Annex XV report

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57

Substance Name(s): 4,4'-isopropylidenediphenol (Bisphenol A)

EC Number: 201-245-8

CAS Number: 80-05-7

Submitted by: France

Date: 30 August 2016

This document has been prepared according to template: TEM-0049.03

CONTENTS

TABLES

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57

Substance Name(s): 4,4'-isopropylidenediphenol (Bisphenol A)

EC Number: 201-245-8

CAS number: 80-05-7

- The substance is proposed to be identified as a substance meeting the criteria of Article 57 (c) of Regulation (EC) No 1907/2006 (REACH) owing to its classification in the hazard class reproductive toxicity category 1B[1].

***Note** – throughout this report the substance 4,4'-isopropylidenediphenol is also referred to as bisphenol A and/or the abbreviation BPA.*

Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation

4,4'-isopropylidenediphenol (Bisphenol A) is covered by index number 604-030-00-0 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class reproductive toxicity category 1B (H360F 'May damage fertility') since its 9th Adaptation to Technical Progress (ATP) (Commission Regulation (EU) 2016/1179).

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification in the hazard class:

- Reproductive toxicity category 1B in accordance with Article 57 (c) of REACH.

Registration dossiers submitted for the substance? Yes

[1] Classification in accordance with section 3.1 of Annex I to Regulation (EC) no 1272/2008 as amended by Commission Regulation (EU) 2016/1179 (9th ATP of the CLP)

PART I

Justification

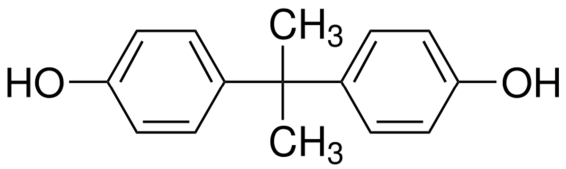
1. Identity of the substance and physical and chemical properties

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	201-245-8
EC name:	4,4'-isopropylidenediphenol
CAS number (in the EC inventory):	80-05-7
Deleted CAS numbers:	27360-89-0; 28106-82-3; 37808-08-5; 137885-53-1; 146479-75-6; 1429425-26-2
CAS name:	phenol, 4,4'-(1-methylethylidene)bis-
IUPAC name:	4,4'-propane-2,2-diyldiphenol
Index number in Annex VI of the CLP Regulation	604-030-00-0
Molecular formula:	$C_{15}H_{16}O_2$
Molecular weight range:	228.29 g/mol
Synonyms:	Bisphenol A BPA 2,2-bis(4-hydroxyphenyl)propane

Structural formula:



1.2 Composition of the substance

Name: 4,4'-isopropylidenediphenol (Bisphenol A)

Description: 80-100%

Substance type: mono-constituent

Table 2: Constituents other than impurities/additives

Constituents	Typical concentration	Concentration range	Remarks
4,4'-isopropylidenediphenol *(bisphenol A)* (EC 201-245-8)	80-100%	No information	

Table 3: Impurities

Impurities	Typical concentration	Concentration range	Remarks
None relevant for SVHC identification			

Table 4: Additives

Additives	Typical concentration	Concentration range	Remarks
None relevant for SVHC identification			

1.3 Identity and composition of degradation products/metabolites relevant for the SVHC assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) REACH.

1.4 Identity and composition of structurally related substances (used in a grouping or read-across approach)

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) REACH.

1.5 Physicochemical properties

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of REACH.

2. Harmonised classification and labelling

Bisphenol A is covered by Index number 640-030-00-0 in part 3 of Annex VI to the CLP Regulation as follows as amended by Commission Regulation (EU) 2016/1179 (9th ATP)[2]:

Table 5: Classification according to Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 (as amended by Commission Regulation (EU) 2016/1179)

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category code(s)	Hazard statement code(s)	Pictogram, Signal Word code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)		
604-030-00-0	bisphenol A; 4,4'-isopropylidenediphenol	201-245-8	80-05-7	Repr. 1B STOT SE 3 Eye Dam. 1 Skin Sens. 1	H360F H335 H318 H317	GHS08 GHS07 GHS05 Dgr	H360F H335 H318 H317			

[2] COMMISSION REGULATION (EU) 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

3. Environmental fate properties

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of REACH.

4. Human health hazard assessment

Bisphenol A has been classified Repr. 1B – H360F in agreement with the opinion adopted by RAC[3] on 14 March 2014, on the basis of effects on female reproductive capacity, on female reproductive organs and male reproductive organs. The opinion can be found on http://echa.europa.eu/documents/10162/777918ff-33b5-46ff-be89-2bdc406d34fa.

This classification has been integrated into Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) in its 9th Adaptation to Technical Progress (ATP) (Commission Regulation (EU) 2016/1179).

ED-related properties of bisphenol A in relation to its reproductive toxicity as well as to other toxic effects will be addressed in a separate Annex XV dossier for identification as SVHC under Article 57 (f) to be submitted in early 2017.

[3] Risk Assessment Committee

5. Environmental hazard assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of REACH.

6. Conclusions on the SVHC Properties

6.1 CMR assessment

4,4'-isopropylidenediphenol (Bisphenol A) is covered by index number 604-030-00-0 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class reproductive toxicity category 1B (H360F 'May damage fertility') since its 9th Adaptation to Technical Progress (ATP) (Commission Regulation (EU) 2016/1179).

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification in the hazard class:

- reproductive toxicity category 1B in accordance with Article 57 (c) of REACH.

6.2 PBT and vPvB assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of REACH.

6.3 Assessment under Article 57(f)

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of REACH.

ED-related properties of bisphenol A in relation to its reproductive toxicity as well as to other toxic effects will be addressed in a separate Annex XV dossier for identification as SVHC under Article 57 (f) to be submitted in early 2017.

Part II

7. Registration and C&L notification status

7.1 Registration status

Table 6 Registration status

From the ECHA dissemination site[4]	
Registrations	☒ Full registration(s) (Art. 10) ☒ Intermediate registration(s) (Art. 17 and/or 18)

7.2 CLP notification status

Table 7: CLP notifications

	CLP Notifications[5]
Number of aggregated notifications	46
Total number of notifiers	1837

8. Total tonnage of the substance

Table 8: Tonnage status

Total tonnage band for the registered substance (excluding the volume registered under Art 17 or Art 18)[6]	1 000 000 – 10 000 000 t/pa
Tonnage information from public sources other than registration dossiers	1.6 Mt/pa in 2005 (Anses 2011)

According to Plastics Europe[7] the production of polycarbonate, that constitutes the major use of BPA by volume, continues to increase due to the variety of applications of polycarbonate and its very good properties of impact resistance, transparency and smooth surface aspect.

