported concentrations	were from outside Europe the comprehensive number and range of sample types provided data not available for European samples
Determination of Bisphenol A in Water by Isotope Dilution Headspace Solid-Phase Microextraction and Gas Chromatography/Mass Spectrometry Without Derivatization. Cao, X.-L. and Corriveau, J. Journal of AOAC International. 2008. 91, 622-629. Not given	Samples were purchased in Canada	3 polycarbonate baby bottles and 2 water bottles	25ºC for 24 hours	Following the addition of sodium chloride the BPA was extracted from the sample using SPME. Analysis was carried out by GC-MS LOD = 0.5 µg/L LOQ = Not given Recovery = Not given Repeatability = 9.7 % (n=6 replicates at 5 µg/L) and 8.9 % (n=6 replicates at 20 µg/L) Calibration = 2.5 to 40 µg/L Measures taken to reduce contamination: Deactivated	Included NOTE: although the samples were from outside Europe the range of sample types provided data not available for European samples at the tested conditions

Title Authors Journal. Year. Volume: Issue, Page number DOI	Country of origin of samples	Sample description	Migration test conditions	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
				glassware was used. Method blanks were prepared to determine any contamination through the procedure	
Determination of the Migration of Bisphenol A from Polycarbonate by Dispersive Liquid-Liquid Microextraction Combined with High Performance Liquid Chromatography. Cao, J., Liu, S., Bai, W., Chen, J. and Xie, Q. Analytical Letters. 2013. 46: 1342-1354. 10.1080/00032719.2013.766798	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Migration of Bisphenol A from plastic containers into water. Chatzis V., Nikolaidis, A. K. and Achilias, D. S. Fresenius Environmental Bulletin 2012. 21: 2506-2509. DOI not given	Not considered	Not considered	Not considered	Not considered	Excluded – only abstract available – no relevant data for calculation of exposure from food contact materials
Assessment of bisphenol A released from reusable plastic, aluminium and stainless steel water bottles. Cooper, J. E., Kendig, E. L. and Belcher, S. M. Chemosphere. 2011. 85:6, 943-947. 10.1016/j.chemosphere.2011.06.060	Sample were purchased in the USA	Reusable bottles: Nalgene, 32 ounce loop-top polycarbonate bottles, Tritan™ copolyester bottles, one litre stainless steel bottles,	25ºC for 5 days	BPA was determined in the exposed water samples by direct analysis using ELISA LOD = 0.05 µg/L LOQ = Not given Recovery = Not given Repeatability = Not given Calibration = 0.05 to 10 µg/L Measures taken to reduce contamination: Method blank	Included NOTE: data for PC water bottles only was included. Although the samples were from outside Europe the comprehensive number and range of sample types provided data not available for European samples

Title Authors Journal. Year. Volume: Issue, Page number DOI	Country of origin of samples	Sample description	Migration test conditions	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
		aluminium epoxy resin lined bottles and Eco-Care™ lined bottles		prepared to determine any contamination through the procedure	
Study on the migration of bisphenol-A from baby bottles by stir bar sorptive extraction-thermal desorption-capillary GC-MS. De Coensel, N., David, F. and Sandra, P. Journal of Separation Science. 2009. 32:21, 3829-3836. 10.1002/jssc.200900349	No details were provided on the place of purchase or sampling but the authors are from Belgium	Two commercial brands of baby bottles	Microwave heating (37, 53, 65, 85ºC)	BPA was determined using stir bar sorptive extraction (SBSE) after in situ derivatization with acetic acid anhydride followed by thermal desorption (TD)-capillary GC-MS. LOD = 0.12 ng/L LOQ = 0.40 ng/L Recovery = 65% Repeatability = not given Calibration = 1 ng/L to 10 mg/L Measures taken to reduce contamination: control of background level (set at 8 ng/L) and correction of results	Included
Migration of bisphenol A into water from polycarbonate baby bottles during microwave heating. Ehlert, K. A., Beumer, C. W. and Groot, M. C. Food Additives and Contaminants Part A. 2008. 25:7, 904-910. 10.1080/02652030701867867	Samples were purchased in Europe	Eighteen types of PC bottles from throughout Europe	100ºC for 1 minute	BPA was extracted from the exposed simulant samples using SPE. Analysis was carried out by GC-MS after derivatisation with N-methyl-N-(trimethylsilyl) trifluoroacetamide LOD = 0.1 µg/L LOQ = Not given	Included

Title Authors Journal. Year. Volume: Issue, Page number DOI	Country of origin of samples	Sample description	Migration test conditions	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
				Recovery = 95 % (water spiked with BPA at 1 µg/L, n = 5) Repeatability = 2 % (water spiked with BPA at 1 µg/L, n = 5) Calibration = 0.05 to 5 µg/L Measures taken to reduce contamination: No measures against contamination reported	
Migration of phthalates, alkylphenols, bisphenol A and di(2-ethylhexyl)adipate from food packaging. Fasano, E., Bono-Blay, F., Cirillo, T., Montuori, P. and Lacorte, S. Food Control. 2012. 27:1, 132-138. 10.1016/j.foodcont.2012.03.005	Not given	Eleven food packaging materials	40ºC for 10 days	BPA was extracted from the exposed simulant samples using SPE. Analysis was carried out by GC-MS LOD = 21 to 33 ng/L LOQ = Not given Recovery = 80 % (from water spiked with 100 ng of BPA in 30, 50 or 100 mL simulant, n = 2) Repeatability = Not given Calibration = 0.01 to 1 µg/mL Measures taken to reduce contamination: No measures against contamination reported	Included NOTE: data for PC baby bottles only was included NOTE: although method performance data was not well described the paper provided migration data not available elsewhere at the testing conditions
Are potential sources for human exposure to bisphenol-A overlooked? Geens, T., Goeyens, L. and Covaci, A. International Journal of Hygiene and Environmental Health. 2011. 214:5, 339-347.	Not considered	Not considered	Not considered	Not considered	Excluded – review paper - no relevant data for calculation of exposure of specific polulations from food contact materials

Title Authors Journal. Year. Volume: Issue, Page number DOI	Country of origin of samples	Sample description	Migration test conditions	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
10.1016/j.ijheh.2011.04.005					
Phthalates and bisphenols migration in Mexican food cans and plastic food containers. Gonzalez-Castro, M. I., Olea-Serrano, M. F., Rivas-Velasco, A. M., Medina-Rivero, E., Ordonez-Acevedo, L. G. and De Leon-Rodriguez, A. Bulletin of Environmental Contamination and Toxicology. 2011. 86:6, 627-631. 10.1007/s00128-011-0266-3	Mexico	Not considered	Not considered	Not considered	Excluded – samples from Mexico (i.e. did not meet geographical origin criteria)
Migration of plasticizers phthalates, bisphenol A and alkylphenols from plastic containers and evaluation of risk. Guart, A., Bono-Blay, F., Borrell, A. and Lacorte, S. Food Additives and Contaminants Part A. 2011. 28, 676-685. 10.1080/19440049.2011.555845	No details were provided on the place of purchase or sampling but the authors are from Spain	10 Water samples packed in PC coolers. Migration solutions derived from PC exposed to water for 10 days at 40oC	40ºC for 10 days	BPA was extracted from the water samples using solid phase extraction. Analysis was carried out by GC-MS LOD = 0.009 µg/L (3x standard deviation of the blank samples, n=5) LOQ = Not given Recovery = 97 % for HPLC water spiked at 1 µg/L Repeatability = Not given Calibration = 10 to 10000 µg/L Measures taken to reduce contamination: Method blank prepared to determine any contamination through the procedure	Included
Korean Environmental Health Survey in Children	Not	Not	Not	Not considered	Excluded – paper

Title Authors Journal. Year. Volume: Issue, Page number DOI	Country of origin of samples	Sample description	Migration test conditions	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
and Adolescents (KorEHS-C): Survey design and pilot study results on selected exposure biomarkers. Ha, M., Kwon, H.J., Leem, J.H., Kim, H.C., Lee, K.J., Park, I., Lim, Y.W., Lee, J.H., Kim, Y., Seo, J.H., Hong, S.J., Choi, Y.H., Yu, J., Kim, J., Yu, S.D. and Lee, B.E. International Journal of Hygiene and Environmental Health. 2013. Epub Jun13. 10.1016/j.ijheh.2013.06.001	considered	considered	considered		published after December 2012 (i.e. did not meet publication period criteria)
Release of bisphenol A from polycarbonate: a review. Hoekstra, E. J. and Simoneau, C. Critical Reviews in Food Science and Nutrition. 2013. 53:4, 386-402. 10.1080/10408398.2010.536919	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Sol-gel coated polydimethylsiloxane/beta-cyclodextrin as novel stationary phase for stir bar sorptive extraction and its application to analysis of estrogens and bisphenol A. Hu, Y., Zheng, Y., Zhu, F. and Li, G. Journal of Chromatography A. 2007. 1148:1, 16-22. 10.1016/j.chroma.2007.02.101	China	Not considered	Not considered	Not considered	Excluded – samples from China (i.e. did not meet geographical origin criteria)
Migration Prediction Model of Residual Contaminants from Food Packaging Paper and its Experimental Verification. Huang, C.-X., Duan, D.-D., Yan, M.-M. and Wang, S.-F. Packaging Technology and Science. 2013. 26, 59-69.	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)

Title **Authors** **Journal. Year. Volume: Issue, Page number** **DOI**	**Country of origin of samples**	**Sample description**	**Migration test conditions**	**Method description and quality parameters**	**Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning**
10.1002/pts.2005					
Human exposure to bisphenol A. Kang, J. H., Kondo, F. and Katayama, Y. Toxicology. 2006. 226:2-3, 79-89. 10.1016/j.tox.2006.06.009	Not considered	Not considered	Not considered	Not considered	Excluded – review paper - no relevant data for calculation of exposure of specific populations from food contact materials
Migration of bisphenol A from plastic baby bottles, baby bottle liners and reusable polycarbonate drinking bottles. Kubwabo, C., Kosarac, I., Stewart, B., Gauthier, B. R., Lalonde, K. and Lalonde, P. J. Food Additives and Contaminants Part A. 2009. 26:6, 928-937. 10.1080/02652030802706725	Samples were purchased in Canada	New and used baby bottles, baby bottle liners and re-usable drinks bottles	40ºC for 8 hours, 1 day and 10 days	BPA was extracted from the water samples using solid phase extraction and from the ethanol solutions using solid phase extraction following acidification. Analysis was carried out by GC-MS/MS after derivatisation with N-methyl-N-(trimethylsilyl) trifluoroacetamide LOD = 0.04 ng/L LOQ = 0.11 ng/L Recovery = 93 % (simulant spiked at 0.25 ng/L, n = 7) Repeatability = 9.7 % (simulant spiked at 0.25 ng/L, n = 7) Calibration = Not given Measures taken to reduce contamination: Method blank prepared to determine any contamination through the procedure	Included NOTE: although the samples were from outside Europe the comprehensive number and range of sample types provided data not available in Europe
Bisphenol A is released from polycarbonate drinking	Samples were	New and used	22ºC for 24,	BPA was determined in the	Included

Title Authors Journal. Year. Volume: Issue, Page number DOI	Country of origin of samples	Sample description	Migration test conditions	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
bottles and mimics the neurotoxic actions of estrogen in developing cerebellar neurons. Le, H. H., Carlson, E. M., Chua, J. P. and Belcher, S. M. Toxicology Letters. 2008.176:2, 149-156 10.1016/j.toxlet.2007.11.001	purchased or obtained (used bottles) in the USA	polycarbonate baby bottles	72, 120 and 168 hours; 100ºC for 24 hours	exposed water samples by direct analysis using ELISA LOD = 0.05 µg/L LOQ = Not given Recovery = Not given Repeatability = Not given Calibration = 0.05 to 10 µg/L Measures taken to reduce contamination: Method blank prepared to determine any contamination through the procedure	NOTE: although the samples were from outside Europe the comprehensive number and range of sample types provided data not available in Europe
Voltammetric determination of bisphenol A in food package by a glassy carbon electrode modified with carboxylated multi-walled carbon nanotubes. Li, J., Kuang, D., Feng, Y., Zhang, F. and Liu, M. Microchimica Acta. 2011. 172:3-4, 379-386. 10.1007/s00604-010-0512-0	China	Not considered	Not considered	Not considered	Excluded – samples from China (i.e. did not meet geographical origin criteria)
Simultaneous determination and assessment of 4-nonylphenol, bisphenol A and triclosan in tap water, bottled water and baby bottles. Li, X., Ying, G. G., Su, H. C., Yang, X. B. and Wang, L. Environment International. 2010. 36:6, 557-562. 10.1016/j.envint.2010.04.009	China	Not considered	Not considered	Not considered	Excluded – samples from China (i.e. did not meet geographical origin criteria)
4-Nonylphenol, bisphenol-A and triclosan levels in human urine of children and students in China, and	Not	Not	Not	Not considered	Excluded – paper published after December

Title Authors Journal. Year. Volume: Issue, Page number DOI	Country of origin of samples	Sample description	Migration test conditions	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
the effects of drinking these bottled materials on the levels. Li, X., Ying, G. G., Zhao, J. L., Chen, Z. F., Lai, H. J. and Su, H. C. Environment International. 2013. 52: 81-86. 10.1016/j.envint.2011.03.026	considered	considered	considered		2012 (i.e. did not meet publication period criteria)
Potential risk of bisphenol A migration from polycarbonate containers after heating, boiling, and microwaving. Lim, D. S., Kwack, S. J., Kim, K. B., Kim, H. S. and Lee, B. M. Journal of Toxicology and Environmental Health. Part A. 2009. 72:21-22, 1285-1291. 10.1080/15287390903212329	Korea	Not considered	Not considered	Not considered	Excluded – samples from Korea (i.e. did not meet geographical origin criteria)
Oestrogenicity of paper and cardboard extracts used as food containers. Lopez-Espinosa, M. J., Granada, A., Araque, P., Molina-Molina, J. M., Puertollano, M. C., Rivas, A., Fernandez, M., Cerrillo, I., Olea-Serrano, M. F., Lopez, C. and Olea, N. Food Additives and Contaminants. 2007. 24:1, 95-102. 10.1080/02652030600936375	Not considered	Not considered	Not considered	Not considered	Excluded - migration data for paper and board was not used in the exposure assessment, occurrence in food data was used
Effect of amines in the release of bisphenol A from polycarbonate baby bottles. Maia, J. Cruz, J. M., Sendón, R., Bustos, J., Cirugeda, M. E., Sanchez, J. J. and Paseiro, P. Food Research International. 2010. 43:5, 1283-1288.	Not considered	Not considered	Not considered	Not considered	Excluded - no relevant data for calculation of exposure of specific populations from food contact materials

Title **Authors** **Journal. Year. Volume: Issue, Page number** **DOI**	**Country of origin of samples**	**Sample description**	**Migration test conditions**	**Method description and quality parameters**	**Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning**
10.1016/j.foodres.2010.03.014					
Effect of detergents in the release of bisphenol A from polycarbonate baby bottles. Maia, J., Cruz, J. M., Sendón, R., Bustos, J., Sanchez, J. J. and Paseiro, P. Food Research International. 2009. 42:10, 1410-1444. 10.1016/j.foodres.2009.07.003	Not considered	Not considered	Not considered	Not considered	Excluded – no relevant data for calculation of exposure of specific populations from food contact materials. Model studies determining the worst case migration rather than migration under actual conditions of use
Migration of bisphenol A from polycarbonate baby bottles under real use conditions. Maragou, N. C., Makri, A., Lampi, E. N., Thomaidis, N. S. and Koupparis, M. A. Food Additives and Contaminants Part A. 2008. 25:3, 373-383. 10.1080/02652030701509998	Samples were purchased in Greece	PC baby bottles	70ºC for 2 hours and filling with boiling water and leaving to stand for 45 minutes	BPA analysed by LC-MS LOD = 2.4 µg/L (water) and 1.8 µg/L (3% acetic acid) LOQ = Not given Recovery = Not given Repeatability = 2.9% (water), 4.2% (3% acetic acid) at 30 µg/L Calibration = 0.18 to 180 µg/L Measures taken to reduce contamination: information not provided	Included
Physicochemical processes involved in migration of bisphenol A from polycarbonate. Mercea, P. Journal of Applied Polymer Science. 2009. 112:2, 579-593. 10.1002/app.29421	Not given	Polycarbonate films, discs, plaques, containers and water coolers	Not considered	Not considered	Excluded - no relevant data for calculation of exposure of specific populations from food contact materials. Studies were carried out with tailor made samples or at non-standardised migration test conditions
Bisphenol A in "BPA free" baby feeding bottles.	Not	Not	Not	Not considered	Excluded - letter to the

Title Authors Journal. Year. Volume: Issue, Page number DOI	Country of origin of samples	Sample description	Migration test conditions	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
Moghadam, Z. A., Mirlohi, M. and Pourzamani, H. Journal of Research in Medical Sciences. 2012. 17: 1089-1091. DOI not given	considered	considered	considered		Editor – no relevant data for calculation of exposure of specific populations from food contact materials
Application of ethyl chloroformate derivatization for solid-phase microextraction-gas chromatography-mass spectrometric determination of bisphenol-A in water and milk samples. Mudiam, M. K., Jain, R., Dua, V. K., Singh, A. K., Sharma, V. P. and Murthy, R. C. Analytical and Bioanalytical Chemistry. 2011. 401:5, 1695-1701. 10.1007/s00216-011-5226-6	India	Not considered	Not considered	Not considered	Excluded – samples from India (i.e. did not meet geographical origin criteria)
Bisphenol A migration from polycarbonate baby bottle with repeated use. Nam, S. H., Seo, Y. M. and Kim, M. G. Chemosphere. 2010. 79:9, 949-952. 10.1016/j.chemosphere.2010.02.049	Korea	Not considered	Not considered	Not considered	Excluded – samples from Korea (i.e. did not meet geographical origin criteria)
A novel electrochemical sensor of bisphenol A based on stacked graphene nanofibers/gold nanoparticles composite modified glassy carbon electrode. Niu, X., Yang, W. Wang, G., Ren, J., Guo, H. and Gao, J. Electrochimica Acta. 2013. 98: 167-175. 10.1016/j.electacta.2013.03.064	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Optimization of a GC/MS procedure that uses parallel factor analysis for the determination of bisphenols and their diglycidylethersafter migration	No details were provided on the place of	PC cups	70ºC for 24 hours	BPA was determined in the simulant 50% ethanol by GC-MS after SPE extraction. Procedural	Included

Title **Authors** **Journal. Year. Volume: Issue, Page number** **DOI**	**Country of origin of samples**	**Sample description**	**Migration test conditions**	**Method description and quality parameters**	**Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning**
from polycarbonate tableware. Oca, M.L., Ortiz, M.C., Herrero, A. and Sarabia, L.A. Talanta. 2013. 106, 266-280. 10.1016/j.talanta.2012.10.086	purchase or sampling but the authors are from Spain			blanks were analysed. LOD = 2.65 µg/L LOQ = Not given Recovery = 114 % Repeatability = 5 % Calibration = 0 to 90 µg/l with BPA-d16 as internal standard Measures taken to reduce contamination: No measures against contamination reported	NOTE: although the publication date is post-2012 data for migration from PC tableware is reported that is not available elsewhere
Migration of Bisphenol A and Benzophenones from Paper and Paperboard Products Used in Contact with Food. Ozaki, A., Kawasaki, C., Kawamura, Y. and Tanamoto, K. Journal of the Food Hygienic Society of Japan. 2006. 47:3, 99-104. Not given	Not considered	Not considered	Not considered	Not considered	Excluded - migration data for paper and board was not used in the exposure assessment, occurrence in food data was used
Determination of bisphenol-type endocrine disrupting compounds in food-contact recycled-paper materials by focused ultrasonic solid-liquid extraction and ultra performance liquid chromatography-high resolution mass spectrometry. Perez-Palacios, D., Fernandez-Recio, M. A., Moreta, C. and Tena, M. T. Talanta. 2012. 99, 167-174. 10.1016/j.talanta.2012.05.035	Not considered	Not considered	Not considered	Not considered	Excluded - migration data for paper and board was not used in the exposure assessment, occurrence in food data was used

Title **Authors** **Journal. Year. Volume: Issue, Page number** **DOI**	**Country of origin of samples**	**Sample description**	**Migration test conditions**	**Method description and quality parameters**	**Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning**
Bisphenol A (BPA) and its source in foods in Japanese markets. Sajiki, J., Miyamoto, F., Fukata, H., Mori, C., Yonekubo, J. and Hayakawa, K. Food Additives and Contaminants. 2007. 24:1, 103-112. 10.1080/02652030600936383	Japan	Not considered	Not considered	Not considered	Excluded – samples from Japan (i.e. did not meet geographical origin criteria)
Migration of bisphenol A from polycarbonate baby bottles purchased in the Spanish market by liquid chromatography and fluorescence detection. Santillana, M. I., Ruiz, E., Nieto, M. T., Bustos, J., Maia, J., Sendon, R. and Sanchez, J. J. Food Additives and Contaminants. Part A. 2011. 28:11, 1610-1618. 10.1080/19440049.2011.589036	Samples were purchased in Spain	72 baby bottle samples from 12 brands	70ºC for 2 hours	Aqueous food simulant samples were analysed directly by LC-FLD LOD = 4 to 7 µg/kg LOQ = 30 µg/kg Recovery = 107-118 % (blank spiked with BPA at 0.12, 0.6 and 1.2 mg/kg, n = 9) Repeatability = 3.4 to 5.8 % (blank spiked with BPA at 0.12, 0.6 and 1.2 mg/kg, n = 9) Calibration = 0.03 to 1.2 mg/kg Measures taken to reduce contamination: No measures against contamination reported	Included
Revision of analytical strategies to evaluate different migrants from food packaging materials. Sendón García, R., Sanches Silva, A., Cooper, I., Franz, R. and Paseiro Losada, P. Trends in Food Science and Technology. 2006. 17:7, 354–366.	Not considered	Not considered	Not considered	Not considered	Excluded - no relevant data for calculation of exposure of specific populations from food contact materials

Title Authors Journal. Year. Volume: Issue, Page number DOI	Country of origin of samples	Sample description	Migration test conditions	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
10.1016/j.tifs.2006.01.005					
Comparison of migration from polyethersulphone and polycarbonate baby bottles. Simoneau, C., Valzacchi, S., Morkunas, V. and Van den Eede, L. Food Additives and Contaminants. Part A. 2011. 28:12, 1763-1768. 10.1080/19440049.2011.604644	Samples were purchased in 9 European countries	40 PC baby bottles	70ºC for 2 hours	50% ethanol food simulant samples were analysed directly by LC-DAD and FLD LOD = 0.1 µg/kg LOQ = 0.3 µg/kg Recovery = not given Repeatability = not given Calibration = not given Measures taken to reduce contamination: No measures against contamination reported	Included NOTE: although the method performance data was not well described the paper provided data for a comprehensive number and range of sample types provided data not available elsewhere.
Identification and quantification of the migration of chemicals from plastic baby bottles used as substitutes for polycarbonate. Simoneau, C., Van den Eede, L. and Valzacchi, S. Food Additives and Contaminants. Part A. 2012. 29:3, 469-480. 10.1080/19440049.2011.644588	Not considered	Not considered	Not considered	Not considered	Excluded - no relevant data for calculation of exposure of specific population from food contact materials
Recycled paper–paperboard for food contact materials: Contaminants suspected and migration into foods and food simulant. Suciu, N. A., Tiberto, F., Vasileiadis, S., Lamastra, L. and Trevisan, M. Food Chemistry. 2013. 141:4, 4146-4151. 10.1016/j.foodchem.2013.07.014	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)

Title Authors Journal. Year. Volume: Issue, Page number DOI	Country of origin of samples	Sample description	Migration test conditions	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
Rapid Assay of Bisphenol A Released from Baby Feeding Bottles by Adsorptive Stripping Voltammetry on a Diphenylether Carbon Paste Electrode. Symeonidou, A. Economou, A., Efstathiou, C. E. and Dousikou, M. Analytical Letters 2012. 45:5-6, 436-448. 10.1080/00032719.2011.649447	Not considered	Not considered	Not considered	Not considered	Excluded – conventional exposure conditions wer not used (single sample) and method performance data was not well defined
Ultrasound-assisted emulsification microextraction coupled with gas chromatography-mass spectrometry using the Taguchi design method for bisphenol migration studies from thermal printer paper, toys and baby utensils. Viñas, P., Lopez-Garcia, I., Campillo, N., Rivas, R. E. and Hernandez-Cordoba, M. Analytical and Bioanalytical Chemistry. 2012. 404:3, 671-678. 10.1007/s00216-012-5957-z	Not considered	Not considered	Not considered	Not considered	Excluded - no relevant data for calculation of exposure of specific populations from food contact materials. Reported studies determining the transfer to saliva rather than migration data for food simulants
Comparison of two derivatization-based methods for solid-phase microextraction-gas chromatography-mass spectrometric determination of bisphenol A, bisphenol S and biphenol migrated from food cans Viñas, P., Campillo, N., Martinez-Castillo, N. and Hernandez-Cordoba, M. Analytical and Bioanalytical Chemistry. 2010. 397:1, 115-125. 10.1007/s00216-010-3464-7	Not considered	Not considered	Not considered	Not considered	Excluded – no relevant data for calculation of exposure of specific populations from food contact materials
Sensitive gas chromatographic-mass spectrometric	Not	Not	Not	Not considered	Excluded – no relevant

Title Authors Journal. Year. Volume: Issue, Page number DOI	Country of origin of samples	Sample description	Migration test conditions	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
(GC-MS) method for the determination of bisphenol A in rice-prepared dishes. Zafra-Gómez, A., Morales, J. C., Ballesteros, O. and Navalón, A. Food Additives and Contaminants. 2009. 26:8, 1209-1216. 10.1080/02652030902939663	considered	considered	considered		data for calculation of exposure of specific populations from food contact materials
Electrochemical sensor for bisphenol A based on magnetic nanoparticles decorated reduced graphene oxide. Zhang, Y., Cheng, Y., Zhou, Y., Li, B., Gu, W., Shi, X. and Xian, Y. Talanta. 2013. 107: 211-218. 10.1016/j.talanta.2013.01.012	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)

Table 67: Literature quality table—occurrence in non-food matrices

Title Authors Journal. Year. Volume: Issue, Page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
Composite restorations may lead to increased concentrations of salivary and urinary BPA. Akeroyd, J. M. and Maserejian, N. N. The journal of evidence-based dental practice. 2013. 13:2, 64-66 10.1016/j.jebdp.2013.04.006	Dental	Not considered	Not considered	Not considered	Excluded - dental materials not included in total exposure determination.
Detection and quantification of traces of bisphenol A and bisphenol S in paper samples using analytical pyrolysis-GC/MS. Becerra, V. and Odermatt, J. Analyst. 2012. 137:9, 2250-2259. 10.1039/c2an15961a	Paper	Not considered	Not considered	Not considered	Excluded - analytical method paper - no relevant data for calculation of exposure from non-food sources
Interferences in the direct quantification of bisphenol S in paper by means of thermochemolysis Becerra, V. and Odermatt, J. Journal of Chromatography A. 2013. 1275, 70-77. 10.1016/j.chroma.2012.12.034	Paper	Not considered	Not considered	Not considered	Excluded - analytical method paper - no relevant data for calculation of exposure from non-food sources
Release of bisphenol A from polycarbonate baby bottles: water hardness as the most relevant factor. Biedermann-Brem, S. and Grob, K. European Food Research and Technology. 2009. 228:5, 679-684. 10.1007/s00217-008-0978-8	Food contact material	Not considered	Not considered	Not considered	Excluded - food contact material and migration data only - no relevant data for calculation of exposure from non-food sources
Transfer of bisphenol A from thermal printer paper to the skin. Biedermann, S., Tschudin, P. and Grob, K. Analytical and Bioanalytical Chemistry. 2010. 398:1, 571-576. 10.1007/s00216-010-3936-9	Paper	13 thermal printing papers (receipts and recorders for chromatographic instruments)	Switzerland	BPA was extracted from the paper by immersion in methanol overnight at 60°C. Analysis was carried out by LC-FLD LOD = Not given LOQ = 0.05 µg in 10 mL ethanol Recovery = Not given	Included

Title Authors Journal. Year. Volume: Issue, Page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
				Repeatability = 4 % for repeat (n = 6) analysis of an extract at 1.2 µg/mL Calibration = 0.1 to 50 µg/mL Measures taken to reduce contamination: No measures against contamination reported (levels detected are high and so typical background levels would not influence the concentrations measured in the samples)	
Detection of Bisphenol A on a Screen-Printed Carbon Electrode in CTAB Micellar Medium. Brugnera, M. F., Trindade, M. A. G. and Zanoni, M. V. B. Analytical Letters. 2010. 43:18, 2823-2836. 10.1080/00032711003731332	River water and sewage	Not considered	Not considered	Not considered	Excluded - environmental data only - no relevant data for calculation of exposure from non-food sources
Stir bar sorptive extraction with EG-Silicone coating for 4 bisphenols determination in personal care products by GC-MS. Cacho, J. I., Campillo, N., Viñas, P. and Hernández-Córdoba, M. Journal of Pharmaceutical and Biomedical Analysis. 2013. 78-79, 255-260. 10.1016/j.jpba.2013.02.023	Personal care products	30 cosmetic and personal care products	Spain	Following dilution with water the BPA was extracted using stir bar sorptive extraction, and analysed by thermal desorption GC-MS LOD = 8.7 µg/kg LOQ = 29.2 µg/kg Recovery = 89-114 % (replicate, n=10, analysis of three samples spiked with BPA and 40 and 160 µg/kg) Repeatability = 2.1-11 % (replicate, n=10, analysis of three samples spiked with BPA and 40 and 160 µg/kg) Calibration = 0. 5 - 20 µg/L	Included NOTE: although the paper was published in 2013 the comprehensive number and range of sample types provided data not otherwise available in Europe NOTE: this paper was not included in contractors database but the report provided data for exposure from personal care products that was not available elsewhere

Title Authors Journal. Year. Volume: Issue, Page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
				Measures taken to reduce contamination: No measures against contamination reported	
Dental composite fillings and bisphenol A among children: a survey in South Korea. Chung, S. Y., Kwon, H., Choi, Y. H., Karmaus, W., Merchant, A. T., Song, K. B., Sakong, J., Ha, M., Hong, Y. C. and Kang, D. International Dental Journal. 2012. 62:2, 65-69. 10.1111/j.1875-595X.2011.00089.x	Dental	Not considered	Not considered	Not considered	Excluded - dental materials not included in the calculation of exposure from non-food sources
Quantitative analysis of organophosphate and pyrethroid insecticides, pyrethroid transformation products, polybrominated diphenyl ethers and bisphenol A in residential surface wipe samples. Clifton, M. S., Wargo, J. P., Weathers, W. S., Colon, M., Bennett, D. H. and Tulve, N. S. Journal of Chromatography A. 2013. 1273, 1-11. 10.1016/j.chroma.2012.11.003	Surface wipes	Not considered	USA	Not considered	Excluded – samples from USA (i.e. did not meet geographical origin criteria)
Dermal penetration of bisphenol A in human skin contributes marginally to total exposure. Demierre, A. L., Peter, R., Oberli, A. and Bourqui-Pittet, M. Toxicology Letters. 2012. 213:3, 305-308. 10.1016/j.toxlet.2012.07.001	Absorption data	Not considered	Not considered	Not considered	Excluded – absorption paper - no relevant data for calculation of exposure from non-food sources NOTE: This manuscript was considered for determination of the absorption of BPA, but excluded for methodological reasons
Orthodontic materials research and applications: part 2. Current status and projected future developments in materials and biocompatibility. Eliades, T. American Journal of Orthodontics and Dentofacial	Dental	Not considered	Not considered	Not considered	Excluded - dental materials not included in total exposure determination.