[4] http://echa.europa.eu/registration-dossier/-/registered-dossier/15752 (accessed on 13 June 2016)
[5] C&L Inventory database, http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database (accessed 6 June 2016)
[6] http://echa.europa.eu/registration-dossier/-/registered-dossier/15752 (accessed on 13 June 2016)
[7] ANSES has interviewed Plastics Europe on May 2016 to collect data on uses, alternatives and exposure of Polycarbonate.

9. Information on uses of the substance

The review of uses of bisphenol A has been made on the basis of the aggregated registration dossiers[8], the ECHA's dissemination site, the INERIS report published in 2010, the Anses report published in 2011 compiling the knowledge about the uses of BPA, and on the basis of interviews of some stakeholders.

Table 9 below summarises the uses from the registration dossiers.

Table 9: Uses

	Use(s)	Registered use	Use in the scope of Authorisation
Uses as intermediate	- Manufacture of others substance Manufacture of epoxy resins# - Manufacture of coating materials# - Manufacture of epoxy resin hardeners# - Use of epoxy resin hardeners at industrial sites# - Use of epoxy resin hardeners by professional workers# - Formulation of epoxy resin hardeners - Manufacture of chemicals	Yes	No#
Formulation or repacking	- Industrial and professional repackaging of bisphenol A - Industrial use of bisphenol A for manufacturing thermal paper - Industrial use of bisphenol A as anti-oxidant for processing PVC - Formulation of preparations	Yes	Yes
Uses at industrial sites	- Manufacture of polycarbonate - Blending of polycarbonate - Industrial manufacture of articles made of polycarbonate - Use of bisphenol A as laboratory reagent - Industrial use of bisphenol A for manufacturing chemicals* - Industrial use of bisphenol A for manufacturing polymers - Industrial use of bisphenol A for manufacturing thermal paper - Industrial use of bisphenol A as anti-oxidant for processing PVC - Other industrial use*	Yes	Yes
Uses by professional workers	- Professional repackaging of bisphenol A - Professional Use of bisphenol A as anti-oxidant for processing PVC - Professional use of thermal paper - Professional use of articles made of PVC	Yes	Yes Yes No No
Consumer uses	- Consumer use of bisphenol A in thermal paper - Consumer Use of bisphenol A in articles made of PVC	Yes	No
Article service life	- Professional indoor use of articles made of polycarbonate - Professional outdoor use of articles	Yes	No

[8] Aggregated on 13 May 2016

	made of polycarbonate - Consumer indoor use or articles made of polycarbonate - Consumer outdoor use of articles made of polycarbonate - Consumer use of articles made of polycarbonate - Consumer use of articles made of epoxy resins - Professional use of thermal paper - Professional use of articles made of PVC - Consumer use of thermal paper - Consumer use of articles made of PVC		

* Use considered as an additive. Certain uses as intermediate could also be included in this category but this should be confirmed by appropriate data provided by industry.
[#]BPA can be considered as an intermediate when it is transformed into BADGE that is the monomer in the production of the resin. But it cannot be excluded that BPA may also be used as an additive (e.g. antioxidant or scavenger) in the resin.

It is noted that the function of the substance was identified in the aggregated dossier as an intermediate for all uses at industrial sites and all uses by professional workers. It is however considered that, uses that are not listed in Table 9 above as "Use as intermediate" are either, uses as monomer or, as additive, that do not fulfil the REACH definition of an intermediate.

Based on ANSES's compilation of knowledge, the main uses are further discussed below with a specific interest in describing the range of target sectors for each use.

9.1 Polymers

Polycarbonates

Polycarbonate is an amorphous, clear polymer with high transparency, superior dimensional stability, good electrical properties, good thermal stability, and outstanding impact strength and ductility (ANSES, 2012).

Not all polycarbonates are made from BPA and not all polycarbonates are plastics. However, polycarbonate plastic must be synthesised from bisphenol A. BPA reacts first with sodium hydroxide to form a sodium salt of bisphenol A, with then reacts with phosgene to produce polycarbonate.

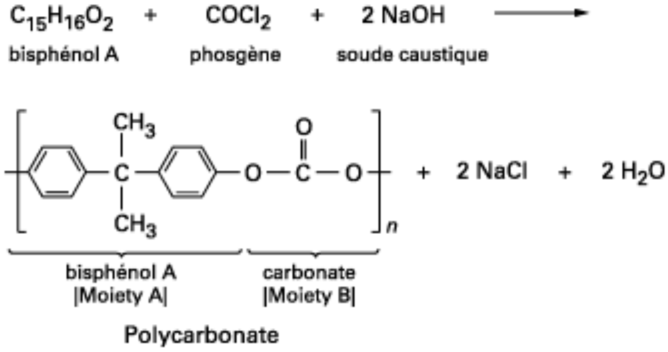


Figure 1 : Polycarbonate formation reaction (ANSES, 2011)

There are two types of polycarbonates depending on the reagents and synthesis processes: thermoset and thermoplastic. The bisphenol A polycarbonate belongs to the second family: thermoplastics. These polymers are clear, and display heat and impact resistance. However, they have limited resistance to chemical agents: hydrolysis of the polymer can occur at high temperature and alkaline pH, a reaction that can release bisphenol A (ANSES, 2011).

Applications of polycarbonate are summarised in Table 10 below.

Table 10: Applications of polycarbonate (ANSES, 2011)

Sectors	Applications
Optical media	CDs, DVDs, Blu-Ray and other audio or video media/formats
Electrical and electronic goods	Electrical equipment such as sockets and switches Housings for electronic equipment: injection-moulded items with polycarbonate mixtures, used mainly in the electrical and electronics industry (alarm devices, mobile phone cases, coils, screens, computers, domestic appliances, lamps, power sockets, cables, etc.)
Domestic appliances	Kettles (transparent water level gauge)…
Construction	Covers for solar panels Roofs of stadiums and sports facilitites
Automotive	Certain items for motor vehicles (safety glazing, light reflectors, headlamps, bumpers, radiator and ventilation grilles, interior lighting, motorcycle windshields and helmets, car roof modules, decorative trimmings for dashboards or door interiors, etc.)
Reusable containers and bottles	Food containers such as reusable water bottles, shockproof baby bottles* Tableware items such as plates, cups, water bottles
Medical and healthcare items[9]	Medical equipment (blood oxygenators, respirators, dialysers, incubators, breathing apparatuses, disposable instruments, non implantable medical devices, implantable urogynaecology medical devices, ventilation mask, humidifier, administration sets, drug containers, catheter, stopcock, injection caps, enteral nutrition kit…);
Leisure and safety	Optical equipment (prescription glasses, protective glasses, frames, sunglasses, thermal camera lenses, etc.)