Title Authors Journal. Year. Volume: Issue, Page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
Orthopedics. 2007. 131:2, 253-262. 10.1016/j.ajodo.2005.12.029					
Assessment of bisphenol-A release from orthodontic adhesives. Eliades, T., Hiskia, A., Eliades, G. and Athanasiou, A. E. American Journal of Orthodontics and Dentofacial Orthopedics. 2007. 131:1, 72-75. 10.1016/j.ajodo.2006.08.013	Dental	Not considered	Not considered	Not considered	Excluded - dental materials not included in total exposure determination
Release of bisphenol-A from a light-cured adhesive bonded to lingual fixed retainers. Eliades, T., Voutsa, D., Sifakakis, I., Makou, M. and Katsaros, C. American Journal of Orthodontics and Dentofacial Orthopedics. 2011. 139:2, 192-195. 10.1016/j.ajodo.2009.12.02	Dental	Not considered	Not considered	Not considered	Excluded - dental materials not included in total exposure determination
Bisphenol A and related compounds in dental materials. Fleisch, A. F., Sheffield, P. E., Chinn, C., Edelstein, B. L. and Landrigan, P. J. Pediatrics. 2010. 126:4, 760-768. 10.1542/peds.2009-2693	Dental	Not considered	Not considered	Not considered	Excluded - dental materials not included in total exposure determination
Determination of bisphenol A in thermal printing papers treated by alkaline aqueous solution using the combination of single-drop microextraction and HPLC. Gao, L., Zou, J., Liu, H., Zeng, J., Wang, Y. and Chen, X. Journal of Separation Science. 2013. 36:7, 1298-1303. 10.1002/jssc.201201060	Thermal paper	Not considered	China	Not considered	Excluded – samples from China (i.e. did not meet geographical origin criteria)
Assessment of human exposure to Bisphenol-A, Triclosan and Tetrabromobisphenol-A through	Dust	Dust from 18 houses and 2	Belgium	Dust samples were filtered and BPA was extracted from the dust	Included

Title Authors Journal. Year. Volume: Issue, Page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
indoor dust intake in Belgium. Geens, T., Roosens, L., Neels, H. and Covaci, A. Chemosphere. 2009. 76:6, 755-760. 10.1016/j.chemosphere.2009.05.024		offices collected using a vacuum cleaner		with a mixture of hexane and acetone (3:1). Following solid phase extraction the samples were evaporated to dryness and reconstituted in methanol. A labelled BPA internal standard was used. Analysis was carried out by LC-MS/MS LOD = Not given LOQ = 3 µg/kg of dust Recovery = Not given (results automatically corrected through use of labelled internal standard) Repeatability = 6 % for repeat (n = 6) analysis of a homogenised dust sample Calibration = Range not given (seven levels used) Measures taken to reduce contamination: The procedural blank sample was taken into account when determining the method LOQ	NOTE: although method performance data was not well described the paper provided data for exposure from dust that was not available elsewhere
Are potential sources for human exposure to bisphenol-A overlooked? Geens, T., Goeyens, L. and Covaci, A. International Journal of Hygiene and Environmental Health. 2011. 214:5, 339-347. 10.1016/j.ijheh.2011.04.005	Review paper	Not considered	Not considered	Not considered	Excluded – review paper - no primary data for calculation of exposure from non-food sources
A review of dietary and non-dietary exposure to bisphenol-A. Geens, T., Aerts, D., Berthot, C., Bourguignon, J. P.,	Review paper	Not considered	Not considered	Not considered	Excluded – review paper - no primary data for calculation of exposure from

Title Authors Journal. Year. Volume: Issue, Page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
Goeyens, L., Lecomte, P., Maghuin-Rogister, G., Pironnet, A. M., Pussemier, L., Scippo, M. L., Van Loco, J. and Covaci, A. Food and Chemical Toxicology. 2012. 50:10, 3725-3740. 10.1016/j.fct.2012.07.059					non-food sources
Levels of bisphenol-A in thermal paper receipts from Belgium and estimation of human exposure. Geens, T., Goeyens, L., Kannan, K., Neels, H. and Covaci, A. The Science of the Total Environment. 2012. 435-436, 30-33. 10.1016/j.scitotenv.2012.07.001	Paper	Not considered	Not considered	Not considered	Excluded - no relevant data for calculation strategy of exposure from non-food sources (i.e exposure was calculated using concentration data on skin. s.4.3.3.2)
Simultaneous determination of bisphenol A, tetrabromobisphenol A, and perfluorooctanoic acid in small household electronics appliances of "Prohibition on Certain Hazardous Substances in Consumer Products" instruction using ultra-performance liquid chromatography-tandem mass spectrometry with accelerated solvent extraction Guo, Q., Du, Z., Zhang, Y., Lu, X., Wang, J. and Yu, W.H Journal of Separation Science. 2013. 36:4, 677-683. 10.1002/jssc.201200730	Household appliances	Not considered	China	Not considered	Excluded – samples from China (i.e. did not meet geographical origin criteria) and not addressing the category, i.e. household appliances are not considered in this opinion
Salivary bisphenol-A levels due to dental material/resin: a case-control study in Korean children. Han, D. H., Kim, M. J., Jun, E. J. and Kim, J. B. Journal of Korean Medical Science. 2012. 27:9, 1098-1104. 10.3346/jkms.2012.27.9.1098	Dental	Not considered	Not considered	Not considered	Excluded - dental materials not included in total exposure determination
Comment on "High levels of bisphenol A in paper currencies from several countries, and implications	Paper	Not considered	Not considered	Not considered	Excluded - no primary data for calculation of exposure

Title Authors Journal. Year. Volume: Issue, Page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
for dermal exposure. Heinze, J. E. Environmental Science and Technology. 2011. 45:21, 9464 10.1021/es203169y					from non-food sources
Quantitative Analysis of Bisphenol A Leached from Household Plastics by Solid–Phase Microextraction and Gas Chromatography–Mass Spectrometry (SPME–GC–MS). Johnson, B. O., Burke, F. M., Harrison, R. and Burdette, S. Journal of Chemical Education. 2012. 89, 1555−1560. 10.1021/ed2003884	Consumer products	Not considered	Not considered	Not considered	Excluded – source not included in total exposure determination
No Dental Dilemma for BPA. Josephson, J. Environmental Health Perspectives. 2006. 114:7, A404. None given	Dental	Not considered	Not considered	Not considered	Excluded - dental materials not included in total exposure determination
Release of bisphenol A from resin composite used to bond orthodontic lingual retainers. Kang, Y. G., Kim, J. Y., Kim, J., Won, P. J. and Nam, J. H. American Journal of Orthodontics and Dentofacial Orthopedics. 2011. 140:6, 779-789. 10.1016/j.ajodo.2011.04.022	Dental	Not considered	Not considered	Not considered	Excluded - dental materials not included in total exposure determination
Bisphenol A and other compounds in human saliva and urine associated with the placement of composite restorations. Kingman, A., Hyman, J., Masten, S. A., Jayaram, B., Smith, C., Eichmiller, F., Arnold, M. C., Wong, P. A., Schaeffer, J. M., Solanki S. and Dunn, W. J. Journal of the American Dental Association. 2012.	Dental	Not considered	Not considered	Not considered	Excluded - dental materials not included in total exposure determination.

Title Authors Journal. Year. Volume: Issue, Page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
143, 1292-1302. None given					
Bisphenol-A and residual monomer leaching from orthodontic adhesive resins and polycarbonate brackets: A systematic review. Kloukos, D., Pandis, N. and Eliades, T. American Journal of Orthodontics and Dentofacial Orthopedics. 2013. 143:4, S104-S112.e2. 10.1016/j.ajodo.2012.11.015	Dental	Not considered	Not considered	Not considered	Excluded - dental materials not included in total exposure determination.
In vivo bisphenol-A release from dental pit and fissure sealants: A systematic review. Kloukos, D., Pandis, N. and Eliades, T. Journal of Dentistry. 2013. 41, 659-667. 10.1016/j.jdent.2013.04.012	Dental	Not considered	Not considered	Not considered	Excluded - dental materials not included in total exposure determination.
High levels of bisphenol A in paper currencies from several countries, and implications for dermal exposure. Liao, C. and Kannan, K. Environmental Science and Technology. 2011. 45:16, 6761-6768. 10.1021/es200977t	Paper	Not considered	Various, samples purchased in USA	Not considered	Excluded – samples from various countries worldwide, obtained in USA (i.e. did not meet geographical origin criteria)
Widespread occurrence of bisphenol A in paper and paper products: implications for human exposure. Liao, C. and Kannan, K. Environmental Science and Technology. 2011, 45:21, 9372-9379. 10.1021/es202507f	Paper	Not considered	USA, Japan, Korea and Vietnam	Not considered	Excluded – samples from USA, Japan, Korea and Vietnam (i.e. did not meet geographical origin criteria)
Reply to Comment on “High Levels of Bisphenol A in Paper Currencies from Several Countries, and Implications for Dermal Exposure”. Liao, C. and Kannan, K. Environmental Science and Technology. 2011. 45, 9465-9466.	Paper	Not considered	Not considered	Not considered	Excluded - no primary data for calculation of exposure from non-food sources

Title Authors Journal. Year. Volume: Issue, Page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
10.1021/es203380e					
Occurrence of eight bisphenol analogues in indoor dust from the United States and several Asian countries: implications for human exposure. Liao, C., Liu, F., Guo, Y., Moon, H. B., Nakata, H., Wu, Q. and Kannan, K. Environmental Science and Technology. 2012. 46:16, 9138-9145. 10.1021/es302004w	Dust	Not considered	USA, China, Japan and Korea	Not considered	Excluded - samples from USA, China, Japan and Korea (i.e. did not meet geographical origin criteria)
Bisphenol S, a new bisphenol analogue, in paper products and currency bills and its association with bisphenol A residues. Liao, C., Liu, F. and Kannan, K. Environmental Science and Technology. 2012. 46:12, 6515-6522. 10.1021/es300876n	Paper	Not considered	Not considered	Not considered	Excluded - not related to BPA - no relevant data for calculation of exposure from non-food sources
Occurrence of bisphenol A in indoor dust from two locations in the eastern United States and implications for human exposures. Loganathan, S. N. and Kannan, K. Archives of Environmental Contamination and Toxicology. 2011. 61:1, 68-73. 10.1007/s00244-010-9634-y	Dust	Not considered	USA	Not considered	Excluded - samples from USA (i.e. did not meet geographical origin criteria)
Bisphenol A in supermarket receipts and its exposure to human in Shenzhen, China. Lu, S.-Y., Chang, W.-J., Sojinu, S. O. and Ni, H.-G. Chemosphere. 2013. 92, 1190-1194. 10.1016/j.chemosphere.2013.01.096	Paper	Not considered	China	Not considered	Excluded – samples from China (i.e. did not meet geographical origin criteria)
Exposure to Bisphenol A (BPA) from dental materials is detectable in saliva and urine, and varies significantly between material formulations. Martin, M. D. The Journal of Evidence-Based Dental Practice.	Dental	Not considered	Not considered	Not considered	Excluded - dental materials not included in total exposure determination

Title Authors Journal. Year. Volume: Issue, Page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
2007. 7:2, 79-80. 10.1016/j.jebdp.2007.03.008					
Concentration of bisphenol A in thermal paper. Mendum, T., Stoler, E., VanBenschoten, H. and Warner, J. C. Green Chemistry Letters and Reviews. 2011. 4:1, 81-86. 10.1080/17518253.2010.502908	Paper	Not considered	USA	Not considered	Excluded - samples from USA (i.e. did not meet geographical origin criteria)
The contribution of dermal exposure to the internal exposure of bisphenol A in man. Mielke, H., Partosch, F. and Gundert-Remy, U. Toxicology Letters. 2011. 204:2-3, 190-198. 10.1016/j.toxlet.2011.04.032	Absorption data	Not considered	Not considered	Not considered	Excluded – absorption paper - no primary data for calculation of exposure from non-food sources NOTE: This manuscript was considered for determination of the absorption of BPA, but excluded for methodological reasons
Assessing the quantitative relationships between preschool children's exposures to bisphenol A by route and urinary biomonitoring. Morgan, M. K., Jones, P. A., Calafat, A. M., Ye, X., Croghan, C. W., Chuang, J. C., Wilson, N. K., Clifton, M. S., Figueroa, Z. and Sheldon, L. S. Environmental Science and Technology. 2011. 45:12, 5309-5316. 10.1021/es200537u	Indoor air, outdoor air, house dust, indoor surface	Not considered	USA	Not considered	Excluded - samples from USA (i.e. did not meet geographical origin criteria)
Long-term release of monomers from modern dental-composite materials. Polydorou, O., König, A., Hellwig, E. and Kümmerer, K. European Journal of Oral Science. 2009. 117, 68-75. None given	Dental	Not considered	Not considered	Not considered	Excluded - dental materials not included in total exposure determination

Title Authors Journal. Year. Volume: Issue, Page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
Effect of bleaching on the elution of monomers from modern dental composite materials. Polydorou, O., Beiter, J., König, A., Hellwig, E. and Kümmerer, K. Dental Materials. 2009. 25:2, 254-260. 10.1016/j.dental.2008.07.004	Dental	Not considered	Not considered	Not considered	Excluded - dental materials not included in exposure determination
Release of monomers from different core build-up materials. Polydorou, O., Hammad, M., König, A., Hellwig, E. and Kümmerer, K. Dental Materials. 2009. 25:9, 1090-1095. 10.1016/j.dental.2009.02.014	Dental	Not considered	Not considered	Not considered	Excluded - dental materials not included in total exposure determination
Elution of monomers from two conventional dental composite materials. Polydorou, O., Trittler, R., Hellwig, E. and Kümmerer, K. Dental Materials. 2007. 23:12, 1535-1541. 10.1016/j.dental.2006.12.011	Dental	Not considered	Not considered	Not considered	Excluded - dental materials not included in total exposure determination
Bisphenol A in dental materials and its estrogen like effect Rathee, M., Malik, P. and Singh, J. Indian Journal of Endocrinology and Metabolism. 2012. 16:3, 339-342. 10.4103/2230-8210.95660	Dental	Not considered	Not considered	Not considered	Excluded - dental materials not included in total exposure determination
Indoor airborne particle sources and semi-volatile partitioning effect of outdoor fine PM in offices Sangiorgi, G., Ferrero, L., Ferrini, B. S., Lo Porto, C., Perrone, M. G., Zangrando, R., Gambaro, A., Lazzati, Z. and Bolzacchini, E. Atmospheric Environment. 2013. 65, 205-214. 10.1016/j.atmosenv.2012.10.050	Indoor and outdoor air	Particulate matter taken from air at four sites	Italy	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Occurrence of bisphenol A in surface water, drinking water and plasma from Malaysia with exposure	Surface water	Not considered	Not considered	Not considered	Excluded – environment and drinking water data - no

Title Authors Journal. Year. Volume: Issue, Page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
assessment from consumption of drinking water. Santhi, V. A., Sakai, N., Ahmad, E. D. and Mustafa, A. M. The Science of the Total Environment. 2012. 427-428, 332-338. 10.1016/j.scitotenv.2012.04.041					relevant data for calculation of exposure from non-food sources
How much do resin-based dental materials release? A meta-analytical approach. Van Landuyt, K. L., Nawrot, T., Geebelen, B., De Munck, J., Snauwaert, J., Yoshihara, K., Scheers, H., Godderis, L., Hoet, P. and Van Meerbeek, B. Dental Materials. 2011. 27:8, 723-747. 10.1016/j.dental.2011.05.001	Dental	Not considered	Not considered	Not considered	Excluded - dental materials not included in total exposure determination
Systematic review of the chemical composition of contemporary dental adhesives. Van Landuyt, K. L., Snauwaert, J., De Munck, J., Peumans, M., Yoshida, Y., Poitevin, A., Coutinho, E., Suzuki, K., Lambrechts, P. and Van Meerbeek, B. Biomaterials. 2007. 28:26, 3757-3785. 10.1016/j.biomaterials.2007.04.044	Dental	Not considered	Not considered	Not considered	Excluded - dental materials not included in total exposure determination
Ultrasound-assisted emulsification microextraction coupled with gas chromatography-mass spectrometry using the Taguchi design method for bisphenol migration studies from thermal printer paper, toys and baby utensils. Viñas, P., López-Garcia, I., Campillo, N., Rivas, R. E. and Hernandez-Córdoba, M. Analytical and Bioanalytical Chemistry. 2012. 404:3, 671-678. 10.1007/s00216-012-5957-z	Paper and Toys	Fifteen samples, including thermal printer paper, CDs, DVDs, small tight-fitting waistcoats, baby's bottles, baby bottle nipples and children's toys	Spain	BPA was extracted from the paper by immersion in water. Toys were immersed in saliva simulant. Derivatisation with acetic anhydride and BSTFA were compared. Analysis was carried out by GC. LOD = 0.1 µg/L LOQ = 0.3 µg/L Recovery = Not given Repeatability = 7.6 % (replicate, n=10, analyses of samples at	Excluded – experimental setup not appropriate for exposure determination

Title Authors Journal. Year. Volume: Issue, Page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
				1 µg/L) Calibration = 0.1 to 3 µg/L Measures taken to reduce contamination: No measures against contamination reported	
Bisphenol a: how the most relevant exposure sources contribute to total consumer exposure. von Goetz, N., Wormuth, M., Scheringer, M. and Hungerbuhler, K. Risk Analysis. 2010. 30:3, 473-487. 10.1111/j.1539-6924.2009.01345.x	Various - review paper	Not considered	Not considered	Not considered	Excluded – modelling paper - no primary data for calculation of exposure from non-food sources
SVOC exposure indoors: fresh look at dermal pathways. Weschler, C. J. and Nazaroff, W. W. Indoor Air. 2012. 22:5, 356-377. 10.1111/j.1600-0668.2012.00772.x	Indoor surfaces	Not considered	Not considered	Not considered	Excluded – modelling paper - no primary data for calculation of exposure from non-food sources
An observational study of the potential exposures of preschool children to pentachlorophenol, bisphenol-A, and nonylphenol at home and daycare. Wilson, N. K., Chuang, J. C., Morgan, M. K., Lordo, R. A. and Sheldon, L. S. Environmental Research. 2007. 103:1, 9-20. 10.1016/j.envres.2006.04.006	Indoor air, outdoor air, house dust, indoor surfaces	Not considered	USA	Not considered	Excluded – samples from USA (i.e. did not meet geographical origin criteria)
Pt/graphene-CNTs nanocomposite based electrochemical sensors for the determination of endocrine disruptor bisphenol A in thermal printing papers. Zheng, Z., Du, Y., Wang, Z., Feng, Q. and Wang, C. Analyst. 2013. 138:2, 693-701. 10.1039/c2an36569c	Paper	Not considered	China	Not considered	Excluded – samples from China (i.e. did not meet geographical origin criteria)
Molecularly imprinted layer-coated silica nanoparticles for selective solid-phase extraction of	Cosmetics	Not considered	China	Not considered	Excluded - samples from China (i.e. did not meet

Title Authors Journal. Year. Volume: Issue, Page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A and reasoning
bisphenol A from chemical cleansing and cosmetics samples. Zhu, R., Zhao, W., Zhai, M., Wei, F., Cai, Z., Sheng, N. and Hu, Q. Analytica Chimica Acta. 2010. 658:2, 209-216. 10.1016/j.aca.2009.11.008					geographical origin criteria)
Bisphenol A Blood and Saliva Levels Prior To and After Dental Sealant Placement In Adults Zimmerman Downs, J. M., Shuman, D., Stull, S. C. and Ratzlaff, R. E. The Journal of Dental Hygiene. 2010. 84, 145-150. None given	Dental	Not considered	Not considered	Not considered	Excluded - dental materials not included in total exposure determination

Table 68: Literature quality table—occurrence in the environment

Title Authors Journal. Year. Volume: issue, page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[27] and reasoning
Sensitive gas chromatographic-mass spectrometric method for the determination of phthalate esters, alkylphenols, bisphenol A and their chlorinated derivatives in wastewater samples. Ballesteros, O. Zafra, A. Navalon, A. and Vilchez, J. L. Journal of Chromatography A. 2006. 1121:2, 154-162. 10.1016/j.chroma.2006.04.014	Waste water	Not considered	Not considered	Not considered	Excluded - waste water not included in exposure determination
Determination of bisphenols A and F and their diglycidyl ethers in wastewater and river water by coacervative extraction and liquid chromatography-fluorimetry. Ballesteros-Gomez, A., Ruiz, F. J., Rubio, S. and Perez-Bendito, D. Analytica Chimica Acta. 2007. 603:1, 51-59. 10.1016/j.aca.2007.09.048	Surface water	Not considered	Not considered	Not considered	Excluded - surface water not included in exposure determination
Multiresidue analytical methods for the ultra-trace quantification of 33 priority substances present in the list of REACH in real water samples Baugros, J. B., Giroud, B., Dessalces, G., Grenier-Loustalot, M. F. and Cren-Olive, C. Analytica Chimica Acta. 2008. 607:2, 191-203. 10.1016/j.aca.2007.11.036	Surface water	Not considered	Not considered	Not considered	Excluded - surface water not included in exposure determination
Biologically directed environmental monitoring, fate, and transport of estrogenic endocrine disrupting compounds in water: A review. Campbell, C. G., Borglin, S. E., Green, F. B., Grayson, A., Wozei, E. and Stringfellow, W. T. Chemosphere. 2006. 65:8, 1265-1280. 10.1016/j.chemosphere.2006.08.003	Surface water	Not considered	Not considered	Not considered	Excluded - surface water not included in exposure determination
Bisphenol A occurred in Kao-Pin River and its tributaries in Taiwan. Chen, T. C., Shue, M. F., Yeh, Y. L. and Kao, T. J. Environmental Monitoring and Assessment. 2010. 161:1-4, 135-145. 10.1007/s10661-008-0733-4	Surface water	Not considered	Not considered	Not considered	Excluded - surface water not included in exposure determination
Determination of bisphenol A in water via inhibition of silver	Industrial	Not	Not	Not considered	Excluded - waste water

[27] For inclusion/exlusion criteria see Appendix A.

Title Authors Journal. Year. Volume: issue, page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[27] and reasoning
nanoparticles-enhanced chemiluminescence. Chen, X., Wang, C., Tan, X. and Wang, J. Analytica Chimica Acta. 2011. 689:1, 92-96. 10.1016/j.aca.2011.01.031	wastewater and river water	considered	considered		and river water not included in exposure determination
Hollow fiber liquid-liquid-liquid microextraction combined with high performance liquid chromatography-ultraviolet detection for the determination of various environmental estrogens in environmental and biological samples. Chen, B., Huang, Y., He, M. and Hu, B. Journal of Chromatography A. 2013. 1305, 17-26. 10.1016/j.chroma.2013.06.029	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Occurrence and assessment of treatment efficiency of nonylphenol, octylphenol and bisphenol-A in drinking water in Taiwan. Chen, H. W., Liang, C. H., Wu, Z. M., Chang, E. E., Lin, T. F., Chiang, P. C. and Wang, G. S. The Science of the Total Environment. 2013. 449, 20-28. 10.1016/j.scitotenv.2013.01.038	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Alkylphenolic compounds and bisphenol A contamination within a heavily urbanized area: case study of Paris. Cladière, M., Gasperi, J., Lorgeoux, C., Bonhomme, C., Rocher, V. and Tassin, B. Environmental Science and Pollution Research. 2013. 20:5, 2973-2983. 10.1007/s11356-012-1220-6	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Emerging pollutants in wastewater: a review of the literature. Deblonde, T., Cossu-Leguille, C. and Hartemann, P. International Journal of Hygiene and Environmental Health. 2011. 214:6, 442-448. 10.1016/j.ijheh.2011.08.002	Waste water	Not considered	Not considered	Not considered	Excluded - waste water not included in exposure determination
Uptake and accumulation of four PPCP/EDCs in two leafy vegetables. Dodgen, L. K., Li, J., Parker, D. and Gan, J. J. Environmental Pollution. 2013. 182, 150-156. 10.1016/j.envpol.2013.06.038	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet

Title Authors Journal. Year. Volume: issue, page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[27] and reasoning
					publication period criteria)
Detection and occurrence of chlorinated byproducts of bisphenol a, nonylphenol, and estrogens in drinking water of china: comparison to the parent compounds. Fan, Z., Hu, J., An, W. and Yang, M. Environmental Science and Technology. 2013. 47:19, 10841-10850. 10.1021/es401504a	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Gas-liquid chromatography-tandem mass spectrometry methodology for the quantitation of estrogenic contaminants in bile of fish exposed to wastewater treatment works effluents and from wild populations. Fenlon, K. A., Johnson, A. C., Tyler, C. R. and Hill, E. M. Journal of Chromatography A. 2010. 1217:1, 112-118. 10.1016/j.chroma.2009.10.063	Not applicable	Not considered	Not considered	Not considered	Excluded - environmental risk paper - not relevant for occurrence in the environment
Bisphenol A exposure, effects, and policy: a wildlife perspective. Flint, S., Markle, T., Thompson, S. and Wallace, E. Journal of Environmental Management. 2012. 104, 19-34. 10.1016/j.jenvman.2012.03.021	Not applicable	Not considered	Not considered	Not considered	Excluded - environmental risk paper - not relevant for occurrence in the environment
A national reconnaissance for pharmaceuticals and other organic wastewater contaminants in the United States--II) untreated drinking water sources. Focazio, M. J., Kolpin, D. W., Barnes, K. K., Furlong, E. T., Meyer, M. T., Zaugg, S. D., Barber, L. B. and Thurman, M. E. The Science of the Total Environment. 2008. 402:2-3, 201-216. 10.1016/j.scitotenv.2008.02.021	Waste water	Not considered	Not considered	Not considered	Excluded - waste water not included in exposure determination
Ubiquity of bisphenol A in the atmosphere. Fu, P. and Kawamura, K. Environmental Pollution. 2010. 158:10, 3138-3143. 10.1016/j.envpol.2010.06.040	Outdoor air	Not considered	Not considered	Not considered	Excluded - outdoor atmosphere not included in exposure determination
On-line solid phase extraction fast liquid chromatography-tandem mass spectrometry for the analysis of bisphenol A and its chlorinated	Surface water	Not considered	Not considered	Not considered	Excluded - surface water not included in exposure

Title Authors Journal. Year. Volume: issue, page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[27] and reasoning
derivatives in water samples. Gallart-Ayala, H., Moyano, E. and Galceran, M. T. Journal of Chromatography A. 2010. 1217:21, 3511-3518. 10.1016/j.chroma.2010.03.028					determination
Determination of acidic pharmaceuticals and potential endocrine disrupting compounds in wastewaters and spring waters by selective elution and analysis by gas chromatography-mass spectrometry Gibson, R., Becerril-Bravo, E., Silva-Castro, V. and Jimenez, B. Journal of Chromatography A, 2007. 1169:1-2, 31-39. 10.1016/j.chroma.2007.08.056	Waste water	Not considered	Not considered	Not considered	Excluded - waste water not included in exposure determination
A new method for monitoring oestrogens,N-octylphenol, and bisphenol A in wastewater treatment plants by solid-phase extraction–gas chromatography–tandem mass spectrometry. Gómez, M. J., Mezcua, M., Martinez, M. J., Fernández-Alba, A R. and Agüera, A. International Journal of Environmental Analytical Chemistry. 2006, 86:1-2, 3-13. 10.1080/03067310500247983	Waste water	Not considered	Not considered	Not considered	Excluded - waste water not included in exposure determination
Multi-residue analytical method for the determination of endocrine disruptors and related compounds in river and waste water using dual column liquid chromatography switching system coupled to mass spectrometry. Gorga, M., Petrovic, M. and Barceló, D. Journal of Chromatography A. 2013. 1295, 57-66. 10.1016/j.chroma.2013.04.028	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Simultaneous determination of hexabromocyclododecane, tetrabromobisphenol A, and related compounds in sewage sludge and sediment samples from Ebro River basin (Spain). Guerra, P., Eljarrat, E. and Barcelo, D. Analytical and Bioanalytical Chemistry. 2010. 397:7, 2817-2824. 10.1007/s00216-010-3670-3	Sewage water	Not considered	Not considered	Not considered	Excluded - sewage water not included in exposure determination
Occurrence of phenols and phenoxyacid herbicides in environmental waters using an imprinted polymer as a selective sorbent.	Not	Not	Not	Not considered	Excluded – paper published after