[9] ANSES has interviewed SNITEM (The National Association of Medical Technology Industry) on 8 June 2016 to collect data on uses, alternatives and exposure of bisphenol A in medical devices.

	Sporting goods and protective gear (e.g. hockey helmet visors)
Other	All applications that fall within the other categories, such as furniture and decorative items

*BPA is banned from baby bottles in Europe according to the EU Commission Regulation N°321/2011[10]

Others polymers

BPA can be used for the synthesis of other polymers such as (INERIS, 2010; ANSES, 2011):

- Polyester carbonate: used in automotive and transport; consumer products (hair dryer parts, laundry iron parts, microwave doors, etc.); electrical/electronics (fuses, switches, light reflectors and diffusers, etc.); industry (protective masks, indicator lights, etc.); medical (autoclaves, surgical lighting systems, medical packaging, etc.)[9]

- Polyarylates: used in medical equipment[9], water treatment, automotive and aeronautics

- Polysulfones: used in medical equipment (catheter, canula…)[9], in domestic appliances (microwave utensils, dispensers, parts for coffee-makers, cookers, hair-dryers, etc.), as a material for filtration membranes (hemodialysis, drinking water, gas separation, food industry, etc.), in plumbing

- Polyetherimides: used in medical, electronic and electrical equipment (satellite antenna parts, components for methanol fuel cells), automotive, aeronautical (aviation parts, cockpit components, radomes), food equipment (pump components in beverage vending machines)

- Polyols: used in the production of polyurethane

- Polyamides: BPA can be introduced as an additive in a polyamide to give stability.

- Polybenzoxazines: BPA can be a precursor in the synthesis of benzoxazine monomers. These polymers have various applications: composites industry, in coatings, adhesives and encapsulants.

9.2 Resins

Epoxy resins

Bisphenol A diglycidyl ether (BADGE) is the most widely used epoxy resin (95% of world tonnage for epoxy resins). It is synthesised from bisphenol A and epichlorhydrin in the presence of soda according to the reaction schema below:

[10] EU Commission Regulation n°321/2011 amending Regulation (EU) N°10/2011 as regards the restriction of use of bisphenol A in plastic infant feeding bottles.

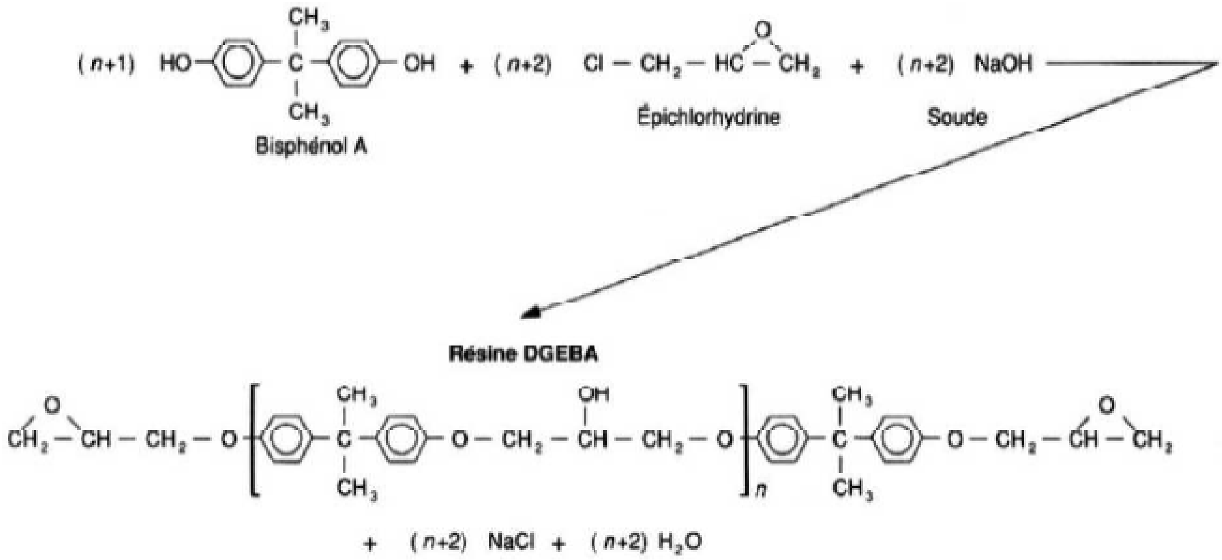


Figure 2 : Synthesis of resins based on bisphenol A (ANSES, 2011)

Epoxy resins are used for their ability to protect against corrosion and their thermal stability. These resins are used as protective coatings, composites and laminates, in electrical and electronic applications, in the construction industry and in the manufacture of adhesives (ANSES, 2011).

Applications of epoxy resins are summarised in Table 11 below.

Table 11: Applications of epoxy resins (ANSES, 2011)

Sectors	Applications
Composites	Rackets, surfboards, helmets, pipe, wind turbine blades Composites in the hulls of ships, aircraft and coach structures
Electrical and electronic goods	Printed circuits and boards
Insulation materials	Flooring (industrial and public buildings) Garden tools and equipment Cutting tools for food Coatings in cookware
Coatings for cans and reels	Coatings for canned food and drinks Domestic appliances (refrigerators, dishwashers, vacuum cleaners) Heating, ventilation and air conditioning equipment
Coatings in the automotive sector	Vehicle parts and coatings

Adhesives	Consumer and multi-purpose adhesives Adhesives and sealants for civil engineering Mortar for tiling and flooring Adhesives for floor coverings (linoleum, tiles) Varnish wood mastic
Products for protection against light	Printing ink Wood coatings Varnish on paper, cardboard, packaging Coatings for plastics and metals
Civil engineering	Products for reinforcing/repairing concrete surfaces, various materials pre-impregnated with resins: movable partitions, decorative panels, bonded gravel… Coatings for aluminium formwork, concrete or plaster moulds, in civil engineering Coatings for metal containers (shipping containers, tanks, cooling, towers, industrial storage tanks) Coatings for steel bridges Coatings for gas and drinking water pipes Construction of metal panels (roofs) and chipboard Fibreglass in construction Powder coating on concrete reinforcement bars, on shelving grilles and primer coatings
Marine and Protective coatings	Water ballast tank, underwater ship hulls, cargo tank linings, offshore oil drilling platforms, supporting steel structures, sea containers, steel bridges, storage tanks, power plant scrubbers, electric motors, engines, machinery, drinking water distribution pipes, gas pipes, waterproofing
Medical devices[11]	External carbon orthoses, implantable urogynaecology medical devices…

For food contact applications, epoxy resins with BPA have been removed from the internal coatings of all containers and substituted by others resins in France since the

[11] ANSES has interviewed SNITEM (The National Association of Medical Technology Industry) on 8 June 2016 to collect data on uses, alternatives and exposure of bisphenol A in medical devices.

national law n°2012-1442[12]. According to the French Association for Food Industry (ANIA) and the National Association of Manufacturers of Packaging Boxes and Metal Capping (SNFBM)[13], epoxy resins are still used in the external coating of food-containers and in equipment of the food chain. Epoxy resins are also still utilised for internal coating in the rest of Europe.