Title Authors Journal. Year. Volume: issue, page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[27] and reasoning
Herrero-Hernandez, E., Rodriguez-Gonzalo, E., Andrades, M. S., Sanchez-Gonzalez, S. and Carabias-Martinez, R. The Science of the Total Environment. 2013. 454-455, 299-306. 10.1016/j.scitotenv.2013.03.029	considered	considered	considered		December 2012 (i.e. did not meet publication period criteria)
Preparation of magnetic molecularly imprinted polymers for bisphenol A and its analogues and their application to the assay of bisphenol A in river water. Hiratsuka, Y., Funaya, N., Matsunaga, H. and Haginaka, J. Journal of Pharmaceutical and Biomedical Analysis. 2013, 75, 180-185. 10.1016/j.jpba.2012.11.030	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Environmental temperature changes uptake rate and Bioconcentration factors of bisphenol a in tadpoles of Rana temporaria Honkanen, J. O. and Kukkonen, J. V. K. Environmental Toxicology and Chemistry. 2006. 25:10, 2804-2808. DOI not given	Not applicable	Not considered	Not considered	Not considered	Excluded - environmental risk paper - not relevant for occurrence in the environment
Bisphenol A (BPA) in China: a review of sources, environmental levels, and potential human health impacts. Huang, Y. Q., Wong, C. K., Zheng, J. S., Bouwman, H., Barra, R., Wahlstrom, B., Neretin, L. and Wong, M. H. Environment International. 2012. 42, 91-99. 10.1016/j.envint.2011.04.010	Not applicable	Not considered	Not considered	Not considered	Excluded - review paper - not relevant for occurrence in the environment
BPA and environmental estrogen in potable water sources in Enugu municipality, South-East, Nigeria. Ignatius, C. M., Francis, E. E., Emeka, E. N., Elvis, N. S. and Ebele, J. I. Bulletin of Environmental Contamination and Toxicology. 2010. 85:5, 534-537. 10.1007/s00128-010-0111-0	River water and rain water	Not considered	Not considered	Not considered	Excluded - river water and rain water not included in exposure determination
Identification of organic xenobiotics in urban aquatic environments using time-of-flight mass spectrometry. Jernberg, J., Pellinen, J. and Rantalainen, A. L. The Science of the Total Environment. 2013. 450-451C, 1-6. 10.1016/j.scitotenv.2013.02.006	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period

Title Authors Journal. Year. Volume: issue, page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[27] and reasoning
					criteria)
Direct enrichment and high performance liquid chromatography analysis of ultra-trace Bisphenol A in water samples with narrowly dispersible Bisphenol A imprinted polymeric microspheres column. Jiang, M., Zhang, J. H., Mei, S. R., Shi, Y., Zou, L. J., Zhu, Y. X., Dai, K. and Lu, B. Journal of Chromatography A. 2006. 1110:1-2, 27-34. 10.1016/j.chroma.2006.01.051	Surface water	Not considered	Not considered	Not considered	Excluded - surface water not included in exposure determination
Occurrence, transportation, monitoring and treatment of emerging micro-pollutants in waste water- A review from global views. Jiang, J.-Q., Zhou, Z. and Sharma, V. K. Microchemical Journal. 2013. 110, 292–300. 10.1016/j.microc.2013.04.014	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Determination of bisphenol A, bisphenol F and their diglycidyl ethers in environmental water by solid phase extraction using magnetic multiwalled carbon nanotubes followed by GC-MS/MS. Jiao, Y., Ding, L., Fu, S., Zhu, S., Li, H. and Wang, L. Analytical Methods. 2012. 4:1, 291-298. 10.1039/c1ay05433c	Surface water	Not considered	Not considered	Not considered	Excluded - surface water not included in exposure determination
Bisphenol A in the aquatic environment and its endocrine-disruptive effects on aquatic organisms. Kang, J. H., Asai, D. and Katayama, Y. Critical Reviews in Toxicology. 2007. 37:7, 607-625. 10.1080/10408440701493103	Not applicable	Not considered	Not considered	Not considered	Excluded - environmental risk paper - not relevant for occurrence in the environment
Bisphenol A in the surface water and freshwater snail collected from rivers around a secure landfill. Kang, J. H. and Kondo, F. Bulletin of Environmental Contamination and Toxicology. 2006. 76:1, 113-118. 10.1007/s00128-005-0896-4	Not applicable	Not considered	Not considered	Not considered	Excluded - environmental risk paper - not relevant for occurrence in the environment
Distribution and biodegradation of bisphenol A in water hyacinth.	Not	Not	Not	Not considered	Excluded -

Title Authors Journal. Year. Volume: issue, page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[27] and reasoning
Kang, J. H. and Kondo, F. Bulletin of Environmental Contamination and Toxicology. 2006. 77:4, 500-507. 10.1007/s00128-006-1092-x	applicable	considered	considered		environmental risk paper - not relevant for occurrence in the environment
Liquid phase microextraction with in situ derivatization for measurement of bisphenol A in river water sample by gas chromatography-mass spectrometry. Kawaguchi, M., Ito, R., Endo, N., Okanouchi, N., Sakui, N., Saito, K. and Nakazawa, H. Journal of Chromatography A. 2006. 1110:1-2, 1-5. 10.1016/j.chroma.2006.01.061	Surface water	Not considered	Not considered	Not considered	Excluded - surface water not included in exposure determination
On-line solid-phase microextraction of triclosan, bisphenol A, chlorophenols, and selected pharmaceuticals in environmental water samples by high-performance liquid chromatography-ultraviolet detection. Kim, D., Han, J. and Choi, Y. Analytical and Bioanalytical Chemistry. 2013. 405:1, 377-387. 10.1007/s00216-012-6490-9	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Distribution of pesticides and bisphenol A in sediments collected from rivers adjacent to coral reefs. Kitada, Y., Kawahata, H., Suzuki, A. and Oomori, T. Chemosphere. 2008. 71:11, 2082-2090. 10.1016/j.chemosphere.2008.01.025	Surface water	Not considered	Not considered	Not considered	Excluded - surface water not included in exposure determination
Exposure Analysis of Bisphenol A in Surface Water Systems in North America and Europe. Klecka, G. M., Staples, C. A., Clark, K. E., Van Der Hoeven, N., Thomas, D. E. and Hentges, S. G. Environmental Science and Technology. 2009. 43, 6145-6150. 10.1021/es900598e	Surface water	Not considered	Not considered	Not considered	Excluded - surface water not included in exposure determination
Pharmaceuticals, hormones and bisphenol A in untreated source and finished drinking water in Ontario, Canada--occurrence and treatment efficiency. Kleywegt, S., Pileggi, V., Yang, P., Hao, C., Zhao, X., Rocks, C., Thach,	Surface water	Not considered	Not considered	Not considered	Excluded - surface water not included in exposure determination

Title Authors Journal. Year. Volume: issue, page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[27] and reasoning
S., Cheung, P. and Whitehead, B. The Science of the Total Environment. 2011. 409:8, 1481-1488. 10.1016/j.scitotenv.2011.01.010					
Characterization of trace organic contaminants in marine sediment from Yeongil Bay, Korea: 1. Instrumental analyses. Koh, C. H., Khim, J. S., Villeneuve, D. L., Kannan, K. and Giesy, J. P. Environmental Pollution. 2006. 142:1, 39-47. 10.1016/j.envpol.2005.09.005	Sediment	Not considered	Not considered	Not considered	Excluded - sediment not included in exposure determination
Enzyme-linked immunosorbent assay for bisphenol A: Assay optimization and its application for surface water analysis. Krapivin, A. S., Samsonova, J. V., Uskova, N. A., Ivanova, N. L. and Egorov, Al. M. Toxicological and Environmental Chemistry. 2007. 89:1, 161-172. 10.1080/02772240600954246	Surface water	Not considered	Not considered	Not considered	Excluded - surface water not included in exposure determination
The potential role of water quality parameters on occurrence of nonylphenol and bisphenol A and identification of their discharge sources in the river ecosystems. Lee, C. C., Jiang, L. Y., Kuo, Y. L., Hsieh, C. Y., Chen, C. S. and Tien, C. J. Chemosphere. 2013. 91:7, 904-911. 10.1016/j.chemosphere.2013.02.006	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Development and characterization of an immunoaffinity monolith for selective on-line extraction of bisphenol A from environmental water samples. Li, L., Wang, J., Zhou, S. and Zhao, M. Analytica Chimica Acta. 2008. 620:1-2, 1-7. 10.1016/j.aca.2008.05.036	Surface water	Not considered	Not considered	Not considered	Excluded - surface water not included in exposure determination
Determination of Bisphenol A in Landfill Leachate by Solid Phase Microextraction with Headspace Derivatization and Gas Chromatography-Mass Spectrophotometry. Li, X., Lin, L., Zou, S., Lan, C. and Luan, T. Chinese Journal of Analtical Chemistry. 2006. 34:3, 325-328. 10.1016/s1872-2040(06)60018-2	Surface water	Not considered	Not considered	Not considered	Excluded - surface water not included in exposure determination

Title Authors Journal. Year. Volume: issue, page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[27] and reasoning
Dispersive liquid–liquid microextraction based on ionic liquid in combination with high-performance liquid chromatography for the determination of bisphenol A in water Li, Y. and Liu, J. International Journal of Environmental Analytical Chemistry. 2010. 90:11, 880-890. 10.1080/03067310903045455	Surface water	Not considered	Not considered	Not considered	Excluded - surface water not included in exposure determination
High sensitivity detection of bisphenol A using liposome chromatography. Liu, X. Y., Nakamura, C., Tanimoto, I., Miyake, S., Nakamura, N., Hirano, T. and Miyake, J. Analytica Chimica Acta. 2006. 578:1, 43-49. 10.1016/j.aca.2006.07.016	Surface water	Not considered	Not considered	Not considered	Excluded - surface water not included in exposure determination
Passive sampling and stir bar sorptive extraction for the determination of endocrine-disrupting compounds in water by GC-MS. Magi, E., Di Carro, M. and Liscio, C. Analytical and Bioanalytical Chemistry. 2010. 397:3, 1335-1345. 10.1007/s00216-010-3656-1	Surface water	Not considered	Not considered	Not considered	Excluded - surface water not included in exposure determination
Selective Molecularly Imprinted Polymer Obtained from a Combinatorial Library for the Extraction of Bisphenol A. Martin-Esteban, A. and Tadeo, J. L. Combinatorial Chemistry and High Throughput Screening. 2006. 9, 747-751. None given	Not applicable	Not considered	Not considered	Not considered	Excluded - analytical method paper - not relevant for occurrence in the environment
Simultaneous determination of 76 micropollutants in water samples by headspace solid phase microextraction and gas chromatography-mass spectrometry. Martínez, C., Ramírez, N., Gómez, V., Pocurull, E. and Borrull, F. Talanta. 2013. 116, 937-945. 10.1016/j.talanta.2013.07.055	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Ultrasensitive one-step rapid visual detection of bisphenol A in water samples by label-free aptasensor. Mei, Z., Chu, H., Chen, W., Xue, F., Liu, J., Xu, H., Zhang, R. and Zheng,	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e.

Title Authors Journal. Year. Volume: issue, page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[27] and reasoning
L. Biosensors and Bioelectronics. 2013. 39:1, 26-30. 10.1016/j.bios.2012.06.027					did not meet publication period criteria)
Physico-chemical pre-treatment and biotransformation of wastewater and wastewater sludge--fate of bisphenol A. Mohapatra, D. P., Brar, S. K., Tyagi, R. D. and Surampalli, R. Y. Chemosphere. 2010. 78:8, 923-941. 10.1016/j.chemosphere.2009.12.053	Waste water	Not considered	Not considered	Not considered	Excluded - waste water not included in exposure determination
Application of electro-enhanced solid-phase microextraction for determination of phthalate esters and bisphenol A in blood and seawater samples. Mousa, A., Basheer, C. and Rahman Al-Arfaj, A. Talanta. 2013. 115, 308-313. 10.1016/j.talanta.2013.05.011	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Pharmaceutical chemicals and endocrine disrupters in municipal wastewater in Tokyo and their removal during activated sludge treatment. Nakada, N., Tanishima, T., Shinohara, H., Kiri, K. and Takada, H. Water Research. 2006. 40:17, 3297-3303. 10.1016/j.watres.2006.06.039	Waste water	Not considered	Not considered	Not considered	Excluded - waste water not included in exposure determination
A critical evaluation of the environmental risk assessment for plasticizers in the freshwater environment in Europe, with special emphasis on bisphenol A and endocrine disruption. Oehlmann, J., Oetken, M. and Schulte-Oehlmann, U. Environmental Research. 2008. 108:2, 140-149. 10.1016/j.envres.2008.07.016	Not applicable	Not considered	Not considered	Not considered	Excluded - environmental risk paper - not relevant for occurrence in the environment
Determination of phenolic compounds in river water with on-line coupling bisphenol A imprinted monolithic precolumn with high performance liquid chromatography. Ou, J., Hu, L., Hu, L., Li, X. and Zou, H. Talanta. 2006. 69:4, 1001-1006. 10.1016/j.talanta.2005.12.003	Surface water	Not considered	Not considered	Not considered	Excluded - surface water not included in exposure determination
Simultaneous determination of endocrine-disrupting phenols and steroid	Sediment	Not	Not	Not considered	Excluded - sediment not

Title Authors Journal. Year. Volume: issue, page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[27] and reasoning
estrogens in sediment by gas chromatography-mass spectrometry. Peng, X., Wang, Z., Yang, C., Chen, F. and Mai, B. Journal of Chromatography A. 2006. 1116:1-2, 51-56. 10.1016/j.chroma.2006.03.017		considered	considered		included in exposure determination
Multiresidue analysis of acidic and polar organic contaminants in water samples by stir-bar sorptive extraction-liquid desorption-gas chromatography-mass spectrometry. Quintana, J. B., Rodil, R., Muniategui-Lorenzo, S., Lopez-Mahia, P. and Prada-Rodriguez, D. Journal of Chromatography A. 2007. 1174:1-2, 27-39. 10.1016/j.chroma.2007.07.088	Surface water	Not considered	Not considered	Not considered	Excluded - surface water not included in exposure determination
A study of parabens and bisphenol A in surface water and fish brain tissue from the Greater Pittsburgh Area. Renz, L., Volz, C., Michanowicz, D., Ferrar, K., Christian, C., Lenzner, D., and El-Hefnawy, T. Ecotoxicology. 2013. 22:4, 632-641. 10.1007/s10646-013-1054-0	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Quantification of 17 endocrine disruptor compounds and their spatial and seasonal distribution in the Iberian Ave River and its coastline. Rocha, M. J., Cruzeiro, C. and Rocha, E. Toxicological and Environmental Chemistry. 2013. 95, 386-399. 10.1080/02772248.2013.773002	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Determination of 17 endocrine disruptor compounds and their spatial and seasonal distribution in the Sado River Estuary (Portugal). Rocha, M. J., Cruzeiro, C., Reis, M., Rocha, E., Pardal, M., A. Toxicological and Environmental Chemistry. 2013. 95:2, 237-253. 10.1080/02772248.2012.758730	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Occurrence of bisphenol a, estrone, 17beta-estradiol and 17alpha-ethinylestradiol in Portuguese rivers.	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after

Title Authors Journal. Year. Volume: issue, page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[27] and reasoning
Rocha, S., Domingues, V. F., Pinho, C., Fernandes, V. C., Delerue-Matos, C., Gameiro, P. and Mansilha, C. Bulletin of Environmental Contamination and Toxicology. 2013. 90:1, 73-78. 10.1007/s00128-012-0887-1					December 2012 (i.e. did not meet publication period criteria)
Vesicular coacervative extraction of bisphenols and their diglycidyl ethers from sewage and river water. Ruiz, F. J., Rubio, S. and Perez-Bendito, D. Journal of Chromatography A. 2007. 1163:1-2, 269-276. 10.1016/j.chroma.2007.06.024	Surface water	Not considered	Not considered	Not considered	Excluded - surface water not included in exposure determination
Determination of alkylphenols and bisphenol A in seawater samples by dispersive liquid-liquid microextraction and liquid chromatography tandem mass spectrometry for compliance with environmental quality standards (Directive 2008/105/EC). Salgueiro-Gonzalez, N., Concha-Grana, E., Turnes-Carou, I., Muniategui-Lorenzo, S., Lopez-Mahia, P. and Prada-Rodriguez, D. Journal of Chromatography A. 2012. 1223, 1-8. 10.1016/j.chroma.2011.12.011	Surface water	Not considered	Not considered	Not considered	Excluded - surface water not included in exposure determination
Simultaneous determination of bisphenol A and its halogenated derivatives in river water by combination of isotope imprinting and liquid chromatography-mass spectrometry. Sambe, H., Hoshina, K., Hosoya, K. and Haginaka, J. Journal of Chromatography A. 2006. 1134:1-2, 16-23. 10.1016/j.chroma.2006.08.072	Surface water	Not considered	Not considered	Not considered	Excluded - surface water not included in exposure determination
Polycarbonate baby bottles: study of the release of Bisphenol A. Santillana, M. I., Ruiz, E., Nieto, M. T., Rodríguez Bernaldo de Quirós, A., Sendón, R., Cirugeda, M. E. and Sanchez, J. J. European Food Research and Technology. 2013. 236:5, 883-889. 10.1007/s00217-013-1946-5	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
A direct Capillary Liquid Chromatography with electrochemical detection method for determination of phenols in water samples.	Surface water	Not considered	Not considered	Not considered	Excluded - surface water not included in exposure

Title Authors Journal. Year. Volume: issue, page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[27] and reasoning
Segovia-Martinez, L., Moliner-Martinez, Y. and Campins-Falco, P. Journal of Chromatography A. 2010. 1217:50, 7926-7930. 10.1016/j.chroma.2010.10.078					determination
GC–MS determination of bisphenol A and alkyl phenol ethoxylates in river water from India and their ecotoxicological risk assessment. Selvaraj. K. K., Shanmugam, G., Sampath, S., D.G. Joakim Larsson D. G. J. and Ramaswamy, B. R. Ecotoxicology and Environmental Safety. 2014. 99, 13-20. 10.1016/j.ecoenv.2013.09.006i	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Analysis of endocrine disrupting compounds in wastewater and drinking water treatment plants at the nanogram per litre level. Stavrakakis, C., Colin, R., Hequet, V., Faur, C. and Le Cloirec, P. Environmental Technology. 2008. 29:3, 279-286. 10.1080/09593330802099452	Waste water	Not considered	Not considered	Not considered	Excluded -waste water not included in exposure determination
Human health risk on environmental exposure to Bisphenol-A: a review. Tsai, W. T. Journal of Environmental Science and Health. Part C. 2006. 24:2, 225-255. 10.1080/10590500600936482	Not applicable	Not considered	Not considered	Not considered	Excluded - review paper - not relevant for occurrence in the environment
Investigating the estrogenic risk along the river Po and its intermediate section. Vigano, L., Mandich, A., Benfenati, E., Bertolotti, R., Bottero, S., Porazzi, E. and Agradi, E. Archives of Environmental Contamination and Toxicology. 2006. 51:4, 641-651. 10.1007/s00244-005-0129-1	Surface water	Not considered	Not considered	Not considered	Excluded - surface water not included in exposure determination
Selective determination of bisphenol A (BPA) in water by a reversible fluorescence sensor using pyrene/dimethyl ß-cyclodextrin complex. Wang, X., Zeng, H., Zhao, L. and Lin, J.-M. Analytica Chimica Acta. 2006. 556:2, 313-318. 10.1016/j.aca.2005.09.060	Surface water	Not considered	Not considered	Not considered	Excluded - surface water not included in exposure determination
Analysis of estrogens in environmental waters using polymer monolith in-	Surface	Not	Not	Not considered	Excluded -surface water

Title Authors Journal. Year. Volume: issue, page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[27] and reasoning
polyether ether ketone tube solid-phase microextraction combined with high-performance liquid chromatography. Wen, Y., Zhou, B. S., Xu, Y., Jin, S. W. and Feng, Y. Q. Journal of Chromatography A. 2006. 1133:1-2, 21-28. 10.1016/j.chroma.2006.08.049	water	considered	considered		not included in exposure determination
Seasonal and spatial distribution of 4-tert-octylphenol, 4-nonylphenol and bisphenol A in the Huangpu River and its tributaries, Shanghai, China. Wu, M., Wang, L., Xu, G., Liu, N., Tang, L., Zheng, J., Bu, T. and Lei, B. Environmental Monitoring and Assessment. 2013. 185:4, 3149-3161. 10.1007/s10661-012-2779-6	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Surface-imprinted core-shell Au nanoparticles for selective detection of bisphenol A based on surface-enhanced Raman scattering. Xue, J.-Q., Li, D.-W., Qu, L.-L. and Long, Y.-T. Analytica Chimica Acta.2013. 777, 57-62. 10.1016/j.aca.2013.03.037	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Seasonal variation of endocrine disrupting compounds, pharmaceuticals and personal care products in wastewater treatment plants. Yu, Y., Wu, L. and Chang, A. C. The Science of the Total Environment. 2013. 442, 310-316. 10.1016/j.scitotenv.2012.10.001	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Determination of some endocrine disrupter chemicals in urban wastewater samples using liquid chromatography–mass spectrometry. Zafra-Gómez, A., Ballesteros, O., Navalón, A. and Vílchez, J. L. Microchemical Journal. 2008. 88:1, 87-94. 10.1016/j.microc.2007.10.003	Waste water	Not considered	Not considered	Not considered	Excluded - waste water not included in exposure determination
MCX based solid phase extraction combined with liquid chromatography tandem mass spectrometry for the simultaneous determination of 31 endocrine-disrupting compounds in surface water of Shanghai.	Surface water	Not considered	Not considered	Not considered	Excluded - surface water not included in exposure determination

Title Authors Journal. Year. Volume: issue, page number DOI	Category	Sample description	Country of origin of samples	Method description and quality parameters	Reported data included or excluded from the calculation of the exposure to bisphenol A[27] and reasoning
Zhang, H. C., Yu, X. J., Yang, W. C., Peng, J. F., Xu, T., Yin, D. Q. and Hu, X. L. Journal of Chromatography B. 2011. 879:28, 2998-3004. 10.1016/j.jchromb.2011.08.036					
Optimisation of derivatisation for the analysis of estrogenic compounds in water by solid-phase extraction gas chromatography-mass spectrometry. Zhang, Z. L., Hibberd, A. and Zhou, J. L. Analytica Chimica Acta. 2006. 577:1, 52-61. 10.1016/j.aca.2006.06.029	Surface water	Not considered	Not considered	Not considered	Excluded - surface water not included in exposure determination

Table 69: Literature quality table – colostrum and breast milk

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
Reliable quantification of bisphenol A and its chlorinated derivatives in human breast milk using UPLC–MS/MS method. Cariot, A., Dupuis, A., Albouy-Llaty, M., Legube, B., Rabouan, S and Migeot, V. Talanta. 2012. 100, 175-182. 10.1016/j.talanta.2012.08.034	Colostrum	3 breast milk (colostrum) test samples were collected from donors within a few days after delivery	France	Samples were precipitated with methanol, sonicated and centrifuged. Following sample concentration unconjugated BPA was determined in the samples using on-line SPE-UPLC-MS/MS. d_{16}-BPA internal standard was used. LOD = 0.09 ng/mL (3x S:N) LOQ = 0.40 ng/mL (lowest calibration standard). Recovery >80% at 3.2 ng/ml (n=3) Repeatability (RSD) = 15% (intra-day) and 11% (inter-day) at 0.40 ng/mL and 1% (intra-day) and 14% (inter-day) at 3.2 ng/mL Accuracy = 101% (intra-day) and 103% (inter-day) at 0.40 ng/mL and 93% (intra-day) and 98% (inter-day) at 3.2 ng/mL Calibration = 0.4 to 6.4 ng/mL using spiked milk standards Measures taken to reduce contamination: All solvents and reagents were tested to ensure the absence of contamination, only pre-treated glassware (500°C, 5 hours), teflon seals and high quality	Included

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
				solvents were used. The milk was drawn manually without using any device, materials, wipes or gloves. Samples were stored at -20°C. Chromatograms are presented demonstrating that the background levels of BPA are less than the LOD.	
Potential sources of bisphenol A in the neonatal intensive care unit. Duty, S. M., Mendonca, K., Hauser, R., Calafat, A. M., ye, X., Meeker, J. D., Ackerman, R., Cullinane, J., Faller, J. and Ringer, S. Pediatrics. 2013. 131:3, 483-489. 10.1542/peds.2012-1380	Breast milk	43 mothers each contributed a breast milk sample	United States of America	Total and unconjugated BPA concentrations were determined. Samples were precipitated with 2-propanol and centrifuged. Following acidification of the samples clean-up and analysis was by on-line SPE-HPLC-MS/MS. $^{13}C_{12}$-BPA was used as an internal standard. Deconjugation used β-glucuronidase / sulfatase (Helix pomatia, H1). LOD = 0.3 ng/mL(3x S:N) LOQ = 0.93 ng/mL (10x S:N) Recovery = Not given Repeatability = 6.3-8.3% Accuracy = 98-108% Calibration = 0 to 100 ng/mL NOTE: For method details the authors refer to Ye *et al* 2008 Measures taken to reduce contamination Sample collection	Included. NOTE: although the samples were from the USA this is one of only a few studies reporting breast milk BPA data and so was included NOTE: two statistical outliers were removed by the authors – no explanation as to why – addressed in the uncertainty tables

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
				devices were pre-screened for BPA. Milk was expressed by mechanical pumping and was stored frozen in BPA free containers.	
Evaluation of Organic Environmental Pollutants Detected in Human Milk. Kishikawa, N. and Kuroda, N. Journal of Health Science. 2009. 55:1, 1-10. None given.	Review paper	Not considered	Japan	Not considered	Excluded – Review paper (no new data reported)
Measurement of bisphenol A concentrations in human colostrum. Kuruto-Niwa, R., Tateoka, Y., Usuki, Y. and Nozawa, R. 2007, Chemosphere, 66, 1160-1164. DOI: 10.1016/j.chemosphere.2006.06.073	Colostrum	101 initial breast milk (colostrum) samples were taken from healthy mothers within 3 days after delivery in 2000-2001	Japan	Samples were precipitated with acetonitrile, sonicated and centrifuged. Following sample clean-up using SPE analysis was carried out using ELISA. LOD = 0.3 ng/mL LOQ = Not given Recovery = 102.6% Repeatability (RSD) = Not given Calibration = 1.56 to 100 ng/mL Measures taken to reduce contamination: Colostrum was directly expressed into and was stored in glass bottles at -20°C to avoid contamination from plastic products	Included. NOTE: although samples were from Japan and used less selective ELISA methodology the paper provided data that was not available elsewhere and so was included

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
Bisphenol A and its chlorinated derivatives in human colostrum. Migeot, V., Dupuis, A., Cariot, A., Albuoy-Llaty, M. Pierre, F. and Rabouan, S. Environmental Science and technology. 2013. 47, 13791-13797. dx.doi.org/10.1021/es403071a	Colostrum	21 breast milk (colostrum) test samples were collected from donors within three days after delivery.	France	Samples were precipitated with methanol, sonicated and centrifuged. Following sample concentration unconjugated BPA was determined in the samples using on-line SPE-UPLC-MS/MS. d_{16}-BPA internal standard was used. LOD = 0.09 ng/mL (3x S:N) LOQ = 0.40 ng/mL (lowest calibration standard). Recovery >80% at 3.2 ng/ml (n=3) Repeatability = 1-15% (intra-day) and 11-14% (inter-day) at 0.4-3.2 ng/mL with n=5-13 Accuracy = 93-101% (intra-day) and 98-103% (inter-day) at 0.4-3.2 ng/mL with n=5-13 Calibration = 0.4 to 6.4 ng/mL using spiked milk standards Measures taken to reduce contamination: All solvents and reagents were tested to ensure the absence of contamination, only pre-treated glassware (500°C, 5 hours), teflon seals and high quality solvents were used. The milk was drawn manually without using any device, materials, wipes or gloves. Samples were stored at -20°C. Chromatograms are presented	Included NOTE: this paper was not included in contractors database and was published in 2013 but is one of only a few studies reporting breast milk BPA data and so was included

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
				demonstrating that the background levels of BPA are less than the LOD.	
Bisphenol A concentrations in maternal breast milk and infant urine. Mendonca, K. Hauser, R., Calafat, A. M., Arbuckle, T. E. and Duty, S. M. International Archives of Occupational and Environmental Health. 2014. 87, 13-20. 10.1007/s00420-012-0834-9	Breast milk	Breast milk samples were obtained from 25 mothers of infants in the range 2.3 to 15.1 months	United States of America	Total and unconjugated BPA concentrations were determined. Samples were precipitated with 2-propanol and centrifuged. Following acidification of the samples clean-up and analysis was by on-line SPE-HPLC-MS/MS. $^{13}C_{12}$-BPA was used as an internal standard. Deconjugation used β-glucuronidase / sulfatase (Helix pomatia, H1). LOD = 0.28 ng/mL(3x S:N) LOQ = 0.93 ng/mL (10x S:N) Recovery = Not given Repeatability = Not given Accuracy = Not given Calibration = Not given NOTE: For method details the authors refer to Ye *et al* 2008 Measures taken to reduce contamination: "Rigorous quality control measures were used to ensure valid BPA concentrations". Where breast pumps were used they were made of polypropylene and	Included. NOTE: although samples were from the USA and was not in the contractors database (being published in 2014) this is one of only a few studies reporting breast milk BPA data and so was included

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
				were were reported to be not known to contain BPA. QC materials were prepared by pooling breast milk samples from multiple anonymous donors. Samples were stored at -20°C.	
Measuring environmental phenols and chlorinated organic chemicals in breast milk using automated on-line column-switching-high performance liquid chromatography-isotope dilution tandem mass spectrometry. Ye, X., Kuklenyik, Z., Needham, L. L. and Calafat, A. M. Journal of Chromatography B. 2006. 831, 110-115. 10.1016/j.jchromb.2005.11.050	Breast milk	20 breast milk samples from a group of lactating women without known occupational exposure.	United States of America	Total and unconjugated BPA concentrations were determined. Samples were precipitated with 2-propanol and centrifuged. Following acidification of the samples clean-up and analysis was by on-line SPE-HPLC-MS/MS. $^{13}C_{12}$-BPA was used as an internal standard. Deconjugation used β-glucuronidase (Helix pomatia, H1). LOD = 0.28 ng/mL(3x S:N) LOQ = 0.93 ng/mL (10x S:N) Recovery = 93.7% for SPE clean-up, 97-106% spiked recovery (1, 10, 50 and 100 ng/mL) Repeatability = 8.2-11.4% (combined intra- and inter-day RSD), n=50 repeated measurements of QC materials of 4.8 and 24.8 ng/mL over 2 weeks Accuracy = 97-106% (intra-day) at 1-100 ng/mL (n=5) Calibration = 0.1 to 100 ng/mL, similar curves for milk and water,	Included NOTE: although the samples were from the USA this is one of only a few studies reporting breast milk BPA data and so was included

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
				daily calibration using water Measures taken to reduce contamination: No specific measures described. The authors state "Since standards and unknowns went through the same extraction procedure, reagent contributions were automatically corrected by the calibration curve intercept." Suggesting that any background contribution was accounted for in this way. NOTE: QC materials for milk blanks were prepared by pooling human milk samples taken from multiple donors. Samples were stored at -20°C.	
Automated on-line column-switching HPLC-MS/MS method with peak focusing for measuring parabens, triclosan, and other environmental phenols in human milk Ye, X., Bishop, A. M., Needham, L. L. and Calafat, A. M. Analytica Chimica Acta. 2008. 622, 150-156. 10.1016/j.aca.2008.05.068	Breast milk	4 breast milk samples were collected, these were surplus milk samples that women had expressed and planned to discard, no information was available from the donors about sampling	United States of America	Total and unconjugated BPA concentrations were determined. Samples were precipitated with methanol and centrifuged. Sample clean-up and analysis was by on-line SPE-HPLC-MS/MS. $^{13}C_{12}$-BPA was used as an internal standard. Deconjugation used β-glucuronidase / sulfatase (Helix pomatia, H1). LOD = 0.3 ng/mL(3x S:N) LOQ = 0.93 ng/mL (10x S:N) Recovery = 105% for SPE clean-	Included NOTE: although the samples were from the USA this is one of only a few studies reporting breast milk BPA data and so was included NOTE: Uncertainty in BPA concentrations due to sample handing are addressed in the uncertainty tables

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
		procedures.		up, 90-109% spiked recovery (0.5, 1, 5 and 10 ng/mL) Repeatability = 6.3-8.3% (combined intra- and inter-day RSD), repeated measurements of QC materials of 9.3 and 22.7 ng/mL Accuracy = Not given Calibration = 0.1 to 100 ng/mL, similar curves for milk and water, daily calibration using water Measures taken to reduce contamination: No measures described. The authors note that the proportion of free BPA is quite high and that as no information on collection and storage of the samples were available, the potential for contamination can't be ruled out. QC materials were prepared by pooling breast milk samples from Mother's Milk Bank (purchased in 2002-2003). Test milk samples were collected in 2007 and stored in glass vials at -70°C.	
Biological monitoring of bisphenol A with HLPC/FLD and LC/MS/MS assays Yi, B., Kim, C. and Yang, M. Journal of Chromatography B. 2010. 878, 2606-2610.	Breast milk	100 volunteers, who lived in Seoul, Korea and delivered babies within	Korea	Total and unconjugated BPA concentrations were determined. After enzymatic cleavage of one part of the sample, the samples were extracted with propanol and subjected to HPLC/FLD and LC-	Excluded Note: The study revealed a substantial disagreement between the two analytical methods and the authors

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
10.1016/j.jchromb.2010.02.008		2 weeks		MS/MS analysis. LOD = 0.6 ng/mL (3x S:N) 0.4 ng/ml (LC-MS/MS) LOQ = 1.8 ng/ml (10x S:N) 1.3 ng/ml (LC-MS/MS) Recovery = 65–82% (HPLC/FLD) 68–82% (LC-MS/MS) Repeatability = < 15 % for both methods Accuracy = Not given Calibration = 0.98 – 120 ng/ml Deconjugation: β-glucuronidase Measures taken to reduce contamination: capped brownglass-bottle. Collected breast milk specimens were stored at −80◦C prior to analyses.	state: "…the BPA levels in the HPLC/FLD were lower than those in the LC/MS/MS. Thus, to avoid error in biological monitoring of BPA, we recommend severe guidelines for identification of BPA in the LC/MS/MS method and confirmation of BPA identification with the LC/MS/MS method, particularly in high levels of BPA, which were obtained with the HPLC method"
Association between Endocrine Disrupting Phenols in Colostrums and Maternal and Infant Health Yi, B., Kim, C., Park, M., Han, Y., Park, J. Y. and Yang, M. International Journal of Endocrinology 2013. vol. 2013, Article ID 282381, 7 pages. 10.1155/2013/282381	Colostrum	325 lactating mothers, who stayed in postpartumcare centers.	Korea	Total and unconjugated BPA concentrations were determined. After enzymatic cleavage of one part of the sample, the samples were extracted with propanol and subjected to LC-MS/MS analysis. LOD = not given LOQ = not given Recovery = > 80% Repeatability = Accuracy = Not given	Excluded –) NOTE: see remarks for Yi et al. 2010 NOTE: study was not in the contractors database (being published in 2014).