Ethoxylated bisphenol A can be used in the manufacture of certain types of epoxy resins employed to increase adhesion and resistance against friction and abrasion in UV-curable formulations, such as wood varnish and inks.

Others resins

BPA can be used for the synthesis of other resins such as (INERIS, 2010; ANSES, 2011):

- Vinyl ester resins: these resins are obtained by adding a carboxylic acid to an epoxy resin. They are used in automotive and marine construction, swimming pools, mortars and concretes, coatings (floors, etc.), fibre optic media, aeronautics, gas cylinders.

- Phenolic plastic resins: made from BPA and formaldehyde, these resins have several applications: timber industry (plywood, particle board), paper industry (laminates, separators for collector tank, filters), insulation (agglomeration of fibres, foams), abrasives (for grinders, abrasive papers), friction materials (for brakes and clutches), rubber and adhesives industry, coatings (paints, protective coatings, enamel insulated wires, printing inks), new high-tech applications (obtaining carbon and graphite, composites)

- Unsaturated polyester resins: they are divided into two groups:

  - Bisphenol fumarates

  - BPA epoxy dimethacrylates

  Unsaturated polyester resins are used in the following applications: furniture varnish (old application), gel coats (used as outer layers on boats, aircraft, swimming pools, etc.), buttons, inclusions, mastics (waterproofing, seals, vehicle repair), construction (mortars and concretes), reconstituted marble, fake wood, fake ivory, etc.

9.3 Flame retardants

Tetrabromobisphenol A

Bisphenol A is used in the production of tetrabromobisphenol A (TBBPA), which can be utilised as a monomer in the manufacture of flame retardants for printed circuit boards. TBBPA can be found in consumer products such as computers, televisions and

[12] The French law n°2012-1442 for the Suspension of Manufacture, Import, Export and Marketing of All-Purpose Food Packaging Containing Bisphenol A. The Constitutional Council Decision No 2015-480 QPC stated the suspension of the manufacture in France and the export from France do not affect the marketing of these products in other countries. Hence the “manufacturing” and “export” in the initial were considered invalid.
[13] ANSES has interviewed ANIA and SNFBM on 1 June 2016 to collect data on uses, alternatives and exposure of bisphenol A in food contact materials.

dishwashers. TBBPA can also be used in hydraulic fluids (ANSES 2011).

TBBPA may be partially transformed into bisphenol A in sewage treatment plants or the environment. (INERIS, 2010, ANSES, 2011)

Tetrachlorobisphenol A

BPA is also used in the production of a second flame retardant, tetrachlorobisphenol A, employed as an additive in polymers, epoxy resins, phenolic resins and adhesives. (ANSES, 2011)

Bisphenol A-bis (diphenyl phosphate)

Bisphenol A bis (diphenyl phosphate) (BDP) is another flame retardant derived from BPA, but much less frequently used than TBBPA. It is sometimes proposed as an alternative to halogenated flame retardants. (ANSES, 2011)

9.4 Thermal paper

BPA is an additive in the coating applied to thermal paper and is therefore used as a substance for this application. It is used as a developing agent, which causes a chemical reaction when the paper is heated, resulting in colour being produced when using the paper. (ANSES, 2011; ANSES's restriction dossier, 2014)

There are two types of thermal paper manufactured for different uses:

- Top coating or high-quality paper (which provides high quality images) is used for identification tags (parcels, self-service weighing of fruit and vegetables, identification of pre-packaged fresh foods, etc.), tickets (cinema, concerts, etc.), identification badges, self-adhesive labels, lottery tickets and receipts.

- Eco-paper or unprotected thermal paper is used in receipts, cash register receipts and credit card slips.

BPA has not been used in top coating thermal paper since 2000, as it is not a rapid enough developer for this type of paper. BPA is mainly used in eco-paper, although it is increasingly being substituted (ANSES, 2011). Further to the restriction dossier proposed by France for bisphenol A in thermal paper, RAC and SEAC released a joint opinion supporting restriction of use of BPA as follows:"Shall not be placed on the market in thermal paper in concentration equal to or greater than 0.02% by weight […] from [entry into force + 36 months]". The proposed restriction was approved on the 6th July 2016 by the REACH Committee and its formal adoption and publication is expected shortly.

9.5 Special uses in the automotive industry

Brake fluids

BPA itself is sometimes added in small proportions to brake fluids and hydraulic fluids as an antioxidant. In November 2010, the French Union of Petroleum Industries confirmed to Anses that bisphenol A is only used in some brake fluid formulations (at concentrations less than 1%).

Tyres

According to the 2011 ANSES report, BPA can also be used in tyre manufacturing. BPA is incorporated into the polymer matrix for its antioxidant properties. (ANSES, 2011)

9.6 Other uses

- Paint industry: bisphenols may be used in paint hardeners. (ANSES, 2011)
- Heat transfer fluids and lubricants: BPA can be used in the composition of heat transfer fluids and lubricants, and as a treatment agent for resurfacing concrete. (ANSES, 2011).
- Dental products: dental cements containing BPA-based polymers are reported to be used in resin-based composites for restoration and sealing. BPA can be present as an impurity in the cement (the case of bisphenol A glycidyl methacrylate or bis-GMA) or as a by-product of degradation (the case of bisphenol A dimethacrylate or bis-DMA) (ANSES, 2011; INERIS 2010). COMIDENT[14] has however indicated that they have no report of current use of bis-DMA (personal communication, 22 July 2016).
- Esters: BPA is used as a stabiliser in the manufacture of esters. It acts as an antioxidant to prevent product aging. These BPA-stabilised esters are used as PVC plasticisers primarily in the automotive industry, in pipes, dashboards, etc.
- PVC: BPA is used in the manufacture of PVC and acts as (ANSES, 2011, aggregated dossier):
    - An antioxidant in the treatment of PVC and in the production of plasticisers used in PVC processing.
    - A component of package of additives used in treatment of PVC.

The uses of BPA are thus very widespread.

10. Information on structure of the supply chain

No specific information is available on the structure of the supply chain.

11. Additional information

11.1 Substances with similar hazard and use profiles on the Candidate List

No other substances that have a bisphenol structure are currently on the Candidate List except phenolphthalein (EC 201-004-7) but that is not known to have similar uses as bisphenol A.

[14] France Coordinating Committee of Dental Activities

France is not aware of substances in the Candidate List that have similar uses. In particular, none of the identified potential alternatives of BPA as listed in Section 11.2 are on the Candidate list.

11.2 Alternatives

The review of alternatives has been made on the basis of a) a bibliographical search, b) the restriction dossier for BPA in thermal paper proposed by France and c) a report published by ANSES compiling an inventory of potential alternatives of BPA according to the different uses (ANSES, 2013a). ANSES issued a call for contributions in September 2011, in order to collect any scientific data concerning available substitution products. The work of identifying alternatives to BPA, in the ANSES report, was performed on a review of literature and contacts with industry. 73 alternatives to BPA were identified in the report.

Alternatives to BPA may be identified in several ways:

- Direct substitution of BPA by another substance
- Substitution by another plastic material or another polymer having similar properties to the starting polymer
- Substitution by another material, other type of packaging
- Substitution by a process

Alternatives are discussed for each of the main uses of BPA.

11.2.1 Potential alternatives to polycarbonate (PC)

Polycarbonate can be replaced by other types of plastics polymers or by other materials.

Table 12: Potential alternatives to Polycarbonate: other polymers (ANSES 2013a, CETIM 2015)

Other plastics polymers	
Alternatives	Uses
Polyphenylsulfone	Baby bottles and accessories
Polyethersulfone	Baby bottles, children tableware
Polyamides	PA-6: baby bottles, bottles, food packaging PA-11: bottles, food containers PA-12: baby bottles
Polyethylene	PE-hd: milk bottles, reusable juice bottles, packaging of milk and dairy products PE-bd: food containers, bottles

[15] After SNITEM (The National Association of Medical Technology Industry)'s interview in June 2016, a report performed by CETIM (Technical Centre for Mechanical Industries) on alternatives to polycarbonate, has been sent to ANSES. This report is not public but some new alternatives have been identified.

Polypropylene	Baby bottles, children tableware, childcare articles, reusable water bottles, meal trays
Copolyester	Baby bottles, reusable water bottles, kitchen gears, childcare products, water bottles, household appliances, medical devices
Polyethylene terephtalate	Food bottles and containers
Isosorbide material	Isosorbide polyester: containers used in the microwave, reusable water bottles… Isosorbide polycarbonate: sport bottles, food containers, parts of mixers and blenders
Polyetherimide	Containers used in the microwave
Poly lactic acid (PLA)	Food packaging, bottles
Topas® IT X1	Medical devices, food applications
Melamine material	Tableware, kitchen utensils, meal trays
Acrylonitrile-butadiene-styrene (ABS)	Tableware, kitchen utensils, electric kettles
Methyl methacrylate polystyrene	Perfect for thick parts
Styrene Butadiene Copolymer	Blister packs, Tests on Baby bottles
Styrene Butadiene Methacrylate	Cosmetic and food contact packaging
Methyl polymethacrylate	Cribs in maternities, dialysis cassette
Glycol polyethylene terephthalate	Blister packs

Table 13: Potential alternatives to Polycarbonate: other materials

Other materials	
Alternatives	Uses
Glass	Baby bottles, reusable water bottles, water bottles, food containers
Ceramic	Tableware, kitchen utensils, meal trays
Stainless steel or inox	Bottles and food containers
Silicon	Baby bottles

According to Plastics Europe[16], substitution of BPA for the production of polycarbonate is impossible because polycarbonate can only be synthesised with BPA as monomer. Few studies have been conducted on the substitution of polycarbonate because alternatives are already in use for the major applications: baby bottles made from polypropylene were already manufactured before the ban of BPA, and containers, packaging and utensils used for food contact, are already manufactured with a copolyester to replace polycarbonate. Tritan copolyesters are produced from three monomers: dimethyl terephthalate (DMT, CAS # 120-61-6), 1,4 cyclohexanedimethanol (CHDM, CAS # 105-08-8), and 2,2,4,4-tetramethyl-1,3-cyclobutanediol (TMCD, CAS # 3010-96-6). These monomers are utilised in various ratios depending on the desired performance characteristics. For reusable water bottles, according to Plastics Europe, no alternative is

[16] ANSES has interviewed Plastics Europe on May 2016 to collect data on uses, alternatives and exposure of Polycarbonate.

needed now to replace BPA because reusable water bottles stocks are sufficient to meet the demand. Lifetime of reusable water bottles is estimated between 5 and 7 years. Reusable water bottles produced before 2014 are still on the market. As this use is minor compared to other uses, it did not impact the volume of PC produced. Producers are waiting for stabilisation of BPA's regulation in France and in Europe before working further on alternatives.

According to SNITEM's interview (The National Association of Medical Technology Industry), polycarbonate presents some properties such as transparency, radio sterilisability and heat resistance that are very important for medical devices. Some alternatives have been tested by industry but tests were not conclusive for all products. Certain polymers can replace polycarbonate in some products. In other cases, the product has to be redesigned with a new bonding process. In addition, in medical devices, prices are fixed for each product and substitution is hampered by constraints of cost limitation.

11.2.2 Potential alternatives to epoxy resins

Epoxy resins can be replaced by other resins or other materials or another process (ANSES 2013a, SNFBM 2016, Fache *et al* 2015).