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
				Calibration = not given Deconjugation: β-glucuronidase Measures taken to reduce contamination: dark glass tubes with glass caps and stored −20°C prior to analyses	
Determination of free Bisphenol A (BPA) concentrations in breast milk of U.S. women using a sensitive LC/MS/MS method Zimmers, S. M., Browne, E. P., O'Keefe, P. W., Anderton, D. L., Kramer, L., Reckhow, D. A., Arcaro, K. F. Chemosphere 2014. 104, 237–243. 10.1016/j.chemosphere.2013.12.085	Breast milk	21 samples from an Archive of a larger national study. Samples were collected in acid-washed glass bottles and shipped on ice and stored at –20 °C.	United States of America	After adding an internal standard ($^{13}C_{12}$-BPA) to the sample a partitioning step between hexane and acetonitrile was utilized prior to purification via solid-phase extraction. BPA was then derivatized with Pyridine-3-sulfonyl chloride, and subsequently analysed with LC-MS/MS LOD = 0.22 ng/mL (3x S:N) LOQ = Not given Recovery = 20% to 58% for IS Repeatability = Not given Accuracy = Not given Calibration = Not given Measures taken to reduce contamination: Glass SPE cartridges and glass pipettes. All glassware heated for 8 h at 500 °C	Included NOTE: although samples were from the USA and was not in the contractors database (being published in 2014) this is one of only a few studies reporting breast milk BPA data and so was included

Table 70: Literature quality table – biomonitoring

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
Composite restorations may lead to increased concentrations of salivary and urinary BPA. Akeroyd, J. M. and Maserejian, N. N. The Journal of Evidence-Based Dental Practice. 2013. 13:2, 64-66. 10.1016/j.jebdp.2013.04.006	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Conclusions of the French Food Safety Agency on the toxicity of bisphenol A. Arnich, N., Canivenc-Lavier, M. C., Kolf-Clauw, M., Coffigny, H., Cravedi, J. P., Grob, K., Macherey, A. C., Masset, D., Maximilien, R., Narbonne, J. F., Nesslany, F., Stadler, J. and Tulliez, J. International Journal of Hygiene and Environmental Health. 2011. 214, 271-275. 10.1016/j.ijheh.2010.12.002	Review paper	Not considered	Not considered	Not considered	Excluded – a review paper on BPA toxicity – no relevant data reported for biomonitoring
Recent trends in biomonitoring of bisphenol A, 4-t-octylphenol, and 4-nonylphenol. Asimakopoulos, A. G., Thomaidis, N. S. and Koupparis, M. A. Toxicology Letters. 2012. 210, 141-154. 10.1016/j.toxlet.2011.07.032	Review paper	Not considered	Not considered	Not considered	Excluded – an analytical method review paper – no relevant data reported for biomonitoring
Human Risk Assessment of Endocrine-Disrupting Chemicals Derived from Plastic Food Containers. Bang, D. Y., Kyung, M., Kim, M. J., Jung, B.	Review paper	Not considered	Not considered	Not considered	Excluded – a review paper on human risk assessment – no relevant data reported

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
Y., Cho, M. C., Choi, S. M., Kim, Y. W., Lim, S. K., Lim, D. S., Won, A. J., Kwack, S. J., Lee, Y., Kim, H. S. and Lee, B. M. Comprehensive Reviews in Food Science and Food Safety. 2012. 11:5, 453-470. 10.1111/j.1541-4337.2012.00197.x					for biomonitoring
Determination of bisphenol A exposure in rural and urban area populations in Mersin City, Turkey. Battal, D., Cok, I. Unlusayin, I., Aktas, A. and Tunctan, B. Toxicological Letters, 2013. 221, S59-S256. 10.1016/j.toxlet.2013.05.154	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
GerES IV: phthalate metabolites and bisphenol A in urine of German children. Becker, K., Goen, T., Seiwert, M., Conrad, A., Pick-Fuss, H., Muller, J., Wittassek, M., Schulz, C. and Kolossa-Gehring, M. International Journal of Hygiene and Environmental Health. 2009. 212:6, 685-692. 10.1016/j.ijheh.2009.08.002	Urine	German Environmental Survey (GerES IV): a representative study on the chemical exposure in children in Germany. Morning urine was collected from 599 children (4 age groups covering the age range 3-14 years) in 2003–2006. It it a representative study with random sampling stratified by age class, community and region.	Germany	BPA conjugates were hydrolysed enzymatically and the BPA derivatised with MTBSTFA. Analysis was by GC-MS/MS. d_{16}-BPA was used as an internal standard. Total BPA concentration was determined. LOD = Not given LOQ = 0.15 µg/L Recovery = Not given Repeatability = 8.7% Accuracy = Not given Calibration = Not given	Included NOTE: although the method performance was not well described the paper provides data for biomonitoring not available elsewhere and so was included

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
				Deconjugation: β-glucuronidase (E. coli) Measures taken to reduce contamination: No measures against contamination reported.	
Urinary concentrations of environmental contaminants and phytoestrogens in adults in Israel. Berman, T., Goldsmith, R., Goen, T., Spungen, J., Novack, L., Levine, H., Amitai, Y., Shohat, T. and Grotto, I. Environment International. 2013. 59, 478-484. 10.1016/j.envint.2013.07.012	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Risk to all or none? A comparative analysis of controversies in the health risk assessment of Bisphenol A. Beronius, A., Ruden, C., Hakansson, H. and Hanberg, A. Reproductive Toxicology. 2010. 29, 132-146. 10.1016/j.reprotox.2009.11.007	Overview paper	Not considered	Not considered	Not considered	Excluded – an overview paper on risk assessment – no relevant data reported for biomonitoring
Unclear Relationship Prenatal but not Concurrent Bisphenol A Exposure Linked to Lower Weight and Less Fat. Betts, K.S Environmental Health Perspectives. 2013. 121:4, A135. 10.1289/ehp.1205548	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Sex differences in the association of urinary	Not	Not considered	Not	Not considered	Excluded – paper

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
bisphenol-A concentration with selected indices of glucose homeostasis among U.S. adults. Beydoun, H. A., Khanal, S., Zonderman, A. B., Beydoun, M. A. Annals of Epidemiology. 2013. 1-8. 10.1016/j.annepidem.2013.07.014	considered		considered		published after December 2012 (i.e. did not meet publication period criteria)
Urinary bisphenol A and obesity in U.S. children. Bhandari, R., Xiao, J. and Shankar, A. American Journal of Epidemiology. 2013. 177:11, 1263-1270. 10.1093/aje/kws391	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Serum unconjugated bisphenol A concentrations in men may influence embryo quality indicators during in vitro fertilization. Bloom, M. S., vom Saal, F. S., Kim, D., Taylor, J. A., Lamb, J. D., Fujimoto, V. Y. Environmental Toxicology and Pharmacology, 2011. 32, 319–323. doi:10.1016/j.etap.2011.06.003	Serum	Study in 27 couples undergoing IVF. On the day of oocyte retrieval, fasting and non-fasting blood specimen were collected from female patients and male partners	United States of America	Specimens were extracted with methyl tert-butyl ether, recombined, dried down under nitrogen, and then reconstituted in methanol. Unconjugated BPA was determined by HPLC with Coularray detection. LOD = 0.3 ng/mL LOQ = Not given Recovery = 89% Repeatability = Not given Accuracy = Not given Calibration = Not given Deconjugation: Not used Measures taken to reduce contamination: Blood was collected	Excluded / included Note: the authors studied female patients and male partners. The latter were included, the former were excluded. NOTE: for serum biomonitoring, studies from all geographical regions were included to inform toxicological risk assessment

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
				into SST serum separator Vacutainer tubes; serum was stored in polypropylene cryovials and frozen at −80 °C. V. Empty serum collection tubes and laboratory diluent and extraction blanks were reported to not containing detectable BPA.	
Variability and predictors of urinary bisphenol A concentrations during pregnancy. Braun, J. M., Kalkbrenner, A. E., Calafat, A. M., Bernert, J. T., Ye, X., Silva, M. J., Barr, D. B., Sathyanarayana, S. and Lanphear, B. P. Environmental Health Perspectives. 2011. 119, 131-137. 10.1289/ehp.1002366	Urine	Not considered	United States of America	Not considered	Excluded - samples from the USA (i.e. did not meet geographical origin criteria) NOTE: This study is included in respect to the discussion of the comparison between spot sampling, first morning urine, and 24-h collections.
Variability of urinary phthalate metabolite and bisphenol A concentrations before and during pregnancy. Braun, J. M., Smith, K. W., Williams, P. L., Calafat, A. M., Berry, K., Ehrlich, S. and Hauser, R. Environmental Health Perspectives, 2012. 120, 739-745. 10.1289/ehp.1104139	Urine	Not considered	United States of America	Not considered	Excluded - samples from the USA (i.e. did not meet geographical origin criteria)
Lead and bisphenol A concentrations in the	Urine	Not considered	Canada	Not considered	Excluded - data on

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
Canadian population. Bushnik, T., Haines, D., Levallois, P., Levesque, J., Van Oostdam, J. and Viau, C. Health Reports. 2010. 21, 7-18. None given					urinary BPA reported here was used but was taken from the 2007-2009 CHMS report (Health Canada, 2010)
Exposure to bisphenol A and other phenols in neonatal intensive care unit premature infants. Calafat, A. M., Weuve, J., Ye, X., Jia, L. T., Hu, H., Ringer, S., Hunter, K. and Hauser, R. Environmental Health Perspectives. 2009. 117, 639-644. 10.1289/ehp.0800265	Urine	Focus on association between urinary BPA and the use of medical devices in premature infants undergoing intensive medical treatments. Spot urine was collected in 2003. Analysis of 57 archived urine samples from 41 low-birth-weight infants from neonatal intensive care units (NICUs) in Boston-area hospitals. Spot urine collection from a cotton gauze placed in the infant's diaper or from the cotton filling of the diaper.	United States of America	SPE, HPLC-MS/MS (method from YKN05a), $^{13}C_{12}$-BPA was used as an internal standard., Free and total BPA were determined. LOD = 0.4 ng/mL (3x S:N) LOQ = Not given Recovery = Not given Repeatability = Not given Accuracy = Not given Calibration = Not given Deconjugation: β-glucuronidase/ sulfatase (Helix pomatia, H1) Measures taken to reduce contamination: No measures against contamination reported.	Excluded - Non EU data
Human exposure assessment to environmental chemicals using biomonitoring. Calafat, A. M., Ye, X., Silva, M. J., Kuklenyik, Z. and Needham, L. L. International Journal of Andrology. 2006. 29, 166-171.	Overview paper	Not considered	Not considered	Not considered	Excluded – an overview paper on biomonitoring – no new data reported for biomonitoring

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
10.1111/j.1365-2605.2005.00570.x					
Exposure of the U.S. population to bisphenol A and 4-tertiary-octylphenol: 2003-2004. Calafat, A. M., Ye, X., Wong, L. Y., Reidy, J. A. and Needham, L. L. Environmental Health Perspectives. 2008. 116, 39-44. 10.1289/ehp.10753	Urine	Not considered	United States of America	Not considered	Excluded – data on urinary BPA (2003-2004 NHANES) reported here was used but was taken from the NHANES website of the CDC
Urinary bisphenol A concentrations in pregnant women Callan, A. C., Hinwood, A. L., Heffernan, A., Eaglesham, G., Mueller, J. and Odland, J. O. International Journal of Hygiene and Environmental Health. 2012. 216, 641-644. 10.1016/j.ijheh.2012.10.002	Urine	Not considered	Australia	Not considered	Excluded – samples from Australia (i.e. did not meet geographical origin criteria)
Bisphenol a exposure in Mexico City and risk of prematurity: a pilot nested case control study Cantonwine, D., Meeker, J. D., Hu, H., Sánchez, B. N., Lamadrid-Figueroa, H., Mercado-García, A., Fortenberry, G. Z., Calafat, A. M., Téllez-Rojo, M. M. Environmental Health. 2010. 62, 2-7. 10.1186/1476-069X-9-62	Urine	Not considered	Mexico	Not considered	Excluded – samples from Mexico (i.e. did not meet geographical origin criteria)
Bisphenol A in human placental and fetal liver tissues collected from Greater Montreal area (Quebec) during 1998-2008. Cao, X. L., Zhang, J., Goodyer, C. G., Hayward, S., Cooke, G. M. and Curran, I. H.	Placental and fetal liver tissue	Not considered	Canada	Not considered	Excluded – tissue not considered in biomonitoring

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
Chemosphere. 2012. 89, 505-511. 10.1016/j.chemosphere.2012.05.003					
Polycarbonate bottle use and urinary bisphenol A concentrations. Carwile, J. L., Luu, H. T., Bassett, L. S., Driscoll, D. A., Yuan, C., Chang, J. Y., Ye, X., Calafat, A. M. and Michels, K. B. Environmental Health Perspectives. 2009. 117:9, 1368-1372. 10.1289/ehp.0900604	Urine	Nonrandomized intervention study among n=77 Harvard college students (18-23 yrs old, 53% males, 47% females) in 2008. Urine collection after a 1-week washout phase, during which cold beverages were consumed from stainless steel bottles. In the intervention week, cold beverages were consumed from PC bottles, and urine was collected at the end of the week. Urine collection took place in the evening hours. Urinary BPA concentrations were adjusted for creatinine.	United States of America	Following enzymatic cleavage of the conjugates the urine samples were subjected to on-line SPE coupled with HPLC-MS/MS detection. $^{13}C_{12}$-BPA was used as an internal standard. Total BPA was determined. LOD = 0.4 ng/mL LOQ = Not given Recovery = Not given Repeatability = Not given Calibration = Not given Deconjugation: β-glucuronidase/ sulfatase (Helix pomatia, H1) Measures taken to reduce contamination: Samples were collected in polypropylene containers and stored at -20°C.	Excluded - controlled (intervention) study and not a biomonitoring study
Urinary bisphenol A and obesity: NHANES 2003-2006. Carwile, J. L. and Michels, K. B. Environmental Research. 2011. 111:6, 825-830. 10.1016/j.envres.2011.05.014	Urine	Not considered	United States of America	Not considered	Excluded – data on urinary BPA reported here was used but was taken from the NHANES website of the CDC
Canned soup consumption and urinary	Urine	Randomized, single-blinded, 2×2 crossover design	United States of	SPE, HPLC-MS/MS (method from YKN05a), $^{13}C_{12}$-BPA was used as an	Excluded -

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
bisphenol A: a randomized crossover trial. Carwile, J. L., Ye, X., Zhou, X., Calafat, A. M. and Michels, K. B. The Journal of the American Medical Association. 2011. 306:20, 2218-2220. 10.1001/jama.2011.1721		performed with 75 volunteers (student and university staff, mean age of 28 years, 68% female) in Boston in 2010. Preliminary report comparing canned-soup and fresh-soup consumption (vegetarian).	America	internal standard. Free and total BPA were determined. LOD = 0.4 ng/mL LOQ = Recovery = Repeatability = Accuracy = Calibration = Deconjugation: Measures taken to reduce contamination:	controlled (intervention) study and not a biomonitoring study
Urinary concentrations of phthalates and phenols in a population of Spanish pregnant women and children. Casas, L., Fernandez, M. F., Llop, S., Guxens, M., Ballester, F., Olea, N., Irurzun, M. B., Rodriguez, L. S., Riano, I., Tardon, A., Vrijheid, M., Calafat, A. M. and Sunyer, J. Environment International. 2011. 37:5, 858-866. 10.1016/j.envint.2011.02.012	Urine	INMA: Infancia y Medio Ambiente (Environment and Childhood) project: a population-based birth cohort study in Spain. Recruitment of mother-child pairs between 2004 and 2008. Spot urine samples were collected from women during the 3rd trimester of pregnancy (2004– 2008), and from the 4-yr old children (2005–2006). 120 pregnant 17-43 yrs old women randomly selected from four birth cohorts (located in different spanish regions) and 30 4-yr old boys	Spain	Total BPA was determined. HPLC-MS/MS method as described by Ye et al. 2005 was used. LOD = 0.4 ng/mL (3x S:N) LOQ = Not given Recovery = Not given Repeatability = Not given Accuracy = Not given Calibration = Not given Deconjugation: β-glucuronidase/ sulfatase, a deconjugation standard was also added Measures taken to reduce contamination: Samples were	Included NOTE: although the method performance was not well described the paper provides data for biomonitoring not available elsewhere and so was included

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
		from one birth cohort. These birth cohorts belong to the INMA Project. Spot urine samples, Cr adjustment		collected in polypropylene containers and stored at -20°C.	
Exposure to brominated flame retardants, perfluorinated compounds, phthalates and phenols in European birth cohorts: ENRIECO evaluation, first human biomonitoring results, and recommendations. Casas, M., Chevrier, C., Hond, E. D., Fernandez, M. F., Pierik, F., Philippat, C., Slama, R., Toft, G., Vandentorren, S., Wilhelm, M. and Vrijheid, M. International Journal of Hygiene and Environmental Health. 2012. 216, 230-242. 10.1016/j.ijheh.2012.05.009	Review paper	Not considered	Not considered	Not considered	Excluded – a review paper on exposure – no new data reported for biomonitoring
Dietary and sociodemographic determinants of bisphenol A urine concentrations in pregnant women and children. Casas, M., Valvi, D., Luque, N., Ballesteros-Gomez, A., Carsin, A. E., Fernandez, M. F., Koch, H. M., Mendez, M. A., Sunyer, J., Rubio, S. and Vrijheid, M. Environment International. 2013. 56C, 10-18. 10.1016/j.envint.2013.02.014	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Determination of bisphenol-A levels in human amniotic fluid samples by liquid chromatography coupled with mass	Amniotic fluid	Not considered	United States of America	Not considered	Excluded – tissue not considered in biomonitoring

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
spectrometry. Chen, M., Edlow, A. G., Lin, T., Smith, N. A., McElrath, T. F. and Lu, C. Journal of Separation Science. 2011. 34:14, 1648-1655. 10.1002/jssc.201100152					
Simultaneous determination of multiple phthalate metabolites and bisphenol-A in human urine by liquid chromatography-tandem mass spectrometry. Chen, M., Tao, L., Collins, E. M., Austin, C. and Lu, C. Journal of Chromatograpphy B. 2012. 904, 73-80. 10.1016/j.jchromb.2012.07.022	Urine	Not considered	United States of America	Not considered	Excluded – samples from the USA (i.e. did not meet geographical origin criteria)
Maternal urinary bisphenol a during pregnancy and maternal and neonatal thyroid function in the CHAMACOS study. Chevrier, J., Gunier, R. B., Bradman, A., Holland, N. T., Calafat, A. M., Eskenazi, B. and Harley, K. G. Environmental Health Perspectives. 2013. 121:1, 138-144. 10.1289/ehp.1205092	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Biomonitoring of bisphenol A concentrations in maternal and umbilical cord blood in regard to birth outcomes and adipokine expression: a birth cohort study in Taiwan. Chou, W. C., Chen, J. L., Lin, C. F., Chen, Y.	Plasma	Study in healthy pregnant Taiwanese women (at delivery) which were recruited in 2006-2007. Maternal blood and umbilical cord blood were	Taiwan	Ammonium acetate buffer, hexane and diethyl ether were added to the samples, mixed, immobilised and perchloric acid was added. After cenbtrifugation the orgaic extarct was	Included NOTE: for serum biomonitoring,

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
C., Shih, F. C. and Chuang, C. Y. Environmental Health. 2011. 94, 1-10. 10.1186/1476-069X-10-94		sampled at full-term delivery. 97 mother-newborn pairs from a hospital in a Taiwan county.		evaporated to dryness and reconstituted in mobile phase prior to analysis by HPLC-UV. Free BPA was determined. LOD = 0.13 ng/mL LOQ = Not given Recovery = 96-103% (blanks) 96.1% (samples, RSD: 7.53%) Repeatability = 1.99-7.53% Accuracy = Not given Calibration = 3.9-250 ng/mL ($r^2 > 0.99$) Deconjugation: None Measures taken to reduce contamination: Samples were collected into glass tubes and stored at -80°C. Plastics were excluded throughout sample preparation. QA/QC materials were prepared from pooled plasm.a	studies from all geographical regions were included to inform toxicological risk assessment NOTE: the method used less selective HPLC-UV detection
Population variability of phthalate metabolites and bisphenol A concentrations in spot urine samples versus 24- or 48-h collections Christensen, K. L., Lorber, M., Koch, H. M., Kolossa-Gehring, M. and Morgan, M. K. Journal of Exposure Science and Environmental Epidemiology. 2012. 22:6, 632-640. 10.1038/jes.2012.52	Urine	Not considered	United States of America	Not considered	Excluded – samples from the USA (i.e. did not meet geographical origin criteria) Note: This study is mentioned in the main text when discussing

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
					methodical issues such as the comparability between first-morning voids, spot urine samples and 24-h samples
The contribution of diet to total bisphenol A body burden in humans: Results of a 48hour fasting study. Christensen, K. L., Lorber, M., Koslitz, S., Bruning, T. and Koch, H. M. Environment International. 2012. 50, 7-14. 10.1016/j.envint.2012.09.002	Urine	Fasting study, 48-h urine collection in 2009. 5 healthy volunteers (2 males, 3 females, 27-47 years old), employees of the institute conducting the study, Bochum area in Germany.	Germany	Following enzymatic cleavage of the conjugates clean up of the samples was performed by on-line SPE with detection by HPLC-MS/MS. d_{16}-BPA was used as an internal standard. Total BPA was determined. Free BPA was determined in the same was but without the enzymatic cleavage step. LOD = 0.05 ng/mL LOQ = 0.1 ng/mL Recovery: 88.5–104% (10 ng/mL in urine) Repeatability: 6.5% (2.9 ng/mL) and 3.4% (11.8 ng/mL) for within day RSD and 5.6% (2.9 ng/mL) and 3.4% (11.8 ng/mL) between day RSD Accuracy = Not given Calibration =Not given Deconjugation: β-	Excluded - intervention study were subjects were forced to fasten for 48 hour. Therefore, the study is not considered for exposure estimattion via urinary biomonitoring

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
				glucuronidase/sulfatase Measures taken to reduce contamination: Samples were stored in polypropylene containers at -20°C.	
Dental composite fillings and bisphenol A among children: a survey in South Korea. Chung, S. Y., Kwon, H., Choi, Y. H., Karmaus, W., Merchant, A. T., Song, K. B., Sakong, J., Ha, M., Hong, Y. C. and Kang, D. International Dental Journal. 2012. 62:2, 65-69. 10.1111/j.1875-595X.2011.00089.x	Urine	Not considered	Korea	Not considered	Excluded – samples from Korea (i.e. did not meet geographical origin criteria)
The impact of bisphenol A and triclosan on immune parameters in the U.S. population, NHANES 2003-2006. Clayton, E. M., Todd, M., Dowd, J. B. and Aiello, A. E. Environmental Health Perspectives. 2011. 119:3, 390-396. 10.1289/ehp.1002883	Urine	Not considered	United States of America	Not considered	Excluded – data on urinary BPA reported here was used but was taken from the NHANES website of the CDC
Measurement of bisphenol A and bisphenol B levels in human blood sera from healthy and endometriotic women. Cobellis, L., Colacurci, N., Trabucco, E., Carpentiero, C. and Grumetto, L. Biomedical chromatography. 2009. 23:11, 1186-1190. 10.1002/bmc.1241	Serum	Case-control study using endometriotic patients (n = 58) and controls (n=11). Groups were formed after the operative procedure. 69 women being submitted to a gynaecological department for diagnostic or operative laparoscopy for the evidence of ovarian cysts or to	Italy	Perchloric acid was added to the samples, which were then centrifuged and filtered prior to analysis by HPLC-FLD with confirmation by LC-MS/MS. Free BPA was determined. LOD = 0.15 ng/mL LOQ = 0.50 ng/mL (10x S:N)	Included/Excluded NOTE: serum data for healthy women were included, the data for endometriotic women were excluded

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
		investigate chronic pelvic pain and dysmenorrhea.		Recovery = 85.6% Repeatability = coefficient of variation < 0.5% Accuracy = Not given Calibration = 0.5-20 ng/mL (r^2 = 0.989) Deconjugation: None Measures taken to reduce contamination: Glass syringes and glass tubes were employed throughout the sampling. Samples were stored at -20°C.	
Quantification of free and total bisphenol A and bisphenol B in human urine by dispersive liquid-liquid microextraction (DLLME) and heart-cutting multidimensional gas chromatography-mass spectrometry (MD-GC/MS). Cunha, S. C. and Fernandes, J. O. Talanta. 2010. 83, 117-125. 10.1016/j.talanta.2010.08.048	Urine	Not considered	Portugal	Not conisdered	Excluded – paper focuses on method development – no relevant data reported for biomonitoring
Bisphenol A: do recent studies of health effects among humans inform the long-standing debate? Dash, C., Marcus, M. and Terry, P. D. Mutation Research. 2006. 613:2-3, 68-75. 10.1016/j.mrrev.2006.04.001	Serum Urine	Not considered	Not considered	Not considered	Excluded – a commentary paper – no new data reported for biomonitoring
Human exposure to bisphenol A by	Review	Not considered	Not	Not considered	Excluded – review