Table 14: Potential alternatives to epoxy resins: other resins

Other resins	
Alternatives	Uses
Polyester	Coating of food metal packaging :internal coating of cans
Carbonate polypropylene	Food packaging, internal coating of beer and soda cans, food cans, food containers
Oleoresin	Internal coating of cans
Tannin resin	Cans, aeronautic, defense, and insulation applications,
Biolignine™	Adhesives
Polyurethan	Fixed facilities for production, treatment and distribution of water intended for human consumption: internal coating of pipes, drinking water tank; hot-water tank; … Wastewater, industrial water, sea water pipes; heating circuits; Waterproofing for equipment rooms
Verdanol	Coating of flexible packaging, external coating of packaging (cans for example)
Resin UVL-Eco resin	Sailing applications
Resin SPR	Electrical cables encapsulation, industrial floor coating, drinking water pipe coating (upon certification)

Isosorbid resin	Internal coating of cans, top and metallic lids of bottles and glass jars
Polyacrylate	Floor coatings, electrical insulation
Acrylic	Cans
Vinyl	Cans
PET	No specific information on uses
Vanilin diepoxy monomer	No specific information on uses

Table 15 : Potential alternatives to epoxy resins: other materials

Other materials	
Alternatives	Uses
Glass	Bottle, jar, food packaging
Tetrapack®	Carton packaging
Doypack®	Flexible bag

Table 16 : Potential alternatives to epoxy resins: other process

Other process	
Alternatives	Uses
Decrease BPA migration in food containers[17]	Cans

According to SNFBM (the National Association of Manufacturers of Packaging Boxes and Metal Capping), in France epoxy resins have been replaced by three types of resin in internal coatings of containers:

- Polyester
- Acrylic resin
- Vinyl resin

No single alternative exists to substitute BPA in epoxy resin for all food contact applications. Indeed, it is difficult to find an alternative that is adequate for both acid and non-acid food. SNFBM notes that the work on substitution is ongoing to improve the quality of alternatives (cost and use by date). More information about each alternative are detailed in the Anses Report (2013a).

11.2.3 Potential alternatives to bisphenol A in thermal paper

France has submitted a dossier about the restriction of BPA in thermal paper receipts. A detailed review of the alternatives of BPA for this use has been performed in this context (ANSES's restriction proposal, 2014). Potential alternative substances to bisphenol A in thermal paper can either be another substance or another process (ANSES, 2011).

Substances that have been identified as potential alternatives to BPA in thermal paper are summarised in table 17 below with their regulatory status (harmonised classification and SVHC status).

[17] It consists of adding a PET Film on cans to inactivate the internal surface of cans or using an Epoxy Resin paint to limit the migration of BPA in food.

Table 17 : Potential alternative substances to BPA in thermal paper

Substance	CAS N°	Harmonised classification according CLP regulation	Candidate List
4,4’-methylenediphenol (Bisphenol F - para)	620-92-8	No harmonised classification	No
2,2’methylenediphenol (Bisphenol F – ortho)	2467-02-9	No harmonised classification	No
4,4'-sulphonyldiphenol (Bisphenol S)	80-09-1	No harmonised classification	No
1,1-bis(4-hydroxyphenyl)-1-phenylethane (Bisphenol AP)	1571-75-1	H400: Aquatic Chronic 1 H410: Aquatic acute 1	No
2,2’-diallyl-4,4’-sulfonyldiphenol (TGSA)	41481-66-7	H317: Skin Sens 1 H411: Aquatic Chronic 2	No
4-(4-isopropoxyphenylsulfonyl)phenol (D8)	95235-30-6	H411: Aquatic Chronic 2	No
4-[[4-(2-Propenyloxy)phenyl]sulfonyl]phenol (BPS-MAE)	97042-18-7	No harmonised classification	No
4-4’-methylenebis(oxyethylenethio)diphenol	93589-69-6	H411: Aquatic Chronic 2	No
Phenol, 4,4’-sulfonylbis-,polymer with 1,1’-oxybis[2-chloroethane] (D90)	191680-83-8	No harmonised classification *	No
biphenyl-4-ol	92-69-3	No harmonised classification	No
4,4’-thiobisphenol	2664-63-3	No harmonised classification	No
4-tert-butylphenol	98-54-4	H315: Skin irrit 2 H318: Eye Dam 1 H361f: Repr 2	No
benzyl 4-hydroxybenzoate	94-18-8	No harmonised classification	No
dimethyl 4-hydroxyphthalate	120-47-8	No harmonised classification	No
dimethyl 4-hydroxyphthalate (DMP-OH)	22479-95-4	No harmonised classification	No
3,5-bis-tert-butylsalicylic acid	19715-19-6	No harmonised classification	No
zinc 3,5-bis(α-methylbenzyl)salicylate	53770-52-8	No harmonised classification	No
Benzenesulfonamide, 4-methyl-N-[[[3-[[(4-methylphenyl)sulfonyl]oxy]phenyl]amino]carbonyl]-	232938-43-1	H411: Aquatic Chronic 2	No
p-[[p-benzyloxyphenyl]sulfonyl]phenol	63134-33-8	No harmonised classification	No
Urea-urethane Compound	321860-75-7	No harmonised classification*	No
4,4’-bis(N-carbamoyl-4-methylbenzenesulfonamide)diphenylmethane	151882-81-4	H351: Carc 2	No

o-[(4-hydroxyphenyl) sulfony]phenol	5397-34-2	No harmonised classification	No
4,4'-isopropylidenedi-o-cresol	79-97-0	No harmonised classification	No
methyl bis(4-hydroxyphenyl)acetate (MBHA)	5129-00-0	No harmonised classification	No
4,4'-isopropyllidenebis (2-phenylphenol)	24038-68-4	No harmonised classification	No
6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol	85-60-9	No harmonised classification	No
2,6-di-tert-butyl-p-cresol	128-37-0	No harmonised classification	No
octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	2082-79-3	No harmonised classification	No
pentaerythritol tetrakis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)	6683-19-8	No harmonised classification	No
4,4',4''-(1-methylpropanyl-3-ylidene) tris [6-tert-butyl-m-cresol]	1843-03-4	No harmonised classification	No
1,2-diphenoxyethane	104-66-5	No harmonised classification	No
Phenolic compound	Confidential	/	/

*Assumed not to be in the EU market (not referenced in ECHA database)

Substitution processes of BPA in thermal paper are described below.

Other options for the replacement of BPA as a dye developer in thermal paper can be considered. Indeed, on the one hand, one option could consist of adopting another printing technique, still based on paper but not using thermal paper. On the other hand, a more radical approach would be to switch to paper-free techniques, based on electronic and IT technologies.

Matrix printing technique

Matrix printing consists of dot matrix printing or impact matrix printing. This is a type of computer printing which uses a print head that runs in either a back and forth, or an up and down motion on the page and prints by impact, striking pins over an ink-soaked cloth ribbon against the paper, much like the print mechanism on a typewriter. However, unlike a typewriter, letters are drawn out of a dot matrix, and thus, varied fonts and arbitrary graphics can be produced. The print-head is composed of 9 to 32 needles operated by several electromagnets (ANSES, 2013a).