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
biomonitoring: methods, results and assessment of environmental exposures. Dekant, W. and Völkel, W. Toxicology and applied pharmacology. 2008. 228:1, 114-134. 10.1016/j.taap.2007.12.008	paper		considered		paper on biomonitoring – no new data reported for biomonitoring
Simultaneous determination of bisphenol A, triclosan, and tetrabromobisphenol A in human serum using solid-phase extraction and gas chromatography-electron capture negative-ionization mass spectrometry. Dirtu, A. C., Roosens, L., Geens, T., Gheorghe, A., Neels, H. and Covaci, A. Analytical and Bioanalytical Chemistry. 2008. 391, 1175-1181. 10.1007/s00216-007-1807-9	Serum	21 samples were collected in Belgium as part of other studies; they consisted of 7 individual serum samples (3 males + 4 females) collected in 2007 and 14 pooled samples (all females) collected in 1999.	Belgium	Free BPA was determined. After adition of an internal standard ($^{13}C_{12}$-BPA) the sample was acidified for protein percepitation, and clean using SPE and Florisil. PFPA was used as derivatision agent improving sensitivity and selectivity of the susequent GC-MS analysis. LOD = Not given LOQ = 0.28 ng/mL (3x standard deviation of procedural blanks) Recovery = 81-83% at 1.56 and 14 ng/mL Repeatability = 1.6-5.1% (within-day) and 2.4-14% (between-day) at 1.56 and 14 ng/mL Accuracy = Not given Calibration = Not given Deconjugation: None Measures taken to reduce contamination: No measures against contamination reported.	Included NOTE: this paper was not included in the contractors database but provides relevant biomonitoring data and so was included NOTE: for serum biomonitoring, studies from all geographical regions were included to inform toxicological risk assessment

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
Prenatal and postnatal bisphenol A exposure and asthma development among inner-city children. Donohue, K. M., Miller, R. L., Perzanowski, M. S., Just, A. C., Hoepner, L. A., Arunajadai, S., Canfield, S., Resnick, D., Calafat, A. M., Perera, F. P. and Whyatt, R. M. The Journal of Allergy and Clinical Immunology. 2013. 131:3, 736-747.	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Fetal bisphenol A exposure: concentration of conjugated and unconjugated bisphenol A in amniotic fluid in the second and third trimesters. Edlow, A. G., Chen, M., Smith, N. A., Lu, C. and McElrath, T. F. Reproductive Toxicology. 2012. 34:1, 1-7. 10.1016/j.reprotox.2012.03.009	Amniotic fluid	Not considered	United States of America	Not considered	Excluded – tissue not considered in biomonitoring
Urinary bisphenol A concentrations and cytochrome P450 19 A1 (Cyp19) gene expression in ovarian granulosa cells: An in vivo human study. Ehrlich, S., Williams, P. L., Hauser, R., Missmer, S. A., Peretz, J., Calafat, A. M. and Flaws, J. A. Reproductive Toxicology. 2013. 42C, 18-23.	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Urinary bisphenol A concentrations and implantation failure among women undergoing in vitro fertilization. Ehrlich, S., Williams, P. L., Missmer, S. A.,	Urine	Not considered	United States of America	Not considered	Excluded – samples from the USA (i.e. did not meet geographical origin

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
Flaws, J. A., Berry, K. F., Calafat, A. M., Ye, X., Petrozza, J. C., Wright, D. and Hauser, R. Environmental health perspectives. 2012. 120:7, 978-983. 10.1289/ehp.1104307					criteria)
Urinary bisphenol A concentrations and implantation failure among women undergoing IVF. Ehrlich, S. R., Williams, P., Wright, D., Petrozza, J., Calafat, A. M. and Hauser, R. Fertility and Sterility. 2009. 92, S136. 10.1016/j.fertnstert.2009.07.1205	Urine	Not considered	United States of America	Not considered	Excluded – samples from the USA (i.e. did not meet geographical origin criteria)
Urinary Bisphenol A concentrations and human semen quality. Ehrlich, S. R., Wright, D., Ford, J. and Hauser, R. Fertility and Sterility. 2008. 90, S186. 10.1016/j.fertnstert.2008.07.752	Urine	Not considered	United States of America	Not considered	Excluded – samples from the USA (i.e. did not meet geographical origin criteria)
Bisphenol-A and chlorinated derivatives in adipose tissue of women. Fernandez, M. F., Arrebola, J. P., Taoufiki, J., Navalon, A., Ballesteros, O., Pulgar, R., Vilchez, J. L. and Olea, N. Reproductive Toxicology. 2007. 24, 259-264. 10.1016/j.reprotox.2007.06.007	Adipose tissue	Not considered	Spain	Not considered	Excluded – tissue not considered in biomonitoring
Bisphenol A and related compounds in dental materials. Fleisch, A. F., Sheffield, P. E., Chinn, C.,	Review paper	Not considered	Not considered	Not considered	Excluded – a review paper on dental sealants – no relevant

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
Edelstein, B. L. and Landrigan, P. J. Pediatrics. 2010. 126, 760-768. 10.1542/peds.2009-2693					data reported for biomonitoring
Quantitation of free and total bisphenol A in human urine using liquid chromatography-tandem mass spectrometry. Fox, S. D., Falk, R. T., Veenstra, T. D. and Issaq, H. J. Journal of Separation Science. 2011. 34, 1268-1274. 10.1002/jssc.201100087	Urine	Not considered	United States of America	Not considered	Excluded – paper focuses on method development – no relevant data reported for biomonitoring
Bisphenol A and other phenols in urine from Danish children and adolescents analyzed by isotope diluted TurboFlow-LC-MS/MS. Frederiksen, H., Aksglaede, L., Sorensen, K., Nielsen, O., Main, K. M., Skakkebaek, N. E., Juul, A. and Andersson, A. M. International Journal of Hygiene and Environmental Health. 2013. 216, 710-720. 10.1016/j.ijheh.2013.01.007	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Urinary excretion of phthalate metabolites, phenols and parabens in rural and urban Danish mother-child pairs. Frederiksen, H., Nielsen, J. K., Morck, T. A., Hansen, P. W., Jensen, J. F., Nielsen, O., Andersson, A. M. and Knudsen, L. E. International Journal of Hygiene and Environmental Health. 2013. 216, 772-783.	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
10.1016/j.ijheh.2013.02.006					
Comparison of Elisa- and LC-MS-Based Methodologies for the Exposure Assessment of Bisphenol A. Fukata, H., Miyagawa, H., Yamazaki, N. and Mori, C. Toxicology Mechanisms and Methods. 2006. 16, 427-430. 10.1080/15376520600697404	Urine, Serum	Blood (30 mL) and urine (50 mL) were collected from 52 volunteers (age 22–51, 21 men and 31 women) between July and September 2004.	Japan	Total and free BPA were determined The urine and blood samples were enzymatically cleaved, subjected to SPE purification before measurement with HPLC/ECD LOD = 0.2 ng/mL LOQ = Not given Recovery = 91.6% to 102.3% Repeatability = less then 5 % Accuracy = Not given Calibration = Not given Deconjugation: β-glucuronidase Measures taken to reduce contamination: the samples were stored at –20◦C until use.	Included - only for serum values NOTE: although the samples were from Japan the paper provides data for biomonitoring not available elsewhere and so was included NOTE: for serum biomonitoring, studies from all geographical regions were included to inform toxicological risk assessment
Daily bisphenol A excretion and associations with sex hormone concentrations: results from the InCHIANTI adult population study. Galloway, T., Cipelli, R., Guralnik, J., Ferrucci, L., Bandinelli, S., Corsi, A. M., Money, C., McCormack, P. and Melzer, D. Environmental Health Perspectives. 2010. 118:11, 1603-1608. 10.1289/ehp.1002367	Urine	Cross-sectional study using data from the InCHIANTI Study, a prospective population-based study of a suburban and rural-town (adult) population (20-74 yrs old, N=715) in Italy (Chianty & Tuscany). 24-h urine was collected.	Italy	Free and conjugated BPA was measured using the method described by Calafat et al, 2008. On-line SPE coupled with HPLC-MS/MS was employed. LOD = < 0.50 ng/mL LOQ = 0.50 ng/mL Recovery = Not given Repeatability = Not given	Included NOTE: although the method performance was not well described the paper provides data for biomonitoring not available elsewhere and so was included

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
				Accuracy = Not given Calibration = 50-100 ng/mL Deconjugation: Not given Measures taken to reduce contamination: No measures against contamination reported.	
Determination of urinary bisphenol A by coacervative microextraction and liquid chromatography-fluorescence detection Garcia-Prieto, A., Lunar, M. L., Rubio, S. And Perez-Bendito, D. Analytica Chimica Acta. 2008. 630:1, 19-27. 10.1016/j.aca.2008.09.060	Urine	Not considered	Spain	Not considered	Excluded – paper focuses on method development – no relevant data reported for biomonitoring
A review of dietary and non-dietary exposure to bisphenol-A. Geens, T., Aerts, D., Berthot, C., Bourguignon, J. P., Goeyens, L., Lecomte, P., Maghuin-Rogister, G., Pironnet, A. M., Pussemier, L., Scippo, M. L., Van Loco, J. and Covaci, A. Food and Chemical Toxicology. 2012. 50:10, 3725-3740. 10.1016/j.fct.2012.07.059	Review paper	Not considered	Not considered	Not considered	Excluded – a review paper – no new data reported for biomonitoring
Sensitive and selective method for the determination of bisphenol-A and triclosan in serum and urine as pentafluorobenzoate-derivatives using GC-ECNI/MS. Geens, T., Neels, H. and Covaci, A. Journal of Chromatography B. 2009. 877:31,	Serum, Urine	The method was applied to 20 serum and 20 urine samples from Belgian adolescents	Belgium	Following enzymatic cleavage of the conjugates the sample was acidified, cleaned-up using SPE and derivatised using PFBCl with detection by GC-MS. ^{13}C12-BPA was used as an internal standard.	Included (only for serum) NOTE: for serum biomonitoring, studies from all

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
4042-4046. 10.1016/j.jchromb.2009.10.017				Total BPA was determined. LOD = Not given LOQ = 0.5 ng/mL in serum and 0.2 ng/mL in urine (3x S:N) Recovery = : 89-97% (at 0.46 ng/mL) and 90-98% (at 2.20 ng/mL) for serum; 93-107% (at 0.73 ng/mL) and 97-103% (at 2.20 ng/mL) for urine Repeatability = RSD 14-21% (at 0.46 ng/mL) and 6-11% (at 2.20 ng/mL) for serum; 3-14% (at 0.73 ng/mL) and 1-5% (at 2.20 ng/mL) for urine Accuracy = Not given Calibration = 0.46–10.5 ng/mL ($r^2 > 0.999$) Deconjugation: β-glucuronidase/ sulfatase Measures taken to reduce contamination: Procedural blanks were used.	geographical regions were included to inform toxicological risk assessment
Distribution of bisphenol-A, triclosan and n-nonylphenol in human adipose tissue, liver and brain. Geens, T., Neels, H. and Covaci, A. Chemosphere. 2012. 87:7, 796-802. 10.1016/j.chemosphere.2012.01.002	Human adipose, tissue, liver, brain	Not considered	Belgium	Not considered	Excluded – tissue not considered in biomonitoring

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
Human excretion of bisphenol A: blood, urine, and sweat (BUS) study. Genuis, S. J., Beesoon, S., Birkholz, D. and Lobo, R. A. Journal of Environmental and Public Health. 2012. 185731. 10.1155/2012/185731	Serum, Sweat, Urine	20 Canadian subjects (10 healthy and 10 "unhealthy"; 9 males and 11 females; 45±14 and 45±10 years old). Assessment of relative [BPA] in serum, 1st morning urine and sweat.	Canada	Following enzymatic cleavage of the conjugates the sample was acidified, cleaned-up using SPE with detection by LC-MS/MS. Labelled BPA was used as an internal standard. Total BPA was determined. LOD = 0.2 ng/mL (3x S:N) LOQ = Not given Recovery = Not given Repeatability = Not given Accuracy = Not given Calibration = Not given Deconjugation: β-glucuronidase, a deconjugation standard was also added Measures taken to reduce contamination: Glass vessels were used to avoid contamination. Quality control materials were used with calf serum as a method blank. Samples were stored at -20°C.	Included (only for serum) NOTE: although the samples were from Canada and the method performance was not well described the paper provides data for biomonitoring not available elsewhere and so was included NOTE: for serum biomonitoring, studies from all geographical regions were included to inform toxicological risk assessment
4-Nonylphenol and bisphenol A in Swedish food and exposure in Swedish nursing women. Gyllenhammar, I., Glynn, A., Darnerud, P. O., Lignell, S., van Delft, R. and Aune, M. Environment International. 2012. 43, 21-28. 10.1016/j.envint.2012.02.010	Serum	Women were recruited by random selection in a hospital a few days after having given birth in 2008-2009. 100 nursing women donated blood samples at home 3 weeks after delivery.	Sweden	The samples were diluted with water and labelled BPA was added as an internal standard. Samples were subjected to enzymatic hydrolysis prior to analysis using on-line SPE wiith HPLC-MS/MS detection. Total BPA was determined.	Included NOTE: this paper was included in contractors database but was not classified as a biomonitoring

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
				Free BPA was determined in the same was but without the enzymatic cleavage step LOD = 0.5 ng/g (free BPA) and 0.8 ng/g (total BPA) LOQ = Not given Recovery = 76-103% Repeatability = Not given Accuracy = Not given Calibration = Not given Deconjugation: β-glucuronidase/ sulfatase, a deconjugation standard was also added Measures taken to reduce contamination: Samples were collected in glass vials and stored at -20°C.	paper but provides relevant biomonitoring data and so was included NOTE: for serum biomonitoring, studies from all geographical regions were included to inform toxicological risk assessment
Human biomonitoring of environmental chemicals--early results of the 2007-2009 Canadian Health Measures Survey for males and females. Haines, D. A. and Murray, J. International journal of hygiene and environmental health. 2012. 215:2, 133-137. 10.1016/j.ijheh.2011.09.008	Urine	Not considered	Canada	Not considered	Excluded – data on urinary BPA reported here was used but was taken from tables published by Health Canada and Statistics Canada
Prenatal and early childhood bisphenol A concentrations and behavior in school-aged	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
children. Harley, K. G., Gunier, R. B., Kogut, K., Johnson, C., Bradman, A., Calafat, A. M. and Eskenazi, B. Environmental Research. 2013. 126, 43-50. 10.1016/j.envres.2013.06.004					(i.e. did not meet publication period criteria)
Bisphenol A-glucuronide measurement in urine samples. Harthe, C., Rinaldi, S., Achaintre, D., de Ravel, M. R., Mappus, E., Pugeat, M. and Dechaud, H. Talanta. 2012. 100, 410-413. 10.1016/j.talanta.2012.07.099	Urine	Not considered	France	Not considered	Excluded – paper focuses on method development – no relevant data reported for biomonitoring
Bisphenol A levels in blood and urine in a Chinese population and the personal factors affecting the levels. He, Y., Miao, M., Herrinton, L. J., Wu, C., Yuan, W., Zhou, Z. and Li, D. K. Environmental Research. 2009. 109:5, 629-633. 10.1016/j.envres.2009.04.003	Urine, Serum	Exposed workers and their relatives: of the eligible participants referred to those without occupational BPA exposure that should be confirmed by worksite visiting or consulting the products, raw materials, processing and their job categories. Anyone who had a dental sealant application within 1 year was excluded	China	Total BPA (conjugated and free) The samples were acidified - one part subjected to enzymatic cleavage - and extracted with ether before analysis by HPCL/FL LOD = Not given LOQ = 0.31 and 0.39mg/L for urin and serum respectively. Recovery = Not given Repeatability = Not given Accuracy = Not given Calibration = Not given Deconjugation: β-glucuronidase Measures taken to reduce contamination: All the biological	Included (only serum) – NOTE: although the samples were from China the paper provides data for biomonitoring not available elsewhere and so was included NOTE: for serum biomonitoring, studies from all geographical regions were included to inform toxicological risk assessment

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
				samples were stored at -70°C in BPA free plastic tubes	
Occupational Exposure Levels of Bisphenol A among Chinese Workers. He, Y. H., Yuan, W., Gao, E., Zhou, Z. and Li, D.-K. Journal of Occupational Health. 2009. 51, 432-436. None given	Urine	Not considered	China	Not considered	Included – samples from China (i.e. did not meet geographical origin criteria)
Critical evaluation of key evidence on the human health hazards of exposure to bisphenol A. Hengstler, J. G., Foth, H., Gebel, T., Kramer, P. J., Lilienblum, W., Schweinfurth, H., Völkel, W., Wollin, K. M. and Gundert-Remy, U. Critical Reviews in Toxicology. 2011. 41:4, 263-291. 10.3109/10408444.2011.558487	Review paper	Not considered	Not considered	Not considered	Excluded – a review paper on exposure – no new data reported for biomonitoring
Urinary concentrations of bisphenol A in an urban minority birth cohort in New York City, prenatal through age 7 years. Hoepner, L.A., Whyatt, R. M., Just, A.C., Calafat, A.M., Perera, F.P. and Rundle, A.G. Environmental Research. 2013. 122, 38-44. 10.1016/j.envres.2012.12.003i	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Pollution gets personal! A first population-based human biomonitoring study in Austria. Hohenblum, P., Steinbichl, P., Raffesberg, W.,	Urine	2008-2011 Austrian population-based HBM study: 150 volunteers (50 families, 6-	Austria	Total BPA was determined. The urine samples were purified on a SPE column and analysed by HPLC-	Included NOTE: this paper

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
Weiss,S., Moche, W., Vallant, B., Scharf, S., Haluza, D., Moshammer, H., Kundi, M., Piegler, B., Wallner, P. and Hutter, H. P. International Journal of Hygiene and Environmental Health. 2012. 215, 176-179. 10.1016/j.ijheh.2011.08.015		49 years) were selected by stratified random sampling from 5 different Austrian regions. 10 woman-child-men pairs living in the same household were randomly selected per region. 1st morning urine was collected. 25 out of 100 urine samples were analyzed for total BPA. Questionnaire data were used to pre-select participants who might have a higher exposure (e.g. occupation, frequent use of canned food/beverages, use of plastic bottles).		MS/MS LOD = Not given LOQ = 0.6 µg/L Recovery = Not given Repeatability = Not given Accuracy = Not given Calibration = Not given Deconjugation: β-glucuronidase Measures taken to reduce contamination: Sample storage in glass containers, storage on dry ice during transport.	was not included in the contractors database but provides relevant biomonitoring data and so was included
Community level exposure to chemicals and oxidative stress in adult population. Hong, Y. C., Park, E. Y., Park, M. S., Ko, J. A., Oh, S. Y., Kim, H., Lee, K. H., Leem, J. H. and Ha, E. H. Toxicology Letters. 2009. 184:2, 139-144. 10.1016/j.toxlet.2008.11.001	Urine	Not considered	Korea	Not considered	Excluded – samples from Korea (i.e. did not meet geographical origin criteria)
Impact of urine preservation methods and duration of storage on measured levels of environmental contaminants. Hoppin, J. A., Ulmer, R., Calafat, A. M., Barr, D. B., Baker, S. V., Meltzer, H. M. and Ronningen, K. S. Journal of Exposure Science and Environmental	Urine	Not considered	United States of America	Not considered	Excluded – samples from the USA (i.e. did not meet geographical origin criteria NOTE: information on the effect of

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
Epidemiology. 2006. 16:1, 39-48. 10.1038/sj.jea.7500435					preservatives, storage temperature and storage duration on the stability of BPA in urine is reported
Determination of Bisphenol A and its chlorinated derivatives in placental tissue samples by liquid chromatography-tandem mass spectrometry. Jimenez-Diaz, I., Zafra-Gomez, A., Ballesteros, O., Navea, N., Navalon, A., Fernandez, M. F., Olea, N. and Vilchez, J. L. Journal of Chromatography B. 2010. 878:32, 3363-3369. 10.1016/j.jchromb.2010.10.021	Placental tissue	Not considered	Spain	Not considered	Excluded – tissue not considered in biomonitoring
A study on bisphenol A, nonylphenol, and octylphenol in human urine samples detected by SPE-UPLC-MS Jing, X., Bing, S., Xiaoyan, W., Xiaojie, S. and Yongning, W. U. Biomedical and Environmental Sciences. 2011. 24, 40-46. 10.3967/0895-3988.2011.01.005	Urine	Not considered	China	Not considered	Excluded – paper focuses on method development – no relevant data reported for biomonitoring
Development of a radioimmunoassay for the measurement of Bisphenol A in biological samples. Kaddar, N., Bendridi, N., Harthé, C., de Ravel, M. R., Bienvenu, A. L., Cuilleron, C. Y., Mappus, E., Pugeat, M. and Déchaud, H.	Serum	207 plasma samples, randomly collected from samples that were sent to a clinical analysis laboratory, were used for an initial screening of serum BPA concentrations in the general	France	RIA Free BPA was determined LOD = 0.08 ng/mL (3x S:N) LOQ = Not given	Excluded / included NOTE: the authors studied the general population and patients undergoing

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
Analytica Chimica Acta. 2009. 645, 1-4. 10.1016/j.aca.2009.04.036		population.		Recovery = 94-101% (at 0.5-1.5 µg/L) Repeatability = intra: 5.6-6.9% and inter: 5.7-8.6% (at 0.7-1.3 µg/L) Accuracy = Not given Calibration = $r^2 > 0.93$ Deconjugation: None Measures taken to reduce contamination: use of polycarbonate-free collection materials.	dialysis. The former were included, the latter were excluded.
Release of bisphenol A from resin composite used to bond orthodontic lingual retainers. Kang, Y. G., Kim, J. Y., Kim, J., Won, P. J. and Nam, J. H. American Journal of Orthodontics and Dentofacial Orthopaedics. 2011. 140:6, 779-789. 10.1016/j.ajodo.2011.04.022	Urine, Saliva	Not considered	Korea	Not considered	Excluded – biomonitoring data from individuals undergoing dental treatment was not considered in biomonitoring
Determination of bisphenol a in urine from mother-child pairs-results from the duisburg birth cohort study, Germany. Kasper-Sonnenberg, Wittsiepe, Koch, Fromme, Wilhelm 2012, J Toxicol Environ Health A, 75, 429-437. 10.1080/15287394.2012.674907	Urine	Birth cohort study with mother-child pairs, 1st morning urine was collected in 2006–2009. Urine samples were collected from 104 mother-child pairs (29–49 and 6–11 years old) in Duisburg. BPA concentrations were given as volume-based and creatinine-adjusted concentrations	Germany	Total BPA was determined by two independent labs by LC/LC-MS/MS according to a method using enzymatic cleavage and internal standard described by Völkel et al. (2008; 2011). Free BPA was also measured by LC/LC-MS/MS before enzymatic treatment but only in one laboratory LOD = Not given LOQ = 0.1 µg/L (total BPA; lab 1),	Included NOTE: this paper was not included in the contractors database but provides relevant biomonitoring data and so was included

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
				0.15 µg/L (free and total BPA; lab 2) Recovery = Not given Repeatability = Not given Accuracy = Not given Calibration = Not given Deconjugation: Measures taken to reduce contamination: Samples were collected in polypropylene containers and stored at -20°C.	
Miniaturized hollow fiber assisted liquid-phase microextraction with in situ derivatization and gas chromatography-mass spectrometry for analysis of bisphenol A in human urine sample. Kawaguchi, M., Ito, R., Okanouchi, N., Saito, K. and Nakazawa, H. Journal of Chromatography B. 2008. 870:1, 98-102. 10.1016/j.jchromb.2008.06.011	Urine	Not considered	Japan	Not considered	Excluded – paper focuses on method development – no relevant data reported for biomonitoring
Bisphenol A and cardiometabolic risk factors in obese children. Khalil, N., Ebert, J. R., Wang, L., Belcher, S., Lee, M., Czerwinski, S. A. and Kannan, K. The Science of the Total Environment. 2014. 470-471C, 736-732. 10.1016/j.scitotenv.2013.09.088	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Association between urinary levels of bisphenol-A and estrogen metabolism in	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
Korean adults. Kim, E. J., Lee, D., Chung, B. C., Pyo, H. and Lee, J. The Science of the Total Environment. 2014. 470-471, 1401-1407. 10.1016/j.scitotenv.2013.07.040					December 2012 (i.e. did not meet publication period criteria)
Association between urinary concentrations of bisphenol A and type 2 diabetes in Korean adults: A population-based cross-sectional study. Kim, K. and Park, H. International Journal of Hygiene and Environmental Health. 2013. 216, 467-471. 10.1016/j.ijheh.2012.07.007	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Urinary concentrations of bisphenol A and triclosan and associations with demographic factors in the Korean population. Kim, K., Park, H., Yang, W. and Lee, J. H. Environmental Research. 2011. 111:8, 1280-1285. 10.1016/j.envres.2011.09.003	Urine	Not considered	Korea	Not considered	Excluded – samples from Korea (i.e. did not meet geographical origin criteria)
Bisphenol A and other compounds in human saliva and urine associated with the placement of composite restorations. Kingman, A., Hyman, J., Masten, S. A., Jayaram, B., Smith, C., Eichmiller, F., Arnold, M. C., Wong, P. A., Schaeffer, J. M., Solanki S. and Dunn, W. J.	Saliva, Urine	Not considered	United States of America	Not considered	Excluded – samples from the USA (i.e. did not meet geographical origin criteria)

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
Journal of the American Dental Association. 2012. 143, 1292-1302. None given					
In vivo bisphenol-A release from dental pit and fissure sealants: A systematic review. Kloukos, D., Pandis, N. and Eliades, T. Journal of Dentistry. 2013. 41, 659-667. 10.1016/j.jdent.2013.04.012	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Are urinary bisphenol A levels in men related to semen quality and embryo development after medically assisted reproduction? Knez, J., Kranvogl, R., Breznik, B. P., Voncina, E. and Vlaisavljevic, V. Fertility and Sterility. 2014. 101:1, 215-221. 10.1016/j.fertnstert.2013.09.030	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Bisphenol A in 24 h urine and plasma samples of the German Environmental Specimen Bank from 1995 to 2009: A retrospective exposure evaluation Koch, H. M., Kolossa-Gehring, M., Schroter-Kermani, C., Angerer, J. and Bruning, T. Journal of Exposure Science and Environmental Epidemiology. 2012. 22:6, 610-616. 10.1038/jes.2012.39	Urine, Plasma	Retrospective study on the extent of BPA body burden in the German population (students) from 1995–2009 based on a total of 600 24-h urine samples. Samples (600 in total) were taken annually from approximately 60 male and 60 female students (20–30 years old) at each of four univercity cities (two from East Germany and two from West Germany).	Germany	Following enzymatic cleavage of the conjugates clean up of the samples was performed by on-line SPE with detection by HPLC-MS/MS. d_{16}-BPA was used as an internal standard. Total BPA was determined. Free BPA was determined in the same was but without the enzymatic cleavage step. LOD = 0.05 ng/mL (3x S:N) LOQ =0.1 ng/mL (9x S:N) Recovery: 88.5–104% (10 ng/mL in	Included

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
				urine) Repeatability: 6.5% (2.9 ng/mL) and 3.4% (11.8 ng/mL) for within day RSD and 5.6% (2.9 ng/mL) and 3.4% (11.8 ng/mL) between day RSD Accuracy = Not given Calibration = Not given Deconjugation: β-glucuronidase/ sulfatase Measures taken to reduce contamination: Samples were stored in polypropylene containers at -20°C.	
A novel method for the quantitative determination of free and conjugated bisphenol A in human maternal and umbilical cord blood serum using a two-step solid phase extraction and gas chromatography/tandem mass spectrometry. Kosarac, I., Kubwabo, C., Lalonde, K. and Foster, W. Journal of Chromatography B. 2012. 898, 90-94. 10.1016/j.jchromb.2012.04.023	Serum	Study was performed as a part of the FAMILY (Family Atherosclerosis Monitoring In Early Life) study conducted at McMaster University. Samples were collected from pregnant women in 2004-2005. Pilot study of 12 individual human maternal serum samples at mid-pregnancy, at delivery and their matching umbilical cord blood serum samples.	Canada	Following enzymatic cleavage of the conjugates liquid-liquid extraction and SPE clean was performed prior to derivatisation MSTFA and detection by HPLC-MS/MS. $^{13}C_{12}$-BPA was used as an internal standard. Total BPA was determined. Free BPA was determined in the same was but without the enzymatic cleavage step. LOD = 0.026 ng/mL LOQ = 0.087 ng/mL Recovery = 65-88% in spiked sheep serum Repeatability = intra-day variability of 6.2% and inter-day reproducibility	Included NOTE: although the samples were from Canada the paper provides data for biomonitoring not available elsewhere and so was included NOTE: for serum biomonitoring, studies from all geographical regions were included to inform toxicological risk assessment

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
				of 17.6% (determined using sheep serum) Accuracy = Not given Calibration = 1-100 ng/mL ($r^2 > 0.998$) Deconjugation: β-glucuronidase, BPA-d6-β-glucuronide was used to optimise the deconjugation reaction Measures taken to reduce contamination: Solvents, water, extraction equipment and method blanks were checked for the presence BPA. Chemically pre-cleaned glass vials, containers and pipettes were used. Results were blank corrected.	
Biomonitoring Equivalents for bisphenol A (BPA). Krishnan, K., Gagne, M., Nong, A., Aylward, L. L. and Hays, S. M. Regulatory Toxicology and Pharmacology. 2010. 58:1, 18-24. 10.1016/j.yrtph.2010.06.005	Urine	Not considered	Not considered	Not considered	Excluded – no new data reported for biomonitoring
Simultaneous quantification of bisphenol A and its glucuronide metabolite (BPA-G) in plasma and urine: applicability to toxicokinetic investigations. Lacroix, M. Z., Puel, S., Collet, S. H., Corbel, T., Picard-Hagen, N., Toutain, P. L., Viguie, C. and Gayrard, V.	Plasma, Urine	Not considered	Not considered	Not considered	Excluded - toxicokinetic study in sheep – no relevant data reported for biomonitoring

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
Talanta. 2011. 85:4, 2053-2059. 10.1016/j.talanta.2011.07.040					
Comparing United States and Canadian population exposures from National Biomonitoring Surveys: bisphenol A intake as a case study. Lakind, J. S., Levesque, J., Dumas, P., Bryan, S., Clarke, J. and Naiman, D. Q. Journal of Exposure Science and Environmental Epidemiology. 2012. 22:3, 219-226. 10.1038/jes.2012.1	Urine	Not considered	United States of America and Canada	Not considered	Excluded – no new data for biomonitoring
Bisphenol A (BPA) daily intakes in the United States: estimates from the 2003-2004 NHANES urinary BPA data. Lakind, J. S. and Naiman, D. Q. Journal of Exposure Science and Environmental Epidemiology. 2008. 18:6, 608-615. 10.1038/jes.2008.20	Urine	Not considered	United States of America	Not considered	Excluded – data on urinary BPA reported here was used but was taken from the NHANES website of the CDC
Daily intake of bisphenol A and potential sources of exposure: 2005-2006 National Health and Nutrition Examination Survey. Lakind, J. S. and Naiman, D. Q. Journal of Exposure Science and Environmental Epidemiology. 2011. 21:3, 272-279. 10.1038/jes.2010.9	Urine	Not considered	United States of America	Not considered	Excluded – data on urinary BPA reported here was used but was taken from the NHANES website of the CDC
Serum Bisphenol A (BPA) and reproductive outcomes in couples undergoing IVF. Lamb, J. D., Bloom, M. S., vom Saal, F. S.,	Serum	Not considered	United States of America	Not considered	Excluded – this is a poster abstract; the related full paper is

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
Taylor, J. A., Sandler, J. R. and Fujimoto, V. Y. Fertility and Sterility. 2008. 90, S186. 10.1016/j.fertnstert.2008.07.751					Bloom et al. (2011); doi: doi:10.1016/j.etap.2011.06.003
Association of urinary bisphenol A concentration with medical disorders and laboratory abnormalities in adults. Lang, I. A., Galloway, T. S., Scarlett, A., Henley, W. E., Depledge, M., Wallace, R. B. and Melzer, D. The Journal of the American Medical Association. 2008. 300, 1303-1310. 10.1001/jama.300.11.1303	Urine	Not considered	United States of America	Not considered	Excluded – data on urinary BPA reported here was used but was taken from the NHANES website of the CDC
Temporal variability in urinary excretion of bisphenol A and seven other phenols in spot, morning, and 24-h urine samples. Lassen, T. H., Frederiksen, H., Jensen, T. K., Petersen, J. H., Main, K. M., Skakkebæk, N. E., Jørgensen, N., Kranich, S. K. and Andersson, A.-M. Environmental Research. 2013. 126, 164-170. 10.1016/j.envres.2013.07.001	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Changes in steroid metabolism among girls with precocious puberty may not be associated with urinary levels of bisphenol A. Lee, S. H., Kang, S. M., Choi, M. H., Lee, J., Park, M. J., Kim, S. H., Lee, W. Y., Hong, J. and Chung, B. C. Reproductive Toxicology. 2014. 44, 1-6.	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
10.1016/j.reprotox.2013.03.008					
Maternal and fetal exposure to bisphenol A in Korea. Lee, Y. J., Ryu, H.-Y., Kim, H.-K., Min, C. S., Lee, J. H., Kim, E., Nam, B. H., Park, J. H., Jung, J. Y., Jang, D. D., Park, E. Y., Lee, K.-H., Ma, J.-Y., Won, H.-S., Im, M.-W., Leem, J.-H., Hong, Y.-C. and Yoon, H.-S. Reproductive Toxicology. 2008. 25:4, 413-419 10.1016/j.reprotox.2008.05.058	Serum	Study on healthy pregnant Korean women at delivery. Maternal blood and umbilical cord blood were sampled at full-term delivery. 300 mother-newborn pairs from a hospital in a Korean county were analyzed.	Korea	Following enzymatic cleavage of the conjugates the serum samples were extracted with MTBE, evaporated to dryness before recoinstituting in acreetonitrile for analysis by HPLC-FLD. Bisphenol B was used as an internal standard. Total BPA was determined. LOD = 0.625 ng/mL LOQ = Not given Recovery = : 95.3% at 5 ng/mL, 93.0% at 20 ng/mL and 91.0% at 80 ng/mL Repeatability = 14.8% at 2.5 ng/mL, 9.4% at 10 ng/mL and 3.6% at 40 ng/mL Accuracy = 99-101% (at 40 ng/mL) Calibration = Not given Deconjugation: β-glucuronidase/ sulfatase (H-2, *H. pomatia*) Measures taken to reduce contamination: Plastic wares were excluded throughout the entire analytic procedure; glassware was used instead. Samples were stored at -80°C.	Included NOTE: although the samples were from Korea the paper provides data for biomonitoring not available elsewhere and so was included NOTE: for serum biomonitoring, studies from all geographical regions were included to inform toxicological risk assessment
Development and comparison of two	Not	Not considered	Not	Not considered	Excluded – paper

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
competitive ELISAs for the detection of bisphenol A in human urine. Lei, Y., Fang, L., Akash, M. S. H., Liu, Z., Shi, W. and Chen, S. Analytical Methods. 2013. 5:21, 6106-6113. 10.1039/c3ay41023d	considered		considered		published after December 2012 (i.e. did not meet publication period criteria)
Predictors of urinary bisphenol A and phthalate metabolite concentrations in Mexican children. Lewis, R. C., Meeker, J. D., Peterson, K. E., Lee, J. M., Pace, G. G., Cantoral, A. and Tellez-Rojo, M. M. Chemosphere. 2013. 93:10, 2390-2398. 10.1016/j.chemosphere.2013.08.038	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Urine Bisphenol-A Level in Relation to Obesity and Overweight in School-Age Children. Li, D.-K., Miao, M., Zhou, Z., Wu, C., Shi, H., Liu, X., Wang, S. and Yuan, W. PLoS One. 2013. 8, e65399. None given	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Urine bisphenol-A (BPA) level in relation to semen quality. Li, D. K., Zhou, Z., Miao, M., He, Y., Wang, J., Ferber, J., Herrinton, L. J., Gao, E. and Yuan, W. Fertility and Sterility. 2011. 95:2, 625-630. 10.1016/j.fertnstert.2010.09.026	Urine	Not considered	China	Not considered	Excluded – samples from China (i.e. did not meet geographical origin criteria)
Relationship between urine bisphenol-A level	Urine	Not considered	China	Not considered	Excluded – samples from China (i.e. did

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
and declining male sexual function. Li, D. K., Zhou, Z., Miao, M., He, Y., Qing, D., Wu, T., Wang, J., Weng, X., Ferber, J., Herrinton, L. J., Zhu, Q., Gao, E. and Yuan, W. Journal of Andrology. 2010. 31:5, 500-506. 10.2164/jandrol.110.010413					not meet geographical origin criteria)
4-Nonylphenol, bisphenol-A and triclosan levels in human urine of children and students in China, and the effects of drinking these bottled materials on the levels. Li, X., Ying, G. G., Zhao, J. L., Chen, Z. F., Lai, H. J. and Su, H. C. Environment International. 2013. 52, 81-86. 10.1016/j.envint.2011.03.026	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Dispersive liquid–liquid microextraction based on ionic liquid in combination with high-performance liquid chromatography for the determination of bisphenol A in water. Li, Y. and Liu, J. International Journal of Environmental Analytical Chemistry. 2010. 90:11, 880-890. 10.1080/03067310903045455	Water	Not considered	China	Not considered	Excluded – paper focuses on methodology – no relevant data reported for biomonitoring
Determination of free and conjugated forms of bisphenol A in human urine and serum by liquid chromatography-tandem mass spectrometry. Liao, C. and Kannan, K. Environmental Science and Technology. 2012.	Serum, Urine	Spot urine samples from 31 healthy volunteers (11-66 years old) from Albany (NY) were collected in 2011. Serum were collected from 14 donors (27-63 years old). Urinary BPA concentrations were	United States of America	6 different forms of BPA were determined: Free BPA, BPA-glucuronide, BPA-disulfate, BPA-mono-Cl, BPA-di-Cl, BPA-tri-Cl Urine and serum samples were spiked with internal standard ($^{13}C_{12}$-BPA), purified using SPE and analysed with	Included (only serum data) NOTE: although the samples were from the USA the paper

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
46:9, 5003-5009. 10.1021/es300115a		adjusted for creatinine.		LC-MS/MS. Free and total BPA were determined separately: after addition of internal standard ($^{13}C_{12}$-BPA) one part of the the urine and serum samples were extracted with ethyl acetate, the other part was enzymatically cleaved before extraction. Both parts were analyses using LC-MS/MS LOD = 0.003 ng/mL (free BPA), 0.02 ng/mL (conjugated / substituted BPA) LOQ = 0.01 ng/mL (free BPA), 0.05 ng/mL (conjugated/substituted BPA) Recovery = spiking of 10-100 ng BPA gave values of 96±14% (blank) and 105±18% (urine), 87±8% (blank) and 80+13% (serum) Repeatability = Urine: 5−16% (10 ng), 3−11% (50 ng), 2−19% (100 ng), Serum: 5−11% (10 ng), 3−15% (50 ng), 8−18% (100 ng). Accuracy = Not given Calibration=0.01-100 ng/mL (r>0.99) Deconjugation: β-glucuronidase/ sulfatase (Helix pomatia) Measures taken to reduce contamination: Samples were stored in polypropylene containers at -20°C. Background subtraction was	provides data for biomonitoring not available elsewhere and so was included NOTE: for serum biomonitoring, studies from all geographical regions were included to inform toxicological risk assessment

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
				performed for BPA.	
Bisphenol S in urine from the United States and seven Asian countries: occurrence and human exposures. Liao, C., Liu, F., Alomirah, H., Loi, V. D., Mohd, M. A., Moon, H. B., Nakata, H. and Kannan, K. Environmental Science and Technology. 2012. 46:12, 6860-6866. 10.1021/es301334j	Urine	Not considered	United States of America	Not considered	Excluded – this paper focuded on bisphenol S – no relevant data reported for biomonitoring
Validation and Application of a Method for the Determination of Bisphenol A in Urine By LC-MS/MS: Short-term Temperature Stability Test. Lim, H., Oh, E., Yaung, M., Kim, S. H., Hwang, Y. S., Park, K.-H., Kang, T. S. and Yu, S. D. Epidemiology. 2011. 22, S246-S246. 10.1097/01.ede.0000392445.38840.6a	Urine	Not considered	Korea	Not considered	Excluded – paper focuses on phthalates rather than bisphenol A – no relevant data reported for biomonitoring
Automated on-line liquid chromatography-photodiode array-mass spectrometry method with dilution line for the determination of bisphenol A and 4-octylphenol in serum. Liu, M., Hashi, Y., Pan, F., Yao, J., Song, G. and Lin, J. M. Journal of Chromatography A. 2006. 1133:1-2, 142-148. 10.1016/j.chroma.2006.08.009	Serum	Samples were obtained from hospital. Samples were collected from healthy subjects.	China	Serum samples were cleaned up using a restricted access media column wth on-line LC–DAD–MS detection. Free BPA was determined. LOD = 0.05 ng/mL in serum (3x S:N) LOQ = 0.1 ng/mL in serum (10x S:N)	Included NOTE: although the samples were from China the paper provides data not available elsewhere and so was included NOTE: for serum biomonitoring,

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
				Recovery = intra-day: 88-101% (at 0.5-500 ng/mL) inter-day: 81-94% (at 0.5-500 ng/mL) Repeatability = intra-day: 2-7% (at 0.5-500 ng/mL), inter-day: 6-7% (at 0.5-500 ng/mL) Accuracy = Not given Calibration = 0.1-500 ng/mL ($r^2 > 0.99$) Deconjugation: None Measures taken to reduce contamination: No measures against contamination reported. Samples were stored at -25°C.	studies from all geographical regions were included to inform toxicological risk assessment
The concentration of bisphenol A in urine is affected by specimen collection, a preservative, and handling. Longnecker, M. P., Harbak, K., Kissling, G. E, Hoppin, J. A., Eggesbo, M., Jusko, T. A., Eide, J. and Koch H. M. Environmental Research. 2013. 126, 211-214. 10.1016/j.envres.2013.07.002i	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Analysis of polyfluoroalkyl substances and bisphenol A in dried blood spots by liquid chromatography tandem mass spectrometry. Ma, W., Kannan, K., Wu, Q., Bell, E. M., Druschel, C. M., Caggana, M. and Aldous, K. M. Analytical and Bioanalytical Chemistry. 2013.	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
405:12, 4127-4138. 10.1007/s00216-013-6787-3					
Temporal variability and predictors of urinary bisphenol A concentrations in men and women. Mahalingaiah, S., Meeker, J. D., Pearson, K. R., Calafat, A. M., Ye, X., Petrozza, J. and Hauser, R. Environmental Health Perspectives. 2008. 116:2, 173-178. 10.1289/ehp.10605	Urine	Not considered	United States of America	Not considered	Excluded – samples from the USA (i.e. did not meet geographical origin criteria)
Association between water consumption from polycarbonate containers and bisphenol A intake during harsh environmental conditions in summer. Makris, K. C., Andra, S. S., Jia, A., Herrick, L., Christophi, C. A., Snyder, S. A. and Hauser, R. Environmental Science and Technology. 2013. 47:7, 3333-3343. 10.1021/es304038k	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Development of a method for the determination of bisphenol A at trace concentrations in human blood and urine and elucidation of factors influencing method accuracy and sensitivity. Markham, D. A., Waechter, J. M. Jr., Wimber, M., Rao, N., Connolly, P., Chuang, J. C., Hentges, S., Shiotsuka, R. N., Dimond, S. and Chappelle, A. H. Journal of Analytical Toxicology. 2010. 34, 293-303.	Blood	Not considered	United States of America	Not conisdered	Excluded – paper focuses on the issue of sample contamination and stability – no relevant data reported for biomonitoring

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
None given					
Distribution, variability, and predictors of urinary concentrations of phenols and parabens among pregnant women in Puerto Rico. Meeker, J. D., Cantonwine, D. E., Rivera-Gonzalez, L. O., Ferguson, K. K., Mukherjee, B., Calafat, A. M., Ye, X., Anzalota Del Toro, L. V., Crespo-Hernandez, N., Jimenez-Velez, B., Alshawabkeh, A. N. and Cordero, J. F. Environmental Science and Technology. 2013. 47:7, 3439-3447. 10.1021/es400510g	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Semen quality and sperm DNA damage in relation to urinary bisphenol A among men from an infertility clinic. Meeker, J. D., Ehrlich, S., Toth, T., L. Wright, D. L. Calafat, A. M., Trisini, A. T., Ye, X. and Hauser, R. Reproductive Toxicology. 2010. 30:4, 532-539. 10.1016/j.reprotox.2010.07.005	Urine	Not considered	United States of America	Not considered	Excluded – samples from the USA (i.e. did not meet geographical origin criteria)
Urinary bisphenol a concentration and angiography-defined coronary artery stenosis. Melzer, D., Gates, P., Osborn, N. J., Henley, W. E., Cipelli, R., Young, A., Money, C., McCormack, P., Schofield, P., Mosedale, D., Grainger, D. and Galloway, T. S. PLoS One. 2012. 7:8, e43378. 10.1371/journal.pone.0043378	Urine	591 patients participating in The Metabonomics and Genomics in Coronary Artery Disease (MaGiCAD) study, an angiography referral study from Cambridgeshire, UK. Subjects provided an urine speciment during their their 1st angiography visit. Urine	United Kingdom	Not considered	Excluded – urinary data from UK patients with different grades of severity of coronary artery disease

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
		collection in 2001-2004.			
Urinary bisphenol A concentration and risk of future coronary artery disease in apparently healthy men and women. Melzer, D., Osborne, N. J., Henley, W. E., Cipelli, R., Young, A., Money, C., McCormack, P., Luben, R., Khaw, K. T., Wareham, N. J. and Galloway, T. S. Circulation. 2012. 125:12, 1482-1490. 10.1161/CIRCULATIONAHA.111.069153	Urine	Nested case-control set within the European Prospective Investigation Into Cancer and Nutrition (EPIC) – Norfolk cohort study, which is a prospective population study. Baseline sample collection in 1993-1997 during clinical examination. Single-spot samples were collected.	United Kingdom	Not considered	Excluded – although the paper was published in 2012 it contained data from 1993-1997
Association of urinary bisphenol a concentration with heart disease: evidence from NHANES 2003/06. Melzer, D., Rice, N. E., Lewis, C., Henley, W. E. and Galloway, T. S. PLoS One. 2010. 5:1, e8673. 10.1371/journal.pone.0008673	Urine	Not considered	United States of America	Not considered	Excluded – data on urinary BPA reported here was used but was taken from the NHANES website of the CDC
Bisphenol A levels in blood depend on age and exposure. Mielke, H. and Gundert-Remy, U. Toxicology Letters. 2009. 190:1, 32-40. 10.1016/j.toxlet.2009.06.861	Blood	Not considered	Not considered	Not considered	Excluded – paper focuses on PBKT modelling – no relevant data reported for biomonitoring
The contribution of dermal exposure to the internal exposure of bisphenol A in man. Mielke, H., Partosch, F. and Gundert-Remy, U. Toxicology Letters. 2011. 204:2-3, 190-198. 10.1016/j.toxlet.2011.04.032	Serum, Urine	Not considered	Not considered	Not considered	Excluded – paper focuses on PBKT modelling – no relevant data reported for biomonitoring

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
Urinary bisphenol A concentrations and ovarian response among women undergoing IVF. Mok-Lin, E., Ehrlich, S., Williams, P. L., Petrozza, J., Wright, D. L., Calafat, A. M., Ye, X. and Hauser, R. International Journal of Andrology. 2010. 33:2, 385-393. 10.1111/j.1365-2605.2009.01014.x	Urine	Not considered	United States of America	Not considered	Excluded – samples from the USA (i.e. did not meet geographical origin criteria)
Simultaneous determination of daidzein, equol, genistein and bisphenol A in human urine by a fast and simple method using SPE and GC-MS. Moors, S., Blaszkewicz, M., Bolt, H. M. and Degen, G. H. Molecular Nutrition and Food Research. 2007. 51, 787-798. 10.1002/mnfr.200600289	Urine	Not considered	Germany	Not considered	Excluded – paper focuses on method development – no relevant data reported for biomonitoring
Assessing the quantitative relationships between preschool children's exposures to bisphenol A by route and urinary biomonitoring. Morgan, M. K., Jones, P. A., Calafat, A. M., Ye, X., Croghan, C. W., Chuang, J. C., Wilson, N. K., Clifton, M. S., Figueroa, Z. and Sheldon, L. S. Environmental Science and Technology. 2011. 45:12, 5309-5316. 10.1021/es200537u	Urine	Not considered	United States of America	Not considered	Excluded – samples from the USA (i.e. did not meet geographical origin criteria)
Application of electro-enhanced solid-phase microextraction for determination of phthalate	Not	Not considered	Not	Not considered	Excluded – paper published after

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
esters and bisphenol A in blood and seawater samples. Mousa, A., Basheer, C. and Rahman Al-Arfaj, A. Talanta. 2013. 115, 308-313. 10.1016/j.talanta.2013.05.011	considered		considered		December 2012 (i.e. did not meet publication period criteria)
Urinary Free Bisphenol A and Bisphenol A-Glucuronide Concentrations in Newborns. Nachman, R. M., Fox, S. D., Golden, W. C., Sibinga, E., Veenstra, T. D., Groopman, J. D. and Lees, P. S. The Journal of Paediatrics. 2013. 162, 870-872. 10.1016/j.jpeds.2012.11.083	Urine	Analysis of unconjugated and glucuronidated BPA urine collected from healthy newborns, whose mothers were recruited from the newborn nursery at the Johns Hopkins Hospital. Duplicate samples from n=12 healthy newborns (7–44 days old). On the day of sample collection, the newborns had received infant formula or breast milk, or a mixture of both.	United States of America	Samples were derivatised with dansyl chloride and the derivatives were analysed by HPCL-MS/MS. d_6-BPA and d_6-BPA-glucuronide were used as internal standards. Free BPA and BPA-glucuronide were determined. LOD = 0.02 ng/mL LOQ = 0.1 ng/mL Recovery = Not given Repeatability = Not given Accuracy = Not given Calibration = Not given Deconjugation: None Measures taken to reduce contamination: BPA-free urine collection bags were used. Samples were stored in pre-cleaned glass vials at -80°C.	Excluded NOTE: the samples were from the USA, and outside the publication period and the method performance was not well described
Urinary bisphenol A concentrations in girls from rural and urban Egypt: a pilot study.	Urine	Not considered	Egypt	Not considered	Excluded – samples from Egypt (i.e. did

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
Nahar, M. S., Soliman, A. S., Colacino, J. A., Calafat, A. M., Battige, K., Hablas, A., Seifeldin, I. A., Dolinoy, D. C. and Rozek, L. S. Environmental Health. 2012. 11, 1-8. 10.1186/1476-069X-11-20					not meet geographical origin criteria)
Social disparities in exposures to bisphenol A and polyfluoroalkyl chemicals: a cross-sectional study within NHANES 2003-2006. Nelson, J. W., Scammell, M. K., Hatch, E. E. and Webster, T. F. Environmental Health. 2012. 11, 1-15. 10.1186/1476-069X-11-10	Urine	Not considered	United States of America	Not considered	Excluded – data on urinary BPA reported here was used but was taken from the 2003-2004 and 2005-2006 NHANES reports
Within-person variability in urinary bisphenol A concentrations: measurements from specimens after long-term frozen storage. Nepomnaschy, P. A., Baird, D. D., Weinberg, C. R., Hoppin, J. A., Longnecker, M. P. and Wilcox, A. J. Environmental Research. 2009. 109:6, 734-737. 10.1016/j.envres.2009.04.004	Urine	Not considered	United States of America	Not considered	Excluded – samples from the USA (i.e. did not meet geographical origin criteria)
Re: Serum Bisphenol-A Concentration and Sex Hormone Levels in Men. Niederberger, C. The Journal of Urology. 2013. 100, 478-482. 10.1016/j.juro.2013.10.119	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Relationship of urinary bisphenol A concentration to risk for prevalent type 2 diabetes in Chinese adults: a cross-sectional	Urine	Not considered	China	Not considered	Excluded – samples from China (i.e. did not meet

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
analysis. Ning, G., Bi, Y., Wang, T., Xu, M., Xu, Y., Huang, Y., Li, M., Li, X., Wang, W., Chen, Y., Wu, Y., Hou, J., Song, A., Liu, Y. and Lai, S. Annals of Internal Medicine. 2011. 155, 368-374. 10.1059/0003-4819-155-6-201109200-00005					geographical origin criteria)
Circulating levels of bisphenol A (BPA) and phthalates in an elderly population in Sweden, based on the Prospective Investigation of the Vasculature in Uppsala Seniors (PIVUS). Olsén, L., Lampa, E., Birkholz, D. A., Lind, L. and Lind, P. M. Ecotoxicology and Environmental Safety. 2012. 75:1, 242-248. 10.1016/j.ecoenv.2011.09.004	Serum	Population-based prospective study on serum BPA levels in Uppsala seniors. Blood samples were taken after overnight fast. Population-based prospective study in 1016 randomly selected Uppsala seniors (70 years old, 50:50 male:female), random selection.	Sweden	Following enzymatic cleavage of the conjugates the urine samples were subjected to SPE clean up with detection by HPLC-MS/MS. $^{13}C_{12}$-BPA was used as an internal standard. Total BPA was determined. LOD = 0.2 ng/mL (3x S:N) LOQ = Not given Recovery = Not given Repeatability = Not given Accuracy = Not given Calibration = Not given Deconjugation: β-glucuronidase (E. coli K12), a deconjugation standard was also added Measures taken to reduce contamination: No measures against contamination reported.	Included NOTE: although the method performance was not well described the paper provides data for biomonitoring not available elsewhere and so was included NOTE: for serum biomonitoring, studies from all geographical regions were included to inform toxicological risk assessment
Maternal bisphenol-A levels at delivery: a	Serum	As part of standard clinical	United	LLE, HPLC-MS/MS, butylphenol as	Included

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
looming problem? Padmanabhan, V., Siefert, K., Ransom, S., Johnson, T., Pinkerton, J., Anderson, L., Tao, L. and Kannan, K. Journal of Perinatology. 2008. 28, 258-263. 10.1038/sj.jp.7211913		hospital procedures, maternal blood samples were collected at the time of delivery from 40 pregnant mothers delivering in a hospital in 2006.	States of America	internal standard, Free BPA was determined. LOD = 0.5 ng/mL LOQ = Not given Recovery = 83-89% for sheep whole blood, serum and plasma Repeatability = Not given Accuracy = Not given Calibration = 0.2-100 ng/mL Deconjugation: None Measures taken to reduce contamination: Blood samples were drawn directly into a vacutainer tube, stored in a glass tube and stored at –80 °C. Trace levels of BPA detected in the blanks (< 0.1 ng) were subtracted from sample concentrations.	NOTE: this paper was not included in the contractors database but provides relevant biomonitoring data and so was included NOTE: although the samples were from the USA the paper provides data for biomonitoring not available elsewhere and so was included NOTE: for serum biomonitoring, studies from all geographical regions were included to inform toxicological risk assessment
From cans and containers to amniotic fluid: bisphenol a exposure during pregnancy. Pasternack, T., Steinauer, J. E., Hunt, P., Taylor, J. A., Fujimoto, V. Y. and Woodruff, T. J. Fertility and Sterility. 2009. 92:3, S43.	Amniotic fluid	Not considered	United States of America	Not considered	Excluded – tissue not considered in biomonitoring

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
10.1016/j.fertnstert.2009.07.167					
Urinary levels of bisphenol A, triclosan and 4-nonylphenol in a general Belgian population. Pirard, C., Sagot, C., Deville, M., Dubois, N. and Charlier, C. Environment International. 2012. 48, 78-83. 10.1016/j.envint.2012.07.003	Urine	131 first-morning urine samples were collected from a non-occupationally exposed population (1–75 yr) living in Liege area (Belgium) in 2011. Small-scale cohort, not fully representative population in terms socio-economical range and geography.	Belgium	Following enzymatic cleavage of the conjugates the sample was cleaned-up using SPE and derivatised using PFBCl with detection by GC-MS/MS. d_{14}-BPA was used as an internal standard. Total BPA was determined. LOD = 0.16 ng/mL LOQ = 0.50 ng/mL Recovery = Not given Repeatability = 3-21% Accuracy = Not given Calibration = 0.5-15 ng/mL Deconjugation: β-glucuronidase/ sulfatase (Helix pomatia) Measures taken to reduce contamination: Samples were stored in polypropylene containers, which were screened for background contamination (BPA was not detected).	Included
Determinants of urinary bisphenol A concentrations in Mexican/Mexican-American pregnant women. Quiros-Alcala, L., Eskenazi, B., Bradman, A., Ye, X., Calafat, A. M. and Harley, K. Environment International. 2013. 59C, 152-	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
160. 10.1016/j.envint.2013.05.016					
Sensitive determination of bisphenol A and bisphenol F in canned food using a solid-phase microextraction fibre coated with single-walled carbon nanotubes before GC/MS. Rastkari, N., Ahmadkhaniha, R., Yunesian, M., Baleh, L. J. and Mesdaghinia, A. Food Additives and Contaminants: Part A. 2010. 27:10, 1460-1468. 10.1080/19440049.2010.495730	Food	Not considered	Iran	Not considered	Excluded – paper focuses on methodology for food – no relevant data reported for biomonitoring
Bisphenol A and human health: A review of the literature. Rochester, J. R. Reproductive Toxicology. 2013. 42C, 132-155. 10.1016/j.reprotox.2013.08.008	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Development and validation of a method for the detection and confirmation of biomarkers of exposure in human urine by means of restricted access material-liquid chromatography-tandem mass spectrometry. Rodriguez-Gonzalo, E., Garcia-Gomez, D. and Carabias-Martinez, R. Journal of Chromatography A. 2010. 1217:1, 40-48. 10.1016/j.chroma.2009.11.002	Urine	Not considered	Spain	Not considered	Excluded – paper focuses on method development – no relevant data reported for biomonitoring
Food packaging and bisphenol A and bis(2-ethyhexyl) phthalate exposure: findings from a	Urine	Not considered	United States of	Not considered	Excluded – paper describes an

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
dietary intervention. Rudel, R. A., Gray, J. M., Engel, C. L., Rawsthorne, T. W., Dodson, R. E., Ackerman, J. M., Rizzo, J., Nudelman, J. L. and Brody, J. G. Environmental Health Perspectives. 2011. 119:7, 914-920. 10.1289/ehp.1003170			America		intervention study – no relevant data reported for biomonitoring
Relationship between urinary bisphenol A levels and prediabetes among subjects free of diabetes. Sabanayagam, C., Teppala, S. and Shankar, A. Acta Diabetol. 2013. 50:4, 625-631. 10.1007/s00592-013-0472-z	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Occurrence of bisphenol A in surface water, drinking water and plasma from Malaysia with exposure assessment from consumption of drinking water. Santhi, V. A., Sakai, N., Ahmad, E. D. and Mustafa, A. M. The Science of the Total Environment. 2012. 427-428, 332-338. 10.1016/j.scitotenv.2012.04.041	Plasma	101 random samples were collected from communities living in a Malaysian River-basin region.	Malaysia	Samples were acidified, cleaned up using SPE and the BPA wasderivatised with BSTFA. Analysis was by GC-MS. d_{16}-BPA was used as an internal standard. Free BPA was determined. LOD = 0.25 ng/mL (3x S:N) LOQ = 0.75 ng/mL (10x S:N) Recovery = 80-97% (0.75-20 ng/mL) in plasma Repeatability = intraday: 2.9-7.0%, interday: 2.7-8.9%, Accuracy = bias: −0.4-8.8%	Included NOTE: although the samples were from Malaysia the paper provides data for biomonitoring not available elsewhere and so was included NOTE: for serum biomonitoring, studies from all geographical regions were included to