Inkjet printing technique

Inkjet printing consists of a non-impact printing process that creates a digital image thanks to magnetised plates which propel droplets of ink onto paper (or plastics, or other substrates) and direct the ink in the desired shapes. The dots are extremely small and the ink dries more quickly than matrix printers. This system requires the use of ink cartridge. Inkjet printers are the most commonly used type of printer today and range from small inexpensive consumer models to very large professional machines that might cost tens of thousands of euros. (ANSES's restriction dossier, 2014)

Laser printing technique

Laser printing is an electrostatic digital non-impact printing process that rapidly produces high quality text and graphics by passing a laser beam over a charged drum to define a differentially charged image. The drum then selectively collects charged toner and transfers the image to paper, which is then heated to permanently fix the image. (ANSES's restriction dossier, 2014)

Thermal transfer printing technique

This digital printing technique seems to be the main competitor to direct thermal printing for labels, especially barcodes. The thermal transfer system consists of the adhesion of a wax-based ink onto paper. A thermal print-head melts wax-based ink from the transfer ribbon onto the paper, so that it stays glued to the material on which the print is applied. This type of thermal printer uses an equivalent panel of ink for each page to be printed, no matter if a full page or only one line of print is transferred. A typical thermal transfer ribbon consists of three layers: the base material, the heat melting ink, and the coating on the print side of the base material. The coating and base material help keep ink from adhering to the print-head which can cause poor print quality. (ANSES's restriction dossier, 2014)

Additionally, the analysis of alternatives to BPA in thermal paper includes herein the possibility to switch to paper-free techniques, based on electronic and IT technologies. This way of understanding substitution is broader and more radical since these alternatives no longer imply the use of (thermal or traditional) paper.

These paper-free alternatives can be sorted into three categories: electronic tickets (e-tickets or e-receipts), contactless payments (mobile or smart card payments) and receipt handling options. (ANSES's restriction dossier, 2014)

An inventory of potential alternatives to BPA was compiled according to the different uses. BPA can be replaced by a substance, or a polymer/resin, or a material/packaging or by a process. It should be noted that a unique alternative to bisphenol A to replace it for all applications does not exist, but it can be underlined that some potential alternatives listed before are already used in certain industries.

This report does not aim to assess the technological issues with these substitutions. Furthermore, it does not seek to assess the health issues associated with the substitutes discussed.

11.2.4 Potential alternatives to other uses

COMIDENT has indicated (personal communication, 22 July 2016) that companies using bisGMA in light-curing dental composite material are looking for alternative components. One of them is a urethane dimethacrylate that is now starting to be found in the composition of some products on the market.

11.3 Existing EU legislation

BPA is not yet addressed under any restriction or authorisation procedure in the framework of the REACH regulation, even if a restriction of BPA in thermal papers has been proposed by France. The Committees for Risk Assessment (RAC) and for Socio-economic Analysis (SEAC) recently released their joint Opinion (December 2015). For cashiers, the RAC concluded that the risks of exposure via thermal paper receipts are not adequately controlled and supported the proposed restriction. These risks include potentially severe effects on the unborn children of pregnant female workers. The SEAC concluded that comparing the socio-economic benefits to the socio-economic costs, the proposed restriction is considered unlikely to be proportionate. However, there may be favourable distributional and affordability considerations. The proposed restriction was approved on the 6th July 2016 by the REACH Committee and its formal adoption and publication is expected shortly.

Furthermore, this substance has a harmonised classification under CLP as presented in section II of part 1.

BPA is already addressed under several EU Directives and Regulations:

- Commission Directive 2009/161/EU of 17 December 2009 establishing an indicative occupational exposure limit of 10 mg/m^3 (8h-TWA) for inhalable dust of BPA. Furthermore, SCOEL recommended on 11 June 2014 the value of 2 mg/m^3 with respiratory tract irritation as critical effect (SCOEL 2014).

- EU Directive 94/33/EC on young people at work as BPA is currently classified as reprotoxic 1B (H361F), irritant (STOT SE 3) and sensitiser (Skin Sens.1) and thus fulfils the criteria specified in Annex I.3 (a-c) of this Directive: young people must not be in contact with this type of substance.

- EU Regulation 1980/2000 on products not eligible for a positive Eco-Label.

- Regulation (EC) No 1223/2009 on cosmetic products, Annex II – list of substances prohibited in cosmetic products (entry 1176). However, according to Article 17, the non-intended presence of a small quantity of a prohibited substance, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable in good manufacturing practice, shall be permitted provided that such presence is in conformity with Article 3 (with regard to the safety for human health when cosmetic product used under normal or reasonably foreseeable conditions of use).

- EU Toy Safety:

1) Annex II.III.3 of Directive 2009/48/EC on the safety of toys: Substances that are classified as […] toxic for reproduction of category […] 2 under Regulation (EC) No 1272/2008 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys. There are however derogations in particular for materials that comply with the specific limit values set out in Appendix C (annex II.III.7).

2) Commission Directive 2014/81/EU of 23 June 2014 amending Appendix C of Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards bisphenol A. The specific limit value for BPA used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth adopted in accordance with Article 46(2) is 0,1 mg/l (migration limit) in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005.

- EU Commission Regulation No 321/2011 amending Regulation (EU) No 10/2011 as regards the restriction of use of bisphenol A in plastic infant feeding bottles. BPA is authorised as additive or monomer in the manufacture of other plastic materials and articles in contact with food and water, except for the manufacture of polycarbonate infant feeding bottles.

- Regulation 10/2011/EU: plastic materials in contact with food – a specific migration limit value of 0.6 mg/kg food has been set.

- 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 established a specific migration limit SML (T) of 0.6 mg/kg (not to be used for the manufacture of polycarbonate infant feeding bottles).

- Water Framework Directive (2000/60/EC):

In the frame of the Review of the Priority Substances, BPA is subject to a review for identification as a possible 'priority substance' or 'priority hazardous substance' (Annex 3 of the Position of the European Parliament adopted at second reading on 17 June 2008 with a view to the adoption of Directive 2008/105/EC of the European Parliament and of the Council on environmental quality standards in the field of water policy).

11.4 Previous assessments by other authorities

11.4.1 Previous assessments in the European regulatory context

A risk assessment for BPA was carried out in accordance with Council Regulation (EEC) 793/931 on the evaluation and control of the risks of “existing” substances (rapporteur member state: UK). The final Risk Assessment Report was published in February 2010.[18] This risk assessment report was also the basis for a transitional Annex XV report submitted by the United Kingdom on 30 November 2008. No restriction on the manufacture or use of bisphenol A was proposed but some risk management measures for occupational uses were proposed:

- Establish an Indicative Occupational Exposure Limit (IOELV).
- Implementation of Risk Management Measures (RMMs) following registration of BPA under REACH.
- Industry to voluntarily update the ‘Safety and Handling Guide’.