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
				Calibration = $r^2 > 0.995$ Deconjugation: None Measures taken to reduce contamination: Use of plasticware was avoided with samples collected in heparinized tubes using a glass syringe. Solvents were distilled. Procedural blanks were tested and the BPA measured was below the LOD.	inform toxicological risk assessment
Unexpected results in a randomized dietary trial to reduce phthalate and bisphenol A exposures. Sathyanarayana, S., Alcedo, G., Saelens, B. E., Zhou, C., Dills, R. L., Yu, J. and Lanphear, B. Journal of Exposure Science and Environmental Epidemiology. 2013. 23:4, 378-384. 10.1038/jes.2013.9	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Bisphenol A (BPA) in U.S. food Schecter, A., Malik, N., Haffner, D., Schecter, S., Haffner, D., Smith, S., Harris, T. R., Paepke, O. and Birnbaum, L. Environmental Science and Technology. 2010. 44, 9425-9430. 10.1021/es102785d	Food	Not considered	United States of America	Not considered	Excluded – analytical method paper for food – no relevant data reported for biomonitoring
Simultaneous monitoring of seven phenolic metabolites of endocrine disrupting compounds (EDC) in human urine using gas chromatography with tandem mass spectrometry. Schmidt, L., Muller, J. and Goen, T.	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
Analytical and Bioanalytical Chemistry. 2013. 405, 2019-2029. 10.1007/s00216-012-6618-y					
Sample clean-up with sol-gel enzyme and immunoaffinity columns for the determination of bisphenol A in human urine. Schoringhumer, K. and Cichna-Markl, M. Journal of Chromatography B. 2007. 850:1-2, 361-369. 10.1016/j.jchromb.2006.12.002	Urine	Not considered	Austria	Not considered	Excluded – paper focuses on method development – no relevant data reported for biomonitoring
Relationship between urinary bisphenol A levels and diabetes mellitus. Shankar, A. and Teppala, S. The Journal of Clinical Endocrinology and Metabolism. 2011. 96:12, 3822-3826. 10.1210/jc.2011-1682	Urine	Not considered	United States of America	Not considered	Excluded – data on urinary BPA reported here was used but was taken from NHANES website of the CDC
Consecutive Online Separation and Determination of Polybrominated Diphenyl Ethers, Phthalate Esters and Bisphenol A in Human Serum by Gas Chromatography-Mass Spectrometry. Shao, M., Chen, Y.-H. and Li, X.-Y. Chinese Journal of Analytical Chemistry. 2012. 40:8, 1139-1146. 10.1016/s1872-2040(11)60569-0	Serum	Not considered	China	Not considered	Excluded – paper focuses on method development – no relevant data reported for biomonitoring
Urine phthalate concentrations are higher in people with stroke: United States National Health and Nutrition Examination Surveys	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
(NHANES), 2001-2004. Shiue, I. European Journal of Neurology. 2013. 20:4, 728-731. 10.1111/j.1468-1331.2012.03862.x					(i.e. did not meet publication period criteria)
The association of bisphenol-A urinary concentrations with antral follicle counts and other measures of ovarian reserve in women undergoing infertility treatments. Souter, I., Smith, K. W., Dimitriadis, I., Ehrlich, S., Williams, P. L., Calafat, A. M. and Hauser, R. Reproductive Toxicology. 2013. 42C, 224-231. 10.1016/j.reprotox.2013.09.008	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Prenatal exposure to bisphenol A and child wheeze from birth to 3 years of age. Spanier, A. J., Kahn, R. S., Kunselman, A. R., Hornung, R., Xu, Y., Calafat, A. M. and Lanphear, B. P. Environmental Health Perspectives. 2012. 120:6, 916-920. 10.1289/ehp.1104175	Urine	Not considered	United States of America	Not considered	Excluded – samples from the USA (i.e. did not meet geographical origin criteria)
Association between bisphenol A and abnormal free thyroxine level in men. Sriphrapradang, C., Chailurkit, L., Aekplakorn, W. and Ongphiphadhanakul, B. Endocrine. 2013. 44:4, 447-447. 10.1007/s12020-013-9889-y	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
Bisphenol A data in NHANES suggest longer than expected half-life, substantial nonfood exposure, or both. Stahlhut, R. W., Welshons, W. V. and Swan, S. H. Environmental Health Perspectives. 2009. 117:5, 784-789. 10.1289/ehp.0800376	Urine	Not considered	United States of America	Not considered	Excluded – data on urinary BPA reported here was used but was taken from the NHANES website of the CDC
Analysis of Bisphenol A in Blood and Urine Samples: A Mini Review. Taskeen, A. and Naeem, I. Asian Journal of Chemistry. 2010. 22:5, 4136-4140. None given	Review paper	Not considered	Not considered	Not considered	Excluded – a review paper – no new data reported for biomonitoring
Twenty-four hour human urine and serum profiles of bisphenol a during high-dietary exposure. Teeguarden, J. G., Calafat, A. M., Ye, X., Doerge, D. R., Churchwell, M. I., Gunawan, R. and Graham, M. K. Toxicological Sciences. 2011. 123:1, 48-57. 10.1093/toxsci/kfr160	Urine, Serum	Measurement of 24-h urinary and serum profiles. 20 randomly selected healthy adults (age 18–55 years) were recruited in 2009. Probands consumed diet rich in canned food.	United States of America	Following enzymatic cleavage of the conjugates clean up of the samples was performed by on-line SPE with detection by HPLC-MS/MS. d_{16}-BPA was used as an internal standard. Total BPA was determined. Free BPA was determined in the same was but without the enzymatic cleavage step. LOD = 0.4 ng/mL (urine) and 0.3 ng/mL (serum) (2x S:N) LOQ = Not given Recovery = 98-113%	Included (only serum – s. below) NOTE: controlled dietary exposure study and and does as an intervention study, not meet the inclusion criteria. However, it was included in the Section "Biomonitoring studies on serum levels" in the

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
				Repeatability = 5.3-7.4% Accuracy = 98-113% (expressed as recovery) Calibration = Not given Deconjugation: β-glucuronidase/ sulfatase. Measures taken to reduce contamination: Plastics other than polypropylene were avoided.	subsection "Methodological aspects".
Temporal variability in urinary concentrations of phthalate metabolites, phytoestrogens and phenols among minority children in the United States. Teitelbaum, S. L., Britton, J. A., Calafat, A. M., Ye, X., Silva, M. J., Reidy, J. A., Galvez, M. P., Brenner, B. L. and Wolff, M. S. Environmental Research. 2010. 106:2, 257-269. 10.1016/j.envres.2007.09.010	Urine	Not considered	United States of America	Not considered	Excluded – samples from the USA (i.e. did not meet geographical origin criteria)
Association between urinary bisphenol A concentration and obesity prevalence in children and adolescents. Trasande, L., Attina, T. M. and Blustein, J. The Journal of the American Medical Association. 2012. 308, 1113-1121. 10.1001/2012.jama.11461	Urine	Not considered	United States of America	Not considered	Excluded – data on urinary BPA reported here was used but was taken from the NHANES website of the CDC
Bisphenol A exposure is associated with low-grade urinary albumin excretion in children of	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
the United States. Trasande, L., Attina, T. M. and Trachtman, H. Kidney International. 2013. 83:4, 741-748. 10.1038/ki.2012.422					December 2012 (i.e. did not meet publication period criteria)
Associations between socioeconomic status and environmental toxicant concentrations in adults in the USA: NHANES 2001-2010. Tyrrell, J., Melzer, D., Henley, W., Galloway, T. S. and Osborne, N. J. Environment International. 2013. 59, 328-335. 10.1016/j.envint.2013.06.017	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Racial disparity in maternal and fetal-cord bisphenol A concentrations. Unal, E. R., Lynn, T., Neidich, J., Salazar, D., Goetzl, L., Baatz, J. E., Hulsey, T. C., Van Dolah, R., Guillette, L. J. Jr. and Newman, R. Journal of Perinatology. 2012. 32:11, 844-850. 10.1038/jp.2012.12	Serum	Nested cross-sectional study was performed from a cohort of 600 healthy, term nulliparous patients treated in Medical University. The women were enrolled at routine office visits at term (>=37 weeks of gestation), and maternal blood was collected. Fetal cord blood was collected at the time of delivery. 27 patients (8 Caucasian, 8 African-American, 11 Hispanic) were finally analysed for BPA concentrations in maternal and fetal-cord serum.	United States of America	LLE, LC-MS/MS, d6-BPA was used as an internal standard. Total BPA was determined. LOD = Not given LOQ = 0.14 ng/mL Recovery = Not given Repeatability = Not given Accuracy = Not given Calibration = Not given Deconjugation: β-glucuronidase/ sulfatase, a deconjugation standard was also added Measures taken to reduce contamination: Serum samples were stored in cryovals at -80°C. Glass labware was used during sample	Included NOTE: this paper was not included in the contractors database but provides relevant biomonitoring data and so was included NOTE: although the samples were from the USA the paper provides data for biomonitoring not available elsewhere and so was included

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
				extraction and hydrolysis. No constituent parts of the LC-MS/MS used were manufactured from materials known to contain BPA. Water blanks were injected with each run to eliminate the possibility of BPA contamination from the LC-MS/MS hardware. No BPA was detected in the blanks.	NOTE: for serum biomonitoring, studies from all geographical regions were included to inform toxicological risk assessment
Association of urinary bisphenol A concentration with allergic asthma: results from the National Health and Nutrition Examination Survey 2005-2006. Vaidya, S. V. and Kulkarni, H. The Journal of Asthma. 2012. 49:8, 800-806. 10.3109/02770903.2012.721041	Urine	Not considered	United States of America	Not considered	Excluded – data on urinary BPA reported here was used but was taken from the 2005-2006 NHANES report
Prenatal bisphenol a urine concentrations and early rapid growth and overweight risk in the offspring. Valvi, D., Casas, M., Mendez, M. A., Ballesteros-Gomez, A., Luque, N., Rubio, S., Sunyer, J. and Vrijheid, M. Epidemiology. 2013. 24:6, 791-799. 10.1097/EDE.0b013e3182a67822	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Urinary, circulating, and tissue biomonitoring studies indicate widespread exposure to bisphenol A. Vandenberg, L. N., Chahoud, I., Heindel, J. J., Padmanabhan, V., Paumgartten, F. J. R. and	Review paper	Not considered	Not considered	Not considered	Excluded – a review paper – no new data reported for biomonitoring

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
Schoenfelder, G. Environmental Health Perspectives. 2010. 118:8, 1055-1070. 10.1289/ehp.0901716					NOTE: publication is cited in introduction of the Biomonitoring chapter.
Human exposure to bisphenol A (BPA). Vandenberg, L. N., Hauser, R., Marcus, M., Olea, N. and Welshons, W. V. Reproductive Toxicology. 2007. 24:2, 139-177. 10.1016/j.reprotox.2007.07.010	Review paper	Not considered	Not considered	Not considered	Excluded – a review paper on exposure – no new data reported for biomonitoring
Bisphenol-A and phthalates contamination of urine samples by catheters in the Elfe pilot study: implications for large-scale biomonitoring studies Vandentorren, S., Zeman, F., Morin, L., Sarter, H., Bidondo, M. L., Oleko, A. and Leridon, H. Environmental Research. 2011. 111:6, 761-764. 10.1016/j.envres.2011.05.018	Urine	Pilot study within the framework of the French longitudinal study of children (Elfe: Etude Longitudinale Française depuis l'Enfance), a national cohort study. Spot samples were collected from parturient women having a natural delivery (n = 164) or a Caesarean/forceps delivery (n = 79) in hospital maternity units.	France	Following enzymatic cleavage of the conjugates samples were subjected to liquid-liquid extraction with detection by GC-MS. d_4-BPA was used as an internal standard. Total BPA was determined. Free BPA was determined in the same was but without the enzymatic cleavage step. LOD = 0.1 ng/mL LOQ = 0.3 ng/mL Recovery = Not given Repeatability = < 20% Accuracy = Not given Calibration = Not given Deconjugation: β-glucuronidase/ sulfatase (Helix pomatia)	Included NOTE: although the method performance was not well described the paper provides data for biomonitoring not available elsewhere and so was included

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
				Measures taken to reduce contamination: Samples were collected in polypropylene vials.	
Maternal bisphenol a exposure during pregnancy and its association with adipokines in Mexican-American children. Volberg, V., Harley, K., Calafat, A. M., Dave, V., McFadden, J., Eskenazi, B. and Holland, N. Environmental and Molecular Mutagenesis. 2013. 54:8, 621-628. 10.1002/em.21803	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Determination of free and total bisphenol A in human urine to assess daily uptake as a basis for a valid risk assessment. Völkel, W., Kiranoglu, M. and Fromme, H. Toxicology Letters. 2008. 179:3, 155-162. 10.1016/j.toxlet.2008.05.002	Urine	Spot urine samples were collected in Munich from 62 (multiple) samples from 21 co-workers (19–52 years old) as well as single samples from 31 woman (18–41 years old) and 30 children (5–6 years old) in 2005-2008.	Germany	Following enzymatic cleavage of the conjugates the samples were centrifuged, clened up using SPE and analysed by HPLC-MS/MS. d_{16}-BPA or $^{13}C_{12}$-BPA were used as internal standards. Total BPA was determined. Free BPA was determined in the same was but without the enzymatic cleavage step. LOD = 0.3 ng/mL LOQ = 1.25 ng/mL Recovery = Not given Repeatability = 10-13% (inter) Accuracy = 80-120% Calibration = 0.25-6 ng/mL	Included

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
				Deconjugation: glucuronidase/ sulfatase, a deconjugation standard was also added Measures taken to reduce contamination: Samples were collected and stored in polypropylene or glass vessels at -20°C.	
Determination of free and total bisphenol A in urine of infants. Völkel, W., Kiranoglu, M. and Fromme, H. Environmental Research. 2011. 111:1, 143-148. 10.1016/j.envres.2010.10.001	Urine	Females who were participating in a birthing class in Munich were randomly selected, and 47 mother-infants pair finally entered into the study. Urine was sampled from each infant at one month and two months of age in 2008.	Germany	Following enzymatic cleavage of the conjugates the samples were centrifuged, clened up using SPE and analysed by HPLC-MS/MS. d_{16}-BPA was used as an internal standard. Total BPA was determined. Free BPA was determined in the same was but without the enzymatic cleavage step and proteins were precipitated with acetonitrile. LOD = 0.15 µg/L LOQ = 0.45 µg/L Recovery = Not given Repeatability = 5-7% (inter) Accuracy = 80-120%. Calibration = Not given Deconjugation: β-glucuronidase/ sulfatase Measures taken to reduce contamination: Use of polyethylene urine bags, sample storage at -20°C.	Inlcuded

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
				procedureal blanks gave a background concentration of 0.01-0.03 ng/mL.	
Large effects from small exposures. II. The importance of positive controls in low-dose research on bisphenol A. vom Saal, F. S. and Welshons, W. V. Environmental Research. 2006. 100:1, 50-76. 10.1016/j.envres.2005.09.001	Not considered	Not considered	Not considered	Not considered	Excluded – focus is on animal studies – no relevant data reported for biomonitoring
Bisphenol A: How the Most Relevant Exposure Sources Contribute to Total Consumer Exposure. von Goetz, N., Wormuth, M., Scheringer, M. And Hungerbuhler, K. Risk Analysis. 2010. 30:3, 473-487. DOI 10.1111/j.1539-6924.2009.01345.x	Urine	Not considered	Not considered	Not considered	Excluded – no new data reported for biomonitoring
Hydroxylated polybrominated diphenyl ethers and bisphenol A in pregnant women and their matching fetuses: placental transfer and potential risks. Wan, Y., Choi, K., Kim, S., Ji, K., Chang, H., Wiseman, S., Johes, P. D., Khim, J. S., Park, S., Park, J., Lam, M. W. and Giesy, J. Environmental Science and Technology. 2010. 44, 5233-5239. 10.1021/es1002764	Serum	26 pregnant women were recruited at 3 Korean hospitals in 2008-2009. With exception of 2 subjects whose blood was collected during 20-25 wk of pregnancy, all blood was drawn during the 3rd trimester of pregnancy.	Korea	Samples were extracted with solvent, extracts were dried and derivatised using dansyl chloride, fractionated using silica gel, extracted with solvent and analysed by LC-MS/MS. d_{16}-BPA was used as as internal standard. Free BPA was determined. LOD = 0.6 ng/mL (3x S:N) LOQ = Not given Recovery = 63.5±15.1%	Included NOTE: although the samples were from Korea and the method performance was not well described the paper provides data for biomonitoring not available elsewhere and so was included

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
				Repeatability = 88-110% Accuracy = Not given Calibration = Not given Deconjugation: None Measures taken to reduce contamination: Samples were stored in polypropylene vials at -70°C, Concentrations were blank corrected (blanks gave a background concentration of 0.3 ng/mL).	NOTE: for serum biomonitoring, studies from all geographical regions were included to inform toxicological risk assessment
Blood plasma concentrations of endocrine disrupting chemicals in Hong Kong populations. Wan, H. T., Leung, P. Y., Zhao, Y. G., Wei, X., Wong, M. H. and Wong, C. K. Journal of Hazardous Materials. 2013. 261, 763-769. 10.1016/j.jhazmat.2013.01.034	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
High urinary bisphenol A concentrations in workers and possible laboratory abnormalities. Wang, F., Hua, J., Chen, M., Xia, Y., Zhang, Q., Zhao, R., Zhou, W., Zhang, Z. and Wang, B. Occupational and Environmental Medicine. 2012. 69:9, 679-684. 10.1136/oemed-2011-100529	Urine	Not considered	China	Not considered	Excluded – samples from China (i.e. did not meet geographical origin criteria)
Rapid and sensitive analysis of phthalate metabolites, bisphenol A, and endogenous steroid hormones in human urine by mixed-	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
mode solid-phase extraction, dansylation, and ultra-performance liquid chromatography coupled with triple quadrupole mass spectrometry. Wang, H. X., Wang, B., Zhou, Y. and Jiang, Q. W. Analytical and Bioanalytical Chemistry. 2013. 405:12, 4313-4319.					(i.e. did not meet publication period criteria)
Widespread occurrence and distribution of bisphenol A diglycidyl ether (BADGE) and its derivatives in human urine from the United States and China Wang, L., Wu, Y., Zhang, W. and Kannan, K. Environmental Science and Technology. 2012. 46, 12968-12976 10.1021/es304050f	Urine	Not considered	China	Not considered	Excluded – the paper fcuses on BADGE rather than BPA – no relevant data reported for biomonitoring
Decline in Urinary Bisphenol A Concentrations in the United States. Wells, E. M., Jackson, L. W. and Koontz, M. B. Epidemiology. 2013. 24, 167-168. 10.1097/EDE.0b013e31827849b4 10.1097/EDE.0b013e3182788a04	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Association between bisphenol A and waist-to-height ratio among children: National Health and Nutrition Examination Survey, 2003-2010. Wells, E. M., Jackson, L. W. and Koontz, M. B. Annals of Epidemiology. 2014. 12:2, 165-167. 10.1016/j.annepidem.2013.06.002	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
Large effects from small exposures. III. Endocrine mechanisms mediating effects of bisphenol A at levels of human exposure Welshons, W. V., Nagel, S. C. and vom Saal, F. S. Endocrinology. 2006. 147, S56-69. 10.1210/en.2005-1159	Serum, Breast milk, Tissue	Not considered	Not considered	Not considered	Excluded – biomonitoring data from before 2006, i.e. outside of the accepted publication period
Pilot Study of Urinary Biomarkers of Phytoestrogens, Phthalates, and Phenols in Girls. Wolff, M. S., Teitelbaum, S. L., Windham, G., Pinney, S. M., Britton, J. A., Chelimo, C., Godbold, J., Biro, F., Kushi, L. H., Pfeiffer, C. M. and Calafat, A. M. Environmental Health Perspectives. 2007. 115:1, 116-121 . 10.1289/ehp.9488	Urine	Not considered	United States of America	Not considered	Excluded – samples from the USA (i.e. did not meet geographical origin criteria)
Long-term study of urinary bisphenol A in elementary school children. Yamano, Y., Miyakawa, S., Iizumi, K., Itoh, H., Iwasaki, M., Tsugane, S., Kagawa, J. and Nakadate, T. Environmental Health and Preventive Medicine. 2008. 13:6, 332-337. 10.1007/s12199-008-0049-6	Urine	Not considered	Japan	Not considered	Excluded – samples from Japan (i.e. did not meet geographical origin criteria)
Urinary concentrations of bisphenol A in relation to biomarkers of sensitivity and effect and endocrine-related health effects.	Urine	Not considered	Korea	Not considered	Excluded – samples from Korea (i.e. did not meet geographical origin

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
Yang, M., Kim, S. Y., Chang, S. S., Lee, I. S. and Kawamoto, T. Environmental and Molecular Mutagenesis. 2006. 47:8, 571-578. 10.1002/em.20230					criteria)
Effects of bisphenol A on breast cancer and its risk factors. Yang, M., Ryu, J. H., Jeon, R., Kang, D. and Yoo, K. Y. Archives of Toxicology. 2009. 83, 281-285. 10.1007/s00204-008-0364-0	Serum	n=167 Study subjects were breast cancer patients who had visited a clinic in Korea between 1994-1997 and were diagnosed with breast cancer for the 1st time, and the hospital controls, who had worried about breast cancer, visited the same clinic during the same period, and not been diagnosed with breast cancer. Blood sampling occurred before breakfest.	Korea	Total and free BPA were determined. Liquid-liquid extraction as described by Yang et al (2003) was used for purification. One part of the sample was enzymatically cleaved before analysis with HPLC/FD. LOD = 0.012 ng/mL (3x S:N) LOQ = 0.04 ng/mL (10x S:N) Recovery = Not given Repeatability = Not given Accuracy = Not given Calibration = Not given Deconjugation: β-glucuronidase/ sulfatase (Helix pomatia, H1) Measures taken to reduce contamination: No measures against contamination reported.	Included / excluded NOTE: the authors studied breast cancer patients and controls. The latter were included, the former were excluded. NOTE: for serum biomonitoring, studies from all geographical regions were included to inform toxicological risk assessment NOTE: although the samples were from Korea and the method performance was not well described the paper provides data for biomonitoring not available elsewhere

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
					and so was included
Quantitative determination of bisphenol A from human saliva using bulk derivatization and trap-and-elute liquid chromatography coupled to electrospray ionization mass spectrometry. Yang, S. H., Morgan, A. A., Nguyen, H. P., Moore, H., Figard, B. J. and Schug, K. A. Environmental Toxicology and Chemistry. 2011. 30:6, 1243-1251 10.1002/etc.498	Saliva	Not considered	Not considered	Not considered	Excluded – saliva not considered in biomonitoring
Bisphenol A exposure is associated with oxidative stress and inflammation in postmenopausal women. Yang, Y. J., Hong, Y. C., Oh, S. Y., Park, M. S., Kim, H., Leem, J. H. and Ha, E. H. Environmental Research. 2009. 109:, 797-801. 10.1016/j.envres.2009.04.014	Urine	Not considered	Korea	Not considered	Excluded – samples from Korea (i.e. did not meet geographical origin criteria)
Temporal stability of the conjugated species of bisphenol A, parabens, and other environmental phenols in human urine. Ye, X., Bishop, A. M., Reidy, J. A., Needham, L. L. and Calafat, A. M. Journal of Exposure Science and Environmental Epidemiology. 2007. 17:6, 567-572. 10.1038/sj.jes.7500566	Urine	Not considered	United States of America	Not considered	Excluded – samples from the USA (i.e. did not meet geographical origin criteria)
Levels of metabolites of organophosphate pesticides, phthalates, and bisphenol A in pooled urine specimens from pregnant women	Urine	The study was performed within the framework of the Norwegian mother and child	Norway	Samples were extracted using steam distillation followed by SPE clean-up. Samples were derivatised using	Included NOTE: although the

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
participating in the Norwegian Mother and Child Cohort Study (MoBa). Ye, X., Pierik, F. H., Angerer, J., Meltzer, H. M., Jaddoe, V. W., Tiemeier, H., Hoppin, J. A. and Longnecker, M. P. International Journal of Hygiene and Environmental Health. 2009. 212:5, 481-491. 10.1016/j.ijheh.2009.03.004		birth cohort (MoBa) study. Spot urine samples were collected from 110 pregnant women at 17–18 weeks of gestation in 2004. Urine samples from groups of 11 subjects each were combined to make 10 pooled samples.		MTBSTFA and analysed by GC-MS/MS. Free BPA was determined. LOD = 0.26 ng/mL LOQ = Not given Recovery = 105% Repeatability = (between-day CV): 8.3% at 2.8 ng/mL and 4.2% at 45.4 ng/mL Accuracy = Not given Calibration = Not given Deconjugation: None Measures taken to reduce contamination: Samples were stored in polypropylene containers at -20°C. Concentrations were blank corrected (blanks gave a background concentration of 0.39 ng/mL).	method performance was not well described the paper provides data for biomonitoring not available elsewhere and so was included
Urinary metabolite concentrations of organophosphorous pesticides, bisphenol A, and phthalates among pregnant women in Rotterdam, the Netherlands: the Generation R study. Ye, X., Pierik, F. H., Hauser, R., Duty, S., Angerer, J., Park, M. M., Burdorf, A., Hofman, A., Jaddoe, V. W., Mackenbach, J. P., Steegers, E. A., Tiemeier, H. and Longnecker, M. P. Environmental Research. 2008. 108:2, 260-267.	Urine	Generation R study: a population-based birth cohort study in Rotterdam (N=9778 mothers, 18-41 yrs old). N=100 randomly selected single spot urine samples were collected from mothers (Rotterdam area) who enrolled after Febr 2004, the sample were collected during pregancy 21-38 wks of	Netherlands	Samples were extracted using steam distillation followed by SPE clean-up. Samples were derivatised using MTBSTFA and analysed by GC-MS/MS. Free BPA was determined. LOD = 0.26 ng/mL LOQ = Not given	Included NOTE: although the method performance was not well described the paper provides data for biomonitoring not available elsewhere and so was included

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
10.1016/j.envres.2008.07.014		gestation. Spot urine was taken between 8 am and 8 pm. BPA concentrations were given as volume-based and creatinine-adjusted concentrations.		Recovery = 105% Repeatability = (between-day CV): 8.3% at 2.8 ng/mL and 4.2% at 45.4 ng/mL Accuracy = Not given Calibration = Not given Deconjugation: Not given Measures taken to reduce contamination: Samples were stored in polypropylene containers at -20°C. Concentrations were blank corrected (blanks gave a background concentration of 0.39 ng/mL).	
Automated on-line column-switching HPLC-MS/MS method for measuring environmental phenols and parabens in serum. Ye, X., Tao, L. J., Needham, L. L. and Calafat, A. M. Talanta. 2008. 76:4, 865-871. 10.1016/j.talanta.2008.04.034	Serum	15 commercial serum samples (collected between 1998-2003 from 4 male and 11 female donors) were purchased from a Blood Bank.	United States of America	Following enzymatic cleavage of the conjugates the samples were acidifed and centrifugedClean-up and analysis were performed by on-line SPE with HPLC-MS/MS. $^{13}C_{12}$-BPA was used as an internal standard. Total BPA was determined. Free BPA was determined in the same was but without the enzymatic cleavage step. LOD = 0.3 ng/mL (3x S:N) LOQ = Not given Recovery = 108-115% Repeatability = 6.2% (9.5 ng/mL) and 9.3% (5.6 ng/mL)	Included NOTE: although the samples were from the USA the paper provides data for biomonitoring not available elsewhere and so was included NOTE: for serum biomonitoring, studies from all geographical regions were included to inform toxicological risk assessment

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
				Accuracy = 108-115% at 0.5-10 ng/mL Calibration = 0.1-100 ng/mL Deconjugation: β-glucuronidase/ sulfatase (Helix pomatia, H1), deconjugation standards were also added Measures taken to reduce contamination: Samples were stored in polypropylene vials at -20°C.	
Variability of urinary concentrations of bisphenol A in spot samples, first morning voids, and 24-hour collections. Ye, X., Wong, L. Y., Bishop, A. M. and Calafat, A. M. Environmental Health Perspectives. 2011. 119:7, 983-988. 10.1289/ehp.1002701	Urine	Not considered	United States of America	Not considered	Excluded – samples from the USA (i.e. did not meet geographical origin criteria) NOTE: This study is included in respect to the discussion of the comparison between spot sampling, first morning urine, and 24-h collections
Stability of the conjugated species of environmental phenols and parabens in human serum. Ye, X., Wong, L. Y., Jia, L. T., Needham, L. L. and Calafat, A. M. Environment International. 2009. 35:8, 1160-1163.	Serum	16 commercially available serum samples collected between 1998 and 2003 from 5 male and 11 female donors were purchased.	United States of America	Following enzymatic cleavage of the conjugates the samples were acidifed and centrifugedClean-up and analysis were performed by on-line SPE with HPLC-MS/MS. $^{13}C_{12}$-BPA was used as an internal standard. Total BPA was determined.	Included NOTE: although the samples were from the USA the paper provides data for biomonitoring not

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
10.1016/j.envint.2009.07.011				Free BPA was determined in the same was but without the enzymatic cleavage step. LOD = 0.3 ng/mL (3x S:N) LOQ = Not given Recovery = 108-115% Repeatability = 6.2% (9.5 ng/mL) and 9.3% (5.6 ng/mL) Accuracy = 108-115% at 0.5-10 ng/mL Calibration = 0.1-100 ng/mL Deconjugation: β-glucuronidase/ sulfatase (Helix pomatia, H1), deconjugation standards were also added Measures taken to reduce contamination: Samples were stored in glass vials at -70°C.	available elsewhere and so was included NOTE: for serum biomonitoring, studies from all geographical regions were included to inform toxicological risk assessment
Potential External Contamination with Bisphenol A and Other Ubiquitous Organic Environmental Chemicals during Biomonitoring Analysis: An Elusive Laboratory Challenge. Ye, X., Zhou, X., Hennings, R., Kramer, J. and Calafat, A. M. Environmental Health Perspectives. 2013. 121:3, 283-286. 10.1289/ehp.1206093	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
In-vitro oxidation of bisphenol A: Is bisphenol A catechol a suitable biomarker for human exposure to bisphenol A? Ye, X., Zhou, X., Needham, L. L. and Calafat, A. M. Analytical and Bioanalytical Chemistry. 2011. 399:3, 1071-1079. 10.1007/s00216-010-4344-x	*in-vitro*	Not considered	Not considered	Not considered	Excluded – paper describes an in-vitro study – no relevant data reported for biomonitoring
Concentrations of bisphenol A and seven other phenols in pooled sera from 3-11 year old children: 2001-2002 National Health and Nutrition Examination Survey. Ye, X., Zhou, X., Wong, L. Y. and Calafat, A. M. Environmental Science and Technology. 2012. 46:22, 12664-12671 10.1021/es303109c	Serum	Samples were collected from 3-11 year old children participating in the 2001-2002 NHANES. 24 serum pools prepared from 936 individual samples. Individual samples were categorized into 12 demographic groups, each representing a combination of age (3-5 yr, 6-11 yr), sex, and race/ethnicity. For each demographic group, 2 pools were prepared that included randomly selected 21 (3−5 years of age) or 57 (6−11 years of age) individual samples. Complex multistage probability design with randomly selected samples.	United States of America	Following enzymatic cleavage of the conjugates the samples were acidifed and centrifuged. Clean-up and analysis were performed by on-line SPE with HPLC-MS/MS. $^{13}C_{12}$-BPA was used as an internal standard. Total BPA was determined. Free BPA was determined in the same was but without the enzymatic cleavage step. LOD = 0.1 ng/mL (3x S:N) LOQ = Not given Recovery = Not given Repeatability = Not given Accuracy = Not given Calibration = Not given Deconjugation: β-glucuronidase/ sulfatase (Helix pomatia, H1), deconjugation standards were also	Included NOTE: although the samples were from the USA and the method performance was not well described the paper provides data for biomonitoring not available elsewhere and so was included NOTE: for serum biomonitoring, studies from all geographical regions were included to inform toxicological risk assessment

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
				added Measures taken to reduce contamination: Samples were stored in polypropylene vials at -20°C.	
GC-MS analysis of bisphenol A in human placental and fetal liver samples. Zhang, J., Cooke, G. M., Curran, I. H., Goodyer, C. G. and Cao, X. L. Journal of Chromatography B. 2011. 879, 209-214. 10.1016/j.jchromb.2010.11.031	Placental tissue	Not considered	Canada	Not considered	Excluded – tissue not considered in biomonitoring
Selective solid-phase extraction of bisphenol A using molecularly imprinted polymers and its application to biological and environmental samples. Zhang, J. H., Jiang, M., Zou, L., Shi, D., Mei, S. R., Zhu, Y. X., Shi, Y., Dai, K. and Lu, B. Analytical and Bioanalytical Chemistry. 2006. 385, 780-786. 10.1007/s00216-006-0406-5	Serum, Urine, Water, Food	Not considered	China	Not considered	Excluded – paper focuses on method development – no relevant data reported for biomonitoring
Blood and urinary bisphenol A concentrations in children, adults, and pregnant women from china: partitioning between blood and urine and maternal and fetal cord blood. Zhang, T., Sun, H. and Kannan, K. Environmental Science and Technology. 2013. 47:9, 4686-4694. 10.1021/es303808b	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
Urinary bisphenol A concentrations and their implications for human exposure in several Asian countries. Zhang, Z., Alomirah, H., Cho, H. S., Li, Y. F., Liao, C., Minh, T. B., Mohd, M. A., Nakata, H., Ren, N. and Kannan, K. Environmental Science and Technology. 2011. 45:16, 7044-7050. 10.1021/es200976k	Urine	Not considered	Asia	Not considered	Excluded – samples from Asia (i.e. did not meet geographical origin criteria)
Serum bisphenol-A concentration and sex hormone levels in men. Zhou, Q., Miao, M., Ran, M., Ding, L., Bai, L., Wu, T., Yuan, W., Gao, E., Wang, J., Li, G. and Li, D. K. Fertility and Sterility. 2013. 100, 478-482. 10.1016/j.fertnstert.2013.04.017	Not considered	Not considered	Not considered	Not considered	Excluded – paper published after December 2012 (i.e. did not meet publication period criteria)
Bisphenol A Blood and Saliva Levels Prior To and After Dental Sealant Placement In Adults. Zimmerman Downs, J. M., Shuman, D., Stull, S. C. and Ratzlaff, R. E. Journal of Dental Hygiene. 2010. 84, 145-150. None given	Blood, Saliva	Not considered	United States of America	Not considered	Excluded – samples from the USA (i.e. did not meet geographical origin criteria)
Vlaams Humaan Biomonitoringsprogramma 2007–2011. Resultatenrapport: deel referentiebiomonitoring. 2010, Milieu en Gezondheid None given	Urine	Flemish Environment and Health Survey 2007–2011 cycle-2 (FLEHS II): Representative sample of the Flemish population with n = 193 adolescents (14–15 year old). Collection of spot urine.	Belgium	GC-MS Total BPA was determined. LOD = 0.1 ng/mL LOQ = 0.2 ng/mL	Included NOTE: this paper was not included in the contractors database but provides

Title Authors Journal. Year. Volume: Issue, Page number DOI	Media covered	Sampling	Country of origin of samples	Method description and quality parameters	Included/excluded and reasoning
		BPA concentrations were given as volume-based and creatinine-adjusted concentrations.		Recovery = Not given Repeatability = Not given Calibration = Not given Deconjugation: Measures taken to reduce contamination: Not given	relevant biomonitoring data and so was included NOTE: although the paper was not peer reviewed it provides data not available elsewhere and so was included

Appendix J. Food products (FoodEx level 4) that have been codified as canned in at least one dietary survey within the Comprehensive Database

FoodEx level 1	FoodEx level 2	FoodEx level 3	FoodEx level 4
Animal and vegetable fats and oils	Fish oil	Cod liver oil	Cod liver oil
Composite food (including frozen products)	Beans-based meals	Beans and meat meals	Beans and meat meals
Composite food (including frozen products)	Beans-based meals	Beans and vegetables meals	Beans and vegetables meals
Composite food (including frozen products)	Cereal-based dishes	Pasta, cooked	Pasta, cooked
Composite food (including frozen products)	Cereal-based dishes	Pasta, cooked	Pasta, cooked, meat and vegetable filling
Composite food (including frozen products)	Cereal-based dishes	Pasta, cooked	Pasta, cooked, meat filling
Composite food (including frozen products)	Fish and seafood-based meals	Seafood-based meals	Seafood-based meals
Composite food (including frozen products)	Meat-based meals	Goulash	Goulash
Composite food (including frozen products)	Meat-based meals	Meat balls	Meat balls
Composite food (including frozen products)	Meat-based meals	Meat stew	Meat stew
Composite food (including frozen products)	Meat-based meals	Meat-based meals	Meat-based meals
Composite food (including frozen products)	Prepared salads	Prepared salads	Prepared salads
Composite food (including frozen products)	Ready-to-eat soups	Legume (beans) soup	Legume (beans) soup
Composite food (including frozen products)	Ready-to-eat soups	Meat/poultry soup	Meat/poultry soup
Composite food (including frozen products)	Ready-to-eat soups	Mushroom soup	Mushroom soup
Composite food (including frozen products)	Ready-to-eat soups	Ready-to-eat soups	Ready-to-eat soups
Composite food (including frozen products)	Ready-to-eat soups	Vegetable/herb soup	Vegetable/herb soup
Composite food (including frozen products)	Vegetable-based meals	Mixed vegetables, boiled	Mixed vegetables, boiled
Composite food (including frozen products)	Vegetable-based meals	Mixed vegetables, braised	Mixed vegetables, braised
Composite food (including frozen products)	Vegetable-based meals	Mixed vegetables, fried	Mixed vegetables, fried
Composite food (including frozen products)	Vegetable-based meals	Vegetable-based meals	Vegetable-based meals
Fish and other seafood	Amphibians, reptiles, snails, insects	Snail (*Helix* sp.)	Snail (*Helix* sp.)
Fish and other seafood	Crustaceans	Crab (*Cancer* spp.)	Crab (*Cancer* spp.)
Fish and other seafood	Crustaceans	Crayfish (*Astacus* spp.)	Crayfish (*Astacus* spp.)
Fish and other seafood	Crustaceans	Crustaceans	Crustaceans
Fish and other seafood	Crustaceans	Lobster (*Homarus vulgaris*)	Lobster (*Homarus vulgaris*)
Fish and other seafood	Crustaceans	Prawns (*Palaemon serratus*)	Prawns (*Palaemon serratus*)
Fish and other seafood	Crustaceans	Shrimps (*Crangon crangon*)	Shrimps (*Crangon crangon*)
Fish and other seafood	Fish and other seafood (unspecified)	Fish and other seafood (unspecified)	Fish and other seafood (unspecified)
Fish and other seafood	Fish meat	Anchovy (*Engraulis*)	Anchovy (*Engraulis*)
Fish and other seafood	Fish meat	Cod and whiting (*Gadus* spp.)	Cod and whiting (*Gadus* spp.)
Fish and other seafood	Fish meat	Eels (*Apodes*)	Eels (*Apodes*)
Fish and other seafood	Fish meat	Fish meat	Fish meat

FoodEx level 1	FoodEx level 2	FoodEx level 3	FoodEx level 4
Fish and other seafood	Fish meat	Herring (*Clupea*)	Herring (*Clupea*)
Fish and other seafood	Fish meat	Mackeral (*Scomber*)	Mackeral (*Scomber*)
Fish and other seafood	Fish meat	Perch (*Perca*)	Perch (*Perca*)
Fish and other seafood	Fish meat	Salmon and trout (*Salmo* spp.)	Salmon and trout (*Salmo* spp.)
Fish and other seafood	Fish meat	Sardine and pilchard (*Sardina*)	Sardine and pilchard (*Sardina*)
Fish and other seafood	Fish meat	Sprat (*Sprattus sprattus*)	Sprat (*Sprattus sprattus*)
Fish and other seafood	Fish meat	Tuna (*Thunnus*)	Tuna (*Thunnus*)
Fish and other seafood	Fish offal	Fish roe	Fish roe
Fish and other seafood	Fish offal	Other fish offal	Other fish offal
Fish and other seafood	Fish products	Fish balls	Fish balls
Fish and other seafood	Fish products	Fish paste	Fish paste
Fish and other seafood	Fish products	Fish products	Fish products
Fish and other seafood	Fish products	Fish pâté	Fish pâté
Fish and other seafood	Water molluscs	Clam (*Mya arenaria*)	Clam (*Mya arenaria*)
Fish and other seafood	Water molluscs	Cockle (*Cardium edule*)	Cockle (*Cardium edule*)
Fish and other seafood	Water molluscs	Mussel (*Mytilus edulis*)	Mussel (*Mytilus edulis*)
Fish and other seafood	Water molluscs	Octopus (*Octopus vulgaris*)	Octopus (*Octopus vulgaris*)
Fish and other seafood	Water molluscs	Squid (*Loligo vulgaris*)	Squid (*Loligo vulgaris*)
Fish and other seafood	Water molluscs	Water molluscs	Water molluscs
Fruit and fruit products	Berries and small fruits	Berries and small fruits	Berries and small fruits
Fruit and fruit products	Berries and small fruits	Bilberry or whortleberry (*Vaccinium* spp.)	Bilberry or whortleberry (*Vaccinium* spp.)
Fruit and fruit products	Berries and small fruits	Blackberries (*Rubus fruticosus*)	Blackberries (*Rubus fruticosus*)
Fruit and fruit products	Berries and small fruits	Raspberries (*Rubus idaeus*)	Raspberries (*Rubus idaeus*)
Fruit and fruit products	Berries and small fruits	Strawberries (*Fragaria × ananassa*)	Strawberries (*Fragaria × ananassa*)
Fruit and fruit products	Dried fruits	Dried vine fruits (currants, raisins and sultanas)	Dried vine fruits (currants, raisins and sultanas)
Fruit and fruit products	Miscellaneous fruits	Lychee (Litchi) (*Litchi chinensis*)	Lychee (litchi) (*Litchi chinensis*)
Fruit and fruit products	Miscellaneous fruits	Mangoes (*Mangifera indica*)	Mangoes (*Mangifera indica*)
Fruit and fruit products	Miscellaneous fruits	Miscellaneous fruits	Miscellaneous fruits
Fruit and fruit products	Miscellaneous fruits	Papaya (*Carica papaya*)	Papaya (*Carica papaya*)
Fruit and fruit products	Miscellaneous fruits	Pineapples (*Ananas comosus*)	Pineapples (*Ananas comosus*)
Fruit and fruit products	Miscellaneous fruits	Table olives (*Olea europaea*)	Table olives (*Olea europaea*)
Fruit and fruit products	Other fruit products (excluding beverages)	Fruit cocktail	Fruit cocktail
Fruit and fruit products	Other fruit products (excluding beverages)	Fruit compote	Fruit compote
Fruit and fruit products	Other fruit products (excluding beverages)	Fruit compote	Fruit compote, apple (*Malus domesticus*)
Fruit and fruit products	Other fruit products (excluding beverages)	Fruit compote	Fruit compote, apricot (*Prunus armeniaca*)

FoodEx level 1	FoodEx level 2	FoodEx level 3	FoodEx level 4
Fruit and fruit products	Other fruit products (excluding beverages)	Fruit compote	Fruit compote, cranberry (*Vaccinium macrocarpon*)
Fruit and fruit products	Other fruit products (excluding beverages)	Fruit compote	Fruit compote, mandarin (*Citrus reticulata*)
Fruit and fruit products	Other fruit products (excluding beverages)	Fruit compote	Fruit compote, mixed fruit
Fruit and fruit products	Other fruit products (excluding beverages)	Fruit compote	Fruit compote, peach (*Prunus persica*)
Fruit and fruit products	Other fruit products (excluding beverages)	Fruit compote	Fruit compote, pear (*Pyrus communis*)
Fruit and fruit products	Other fruit products (excluding beverages)	Fruit compote	Fruit compote, pineapple (*Ananas comosus*)
Fruit and fruit products	Other fruit products (excluding beverages)	Fruit compote	Fruit compote, plum (*Prunus domestica*)
Fruit and fruit products	Other fruit products (excluding beverages)	Fruit compote	Fruit compote, sour cherry (*Prunus cerasus*)
Fruit and fruit products	Other fruit products (excluding beverages)	Fruit compote	Fruit compote, sweet cherry (*Prunus avium*)
Fruit and fruit products	Other fruit products (excluding beverages)	Fruit salad	Fruit salad
Fruit and fruit products	Other fruit products (excluding beverages)	Fruit, canned	Canned fruit, apple (*Malus domesticus*)
Fruit and fruit products	Other fruit products (excluding beverages)	Fruit, canned	Canned fruit, apricot (*Prunus armeniaca*)
Fruit and fruit products	Other fruit products (excluding beverages)	Fruit, canned	Canned fruit, cranberry (*Vaccinium macrocarpon*)
Fruit and fruit products	Other fruit products (excluding beverages)	Fruit, canned	Canned fruit, mandarin (*Citrus reticulata*)
Fruit and fruit products	Other fruit products (excluding beverages)	Fruit, canned	Canned fruit, mixed fruit
Fruit and fruit products	Other fruit products (excluding beverages)	Fruit, canned	Canned fruit, peach (*Prunus persica*)
Fruit and fruit products	Other fruit products (excluding beverages)	Fruit, canned	Canned fruit, pear (*Pyrus communis*)
Fruit and fruit products	Other fruit products (excluding beverages)	Fruit, canned	Canned fruit, pineapple (*Ananas comosus*)
Fruit and fruit products	Other fruit products (excluding beverages)	Fruit, canned	Canned fruit, plum (*Prunus domestica*)
Fruit and fruit products	Other fruit products (excluding beverages)	Fruit, canned	Canned fruit, sour cherry (*Prunus cerasus*)
Fruit and fruit products	Other fruit products (excluding beverages)	Fruit, canned	Canned fruit, sweet cherry (*Prunus avium*)
Fruit and fruit products	Other fruit products (excluding beverages)	Fruit, canned	Fruit, canned
Fruit and fruit products	Other fruit products (excluding beverages)	Fruit, purée	Fruit, purée
Fruit and fruit products	Other fruit products (excluding beverages)	Mixed dried fruits	Mixed dried fruits
Fruit and fruit products	Other fruit products (excluding beverages)	Other fruit products (excluding beverages)	Other fruit products (excluding beverages)
Fruit and fruit products	Stone fruits	Mirabelle (*Prunus domestica* var *syriaca*)	Mirabelle (*Prunus domestica* var *syriaca*)
Fruit and vegetable juices	Concentrated fruit juice	Concentrated fruit juice	Concentrated fruit juice
Fruit and vegetable juices	Fruit juice	Juice, apple	Juice, apple
Fruit and vegetable juices	Fruit juice	Juice, grape	Juice, grape
Fruit and vegetable juices	Fruit juice	Juice, grapefruit	Juice, grapefruit
Fruit and vegetable juices	Fruit juice	Juice, mango	Juice, mango
Fruit and vegetable juices	Fruit juice	Juice, orange	Juice, orange
Fruit and vegetable juices	Fruit juice	Juice, peach	Juice, peach

FoodEx level 1	FoodEx level 2	FoodEx level 3	FoodEx level 4
Fruit and vegetable juices	Fruit juice	Juice, pineapple	Juice, pineapple
Fruit and vegetable juices	Fruit juice	Juice, prune	Juice, prune
Fruit and vegetable juices	Fruit nectar	Fruit nectar	Fruit nectar
Fruit and vegetable juices	Fruit nectar	Nectar, orange	Nectar, orange
Fruit and vegetable juices	Mixed fruit juice	Juice, multi-fruit	Juice, multi-fruit
Fruit and vegetable juices	Mixed fruit juice	Mixed fruit juice	Mixed fruit juice
Fruit and vegetable juices	Mixed vegetable juice	Mixed vegetable juice	Mixed vegetable juice
Fruit and vegetable juices	Mixed vegetable juice	Multi-vegetable juice	Multi-vegetable juice
Fruit and vegetable juices	Vegetable juice	Juice, carrot	Juice, carrot
Fruit and vegetable juices	Vegetable juice	Juice, tomato	Juice, tomato
Grains and grain-based products	Breakfast cereals	Grits	Grits
Grains and grain-based products	Breakfast cereals	Porridge	Rice porridge
Grains and grain-based products	Fine bakery wares	Pastries and cakes	Sponge cake
Grains and grain-based products	Grains and grain-based products	Grains and grain-based products	Grains and grain-based products
Grains and grain-based products	Grains for human consumption	Maize (corn) grain	Maize (corn) grain
Herbs, spices and condiments	Dressing	Mayonnaise, < 25 % oil	Mayonnaise, < 25 % oil
Herbs, spices and condiments	Dressing	Mayonnaise, > 50 % oil	Mayonnaise, > 50 % oil
Herbs, spices and condiments	Savoury sauces	Meat sauce	Meat sauce
Herbs, spices and condiments	Savoury sauces	Savoury sauces	Savoury sauces
Herbs, spices and condiments	Savoury sauces	Vegetable sauce	Vegetable sauce
Herbs, spices and condiments	Seasoning or extracts	Seasoning or extracts	Seasoning or extracts
Herbs, spices and condiments	Spices	Capers (*Capparis spinosa*)	Capers (*Capparis spinosa*)
Legumes, nuts and oilseeds	Legumes, beans, dried	Beans (*Phaseolus vulgaris*)	Beans (*Phaseolus vulgaris*)
Legumes, nuts and oilseeds	Legumes, beans, dried	Black-eyed bean (*Vigna unguiculata*)	Black-eyed bean (*Vigna unguiculata*)
Legumes, nuts and oilseeds	Legumes, beans, dried	Broad bean (*Vicia faba*)	Broad bean (*Vicia faba*)
Legumes, nuts and oilseeds	Legumes, beans, dried	Chick pea (*Cicer arietinum*)	Chick pea (*Cicer arietinum*)
Legumes, nuts and oilseeds	Legumes, beans, dried	Legumes, beans, dried	Legumes, beans, dried
Legumes, nuts and oilseeds	Legumes, beans, dried	Lentils (*Lens culinaris* syn. *L. esculenta*)	Lentils (*Lens culinaris* syn. *L. esculenta*)
Legumes, nuts and oilseeds	Legumes, beans, dried	Lima bean (*Phaseolus lunatis*)	Lima bean (*Phaseolus lunatis*)
Legumes, nuts and oilseeds	Legumes, beans, dried	Mung bean (*Phaseolus aureus*)	Mung bean (*Phaseolus aureus*)
Legumes, nuts and oilseeds	Legumes, beans, dried	Peas (*Pisum sativum*)	Peas (*Pisum sativum*)
Legumes, nuts and oilseeds	Legumes, beans, dried	Scarlet runner bean (*Phaseolus coccineus*)	Scarlet runner bean (*Phaseolus coccineus*)
Legumes, nuts and oilseeds	Legumes, beans, dried	Soya beans (*Glycine max*)	Soya beans (*Glycine max*)
Legumes, nuts and oilseeds	Legumes, beans, green, without pods	Beans, green, without pods (*Phaseolus vulgaris*)	Beans, green, without pods (*Phaseolus vulgaris*)

FoodEx level 1	FoodEx level 2	FoodEx level 3	FoodEx level 4
Legumes, nuts and oilseeds	Legumes, beans, green, without pods	Peas, green, without pods (*Pisum sativum*)	Peas, green, without pods (*Pisum sativum*)
Legumes, nuts and oilseeds	Legumes, nuts and oilseeds	Legumes, nuts and oilseeds	Legumes, nuts and oilseeds
Meat and meat products	Edible offal, farmed animals	Tongue (beef, veal, mutton, lamb, pork)	Tongue (beef, veal, mutton, lamb, pork)
Meat and meat products	Livestock meat	Pork/piglet meat (*Sus scrofa*)	Pork/piglet meat (*Sus scrofa*)
Meat and meat products	Livestock meat	Rabbit meat (*Lepus cuniculus*)	Rabbit meat (*Lepus cuniculus*)
Meat and meat products	Meat and meat products	Meat and meat products	Meat and meat products
Meat and meat products	Meat imitates	Textured soy protein	Textured soy protein
Meat and meat products	Mixed meat	Mixed beef and pork meat	Mixed beef and pork meat
Meat and meat products	Mixed meat	Mixed meat	Mixed meat
Meat and meat products	Pastes, pâtés and terrines	Meat paste	Meat paste
Meat and meat products	Pastes, pâtés and terrines	Pastes, pâtés and terrines	Pastes, pâtés and terrines
Meat and meat products	Pastes, pâtés and terrines	Pâté, pork liver	Pâté, pork liver
Meat and meat products	Preserved meat	Corned beef	Corned beef
Meat and meat products	Preserved meat	Corned pork	Corned pork
Meat and meat products	Preserved meat	Ham, beef	Ham, beef
Meat and meat products	Preserved meat	Ham, pork	Ham, pork
Meat and meat products	Preserved meat	Luncheon meat	Luncheon meat
Meat and meat products	Preserved meat	Preserved meat	Preserved meat
Meat and meat products	Sausages	Cooked smoked sausage	Frankfurters, sausage
Meat and meat products	Sausages	Sausages	Sausages
Milk and dairy products	Cheese	Quark	Quark
Milk and dairy products	Concentrated milk	Condensed milk	Condensed milk
Milk and dairy products	Concentrated milk	Condensed milk	Condensed milk, 10 % fat
Milk and dairy products	Concentrated milk	Condensed milk	Condensed milk, 4 % fat
Milk and dairy products	Concentrated milk	Dried milk	Dried milk
Milk and dairy products	Concentrated milk	Dried milk	Milk powder, semi-skimmed
Milk and dairy products	Concentrated milk	Dried milk	Milk powder, skimmed
Milk and dairy products	Concentrated milk	Dried milk	Milk powder, whole
Milk and dairy products	Concentrated milk	Evaporated milk	Evaporated milk
Milk and dairy products	Fermented milk products	Buttermilk	Buttermilk
Milk and dairy products	Milk and milk product imitates	Milk and milk product imitates	Milk and milk product imitates
Milk and dairy products	Milk and milk product imitates	Soya drink	Soya drink
Milk and dairy products	Milk and milk product imitates	Soya yoghurt	Soya yoghurt
Milk and dairy products	Milk and milk product imitates	Tofu	Tofu

FoodEx level 1	FoodEx level 2	FoodEx level 3	FoodEx level 4
Products for special nutritional use	Food for sports people (labelled as such)	Carbohydrate-rich energy food products for sports people	Carbohydrate-rich energy food products for sports people
Snacks, desserts and other foods	Ices and desserts	Custard	Custard
Snacks, desserts and other foods	Other foods	Other foods	Other foods
Snacks, desserts and other foods	Snack food	Snack food	Snack food
Starchy roots and tubers	Other starchy roots and tubers	Other starchy roots and tubers	Other starchy roots and tubers
Starchy roots and tubers	Potatoes and potatoe products	Mashed potato powder	Mashed potato powder
Sugar and confectionery	Dessert sauces	Fruit sauce	Fruit sauce
Sugar and confectionery	Molasses and other syrups	Molasses and other syrups	Molasses and other syrups
Vegetables and vegetable products	Brassica vegetables	Brassica vegetables	Brassica vegetables
Vegetables and vegetable products	Brassica vegetables	Broccoli (*Brassica oleracea* var. *italica*)	Broccoli (*Brassica oleracea* var. *italica*)
Vegetables and vegetable products	Brassica vegetables	Brussels sprouts (*Brassica oleracea* var. *gemmifera*)	Brussels sprouts (*Brassica oleracea* var. *gemmifera*)
Vegetables and vegetable products	Brassica vegetables	Head cabbage (*Brassica oleracea* convar. *capitata*)	Head cabbage (*Brassica oleracea* convar. *capitata*)
Vegetables and vegetable products	Brassica vegetables	Kale (*Brassica oleracea* convar. *acephalea*)	Kale (Brassica oleracea convar. *acephalea*)
Vegetables and vegetable products	Bulb vegetables	Garlic, bulb (*Allium sativum*)	Garlic, bulb (*Allium sativum*)
Vegetables and vegetable products	Bulb vegetables	Onions, bulb (*Allium cepa*)	Onions, bulb (*Allium cepa*)
Vegetables and vegetable products	Fruiting vegetables	Aubergines (egg plants) (*Solanum melongena*)	Aubergines (egg plants) (*Solanum melongena*)
Vegetables and vegetable products	Fruiting vegetables	Chilli pepper (*Capsicum frutescens*)	Chilli pepper (*Capsicum frutescens*)
Vegetables and vegetable products	Fruiting vegetables	Courgettes (zucchini)	Courgettes (zucchini)
Vegetables and vegetable products	Fruiting vegetables	Cucumbers (*Cucumis sativus*)	Cucumbers (*Cucumis sativus*)
Vegetables and vegetable products	Fruiting vegetables	Gherkins (*Cucumis sativus*)	Gherkins (*Cucumis sativus*)
Vegetables and vegetable products	Fruiting vegetables	Melons (*Cucumis melo*)	Melons (*Cucumis melo*)
Vegetables and vegetable products	Fruiting vegetables	Okra, lady's fingers (*Hibiscus esculentus*)	Okra, lady's fingers (*Hibiscus esculentus*)
Vegetables and vegetable products	Fruiting vegetables	Peppers, paprika	Peppers, paprika
Vegetables and vegetable products	Fruiting vegetables	Pumpkins (*Cucurbita maxima*)	Pumpkins (*Cucurbita maxima*)
Vegetables and vegetable products	Fruiting vegetables	Sweetcorn (*Zea mays* var. *saccharata*)	Sweetcorn (*Zea mays* var. *saccharata*)
Vegetables and vegetable products	Fruiting vegetables	Tomatoes (*Lycopersicum esculentum*)	Tomatoes (*Lycopersicum esculentum*)
Vegetables and vegetable products	Fungi, cultivated	Cultivated mushroom	Cultivated mushroom
Vegetables and vegetable products	Fungi, cultivated	Fungi, cultivated	Fungi, cultivated
Vegetables and vegetable products	Fungi, cultivated	Shiitake mushroom (*Lentinus edodes*)	Shiitake mushroom (*Lentinus edodes*)
Vegetables and vegetable products	Fungi, wild, edible	Cantharelle (*Cantharellus cibarius*)	Cantharelle (*Cantharellus cibarius*)
Vegetables and vegetable products	Fungi, wild, edible	Fungi, wild, edible	Fungi, wild, edible
Vegetables and vegetable products	Fungi, wild, edible	Morel (*Morchella esculenta*)	Morel (*Morchella esculenta*)
Vegetables and vegetable products	Leaf vegetables	Spinach	Spinach

FoodEx level 1	FoodEx level 2	FoodEx level 3	FoodEx level 4
Vegetables and vegetable products	Leaf vegetables	Spinach (fresh) (*Spinacia oleracea*)	Spinach (fresh) (*Spinacia oleracea*)
Vegetables and vegetable products	Leaf vegetables	Vine leaves (grape leaves) (*Vitis euvitis*)	Vine leaves (grape leaves) (*Vitis euvitis*)
Vegetables and vegetable products	Legume vegetables	Beans, with pods (*Phaseolus vulgaris*)	Beans, with pods (*Phaseolus vulgaris*)
Vegetables and vegetable products	Legume vegetables	Peas, with pods (*Pisum sativum*)	Peas, with pods (*Pisum sativum*)
Vegetables and vegetable products	Root vegetables	Beetroot (*Beta vulgaris* subsp. *vulgaris*)	Beetroot (*Beta vulgaris* subsp. *vulgaris*)
Vegetables and vegetable products	Root vegetables	Carrots (*Daucus carota*)	Carrots (*Daucus carota*)
Vegetables and vegetable products	Root vegetables	Celeriac (*Apium graveolens* var. *rapaceum*)	Celeriac (*Apium graveolens* var. *rapaceum*)
Vegetables and vegetable products	Root vegetables	Radishes (*Raphanus sativus* var. *sativus*)	Radishes (*Raphanus sativus* var. *sativus*)
Vegetables and vegetable products	Root vegetables	Root vegetables	Root vegetables
Vegetables and vegetable products	Root vegetables	Salsify (*Tragopogon porrifolius*)	Salsify (*Tragopogon porrifolius*)
Vegetables and vegetable products	Stem vegetables (fresh)	Asparagus (*Asparagus officinalis*)	Asparagus (*Asparagus officinalis*)
Vegetables and vegetable products	Stem vegetables (fresh)	Bamboo shoots (*Bambusa vulgaris*)	Bamboo shoots (*Bambusa vulgaris*)
Vegetables and vegetable products	Stem vegetables (fresh)	Celery (*Apium graveolens* var. *dulce*)	Celery (*Apium graveolens* var. *dulce*)
Vegetables and vegetable products	Stem vegetables (fresh)	Globe artichokes (*Cynara scolymus*)	Globe artichokes (*Cynara scolymus*)
Vegetables and vegetable products	Stem vegetables (fresh)	Palm hearts	Palm hearts
Vegetables and vegetable products	Stem vegetables (fresh)	Rhubarb (*Rheum* × *hybridum*)	Rhubarb (*Rheum* × *hybridum*)
Vegetables and vegetable products	Stem vegetables (fresh)	Stem vegetables (fresh)	Stem vegetables (fresh)
Vegetables and vegetable products	Vegetable products	Mushy peas (*Pisum sativum*)	Mushy peas (*Pisum sativum*)
Vegetables and vegetable products	Vegetable products	Pickled vegetables	Pickled vegetables
Vegetables and vegetable products	Vegetable products	Sauerkraut	Sauerkraut
Vegetables and vegetable products	Vegetable products	Tomato purée	Tomato purée
Vegetables and vegetable products	Vegetable products	Vegetable products	Vegetable products
Vegetables and vegetable products	Vegetables and vegetable products	Vegetables and vegetable products	Vegetables and vegetable products