EFSA performed a full risk assessment of BPA in 2006 and updated its scientific advice on hazard identification several times since 2006 (EFSA, 2008; EFSA 2010).

EFSA published its latest comprehensive re-evaluation of BPA exposure and toxicity in January 2015. New data and refined methodologies have led EFSA’s experts to reduce the safe level of BPA to 4 µg/kg of bw/day. The highest estimates for dietary exposure and for exposure from a combination of sources (called “aggregated exposure” in EFSA’s opinion) are three to five times lower than the new TDI.

In April 2016, EFSA set up a working group of international experts to evaluate new scientific evidence on the potential effects of BPA on the immune system. EFSA is conducting the review following publication of a report by the Dutch National Institute for Public Health and the Environment, which raises concerns about the effects of BPA on the immune system of foetuses and young children.

BPA was included on the Community Rolling Action Plan for Substance Evaluation 2012-2014 (evaluation year 2012, evaluating member state: Germany) and is still ongoing: a substance evaluation decision pursuant to Article 51(6) of the REACH regulation was taken by ECHA in November 2013[19] that required additional data with regard to skin

[18] http://echa.europa.eu/documents/10162/c6a8dcfc-1823-4d31-8a24-2c71168f0d217
[19] http://echa.europa.eu/de/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e375d

absorption and exposure (industrial, professional and consumer) to be included in an update of Registration dossiers by 20 December 2015.

In 2014 RAC evaluated the effects of BPA on fertility and reproductive systems and concluded that BPA meets the criteria Repr. 1B (H360F) by exerting, in animal studies, adverse effects on female reproductive capacity, female reproductive organs and male reproductive organs that are not secondary to other toxic effects and are considered relevant to humans (ECHA 2014).

Also in 2014 SCOEL adopted a recommendation for an OEL (SCOEL 2014). Respiratory tract irritation was taken as the critical effect and an inhalation NOAEC of 10 mg/m^3 as the starting point for recommending the OEL.

In the context of a restriction proposal by France, RAC evaluated the risks posed by BPA contained in thermal paper and a DNEL was derived (ECHA 2015). In accordance with EFSA's assessment, the DNEL was established based on kidney effects. RAC concluded that effects on brain and behaviour, effects on the female reproductive system and proliferative effects on the mammary gland were observed at and below the range where kidney effects occur. RAC considers it prudent to take into account these effects, as well as effects on metabolism and obesity and effects on the immune system, both in hazard and risk assessment and in health impact assessment. RAC however acknowledges that the available information does not allow a quantification of the dose-response relationship for these effects. Therefore, this was taken into account in the setting of Assessment Factors.

11.4.2 Previous French assessments

On 24 October 2008, the French Food Safety Agency (AFSSA) published an opinion regarding BPA in polycarbonate baby bottles likely to be heated in microwave ovens (AFSSA, 2008a). AFSSA concluded that "given the current knowledge and after analyzing the latest publications and reports, it [deemed] that when the contents of polycarbonate baby bottles [were] heated in a microwave oven in realistic conditions (heating for less than 10 minutes), the quantities of BPA that [migrated] into food [were] much less than the maximum value of 50 µg BPA per liter as used in EFSA as a conservative estimate of exposure."

On 21 November 2008, AFSSA published an opinion regarding the exposure assessment of BPA in water intended for human consumption and possible resulting health risks (AFSSA, 2008b). AFSSA concluded that "the daily intake of BPA, including that from migration from water contact materials, [did] not lead to a risk for consumers under normal conditions" and recommended nevertheless "when BPA is present in a compound, that migration of BPA in water be specifically screened for during public health certification procedures of water contact materials with a target quantification limit of 1 µg/L."

On 7 July 2009, AFSSA published a note regarding the publication by Stahlhut et al. (2009) on urinary elimination of BPA in humans (AFSSA, 2009). It concluded that the result of this study [did] not require AFSSA to reconsider either the information already acquired on BPA or the risk assessment previously issued by EFSA, on which AFSSA's risk assessments were based."

On 29 January 2010, AFSSA published an opinion on the critical analysis of the results of a developmental neurotoxicity study of BPA together with other recently-published data on its toxic effects (AFSSA, 2010a). The conclusions were that "toxicity studies performed in compliance with international standards [had] not so far demonstrated any risk to health at current levels of exposure. [...] However, some recent publications, whose methodology [did] not authorise any formal conclusions, [mentioned] warning signals. The Agency also [recommended] investigating sources of exposure to bisphenol A other than food contact materials."

In the clarification of this last opinion published on 2 March 2010 (AFSSA, 2010b), AFSSA concluded that "in order to reduce, through the use of substitute products, human exposure to bisphenol A, particularly for pregnant women and newborns, AFSSA stresses the importance of a rigorous risk assessment process for any products being considered as substitutes for bisphenol A."

On 7 June 2010, AFSSA published an opinion regarding exposure to BPA in the French population and maximum levels of BPA in foods (AFSSA, 2010c). The conclusions were that BPA levels in foods, analysed mainly in France, were "appreciably lower than the specific migration limit that [had] been established in Europe". Dietary exposure levels in French population, including infants and children under 3 were "significantly lower than the TDI set by EFSA" and were "comparable to those observed in other international studies". AFSSA considered that "consumer exposure to BPA should be kept as low as possible, especially for the most sensitive consumers. It therefore [recommended] reassessing BPA's specific migration limit by using the best technologies currently available […] and the systematic labelling of household utensils that are in contact with foods and that contains BPA".

In 2010, the French Institute for Environment and Industrial Risks (INERIS) published a report compiling the technico-economic data about BPA (INERIS, 2010). In this report, the various uses of BPA were presented and a focus on emissions was made. The conclusion was that, at the European level, BPA was mainly emitted in water. The main source was industrial recycling of thermal paper (representing 70% of total emissions in water). Substitution of BPA in thermal paper was thus considered as a priority but, according to this report, the technical difficulties encountered with substitution were important. Recent papers show that water is not a major route of human exposure to BPA[20].

In 2011, ANSES published the results of an extensive work in order to identify the uses of reprotoxic substances and/or potential endocrine disruptors, and BPA in particular. It examined nearly sixty industry sectors that potentially use BPA, which were identified either through a literature search or through a questionnaire sent to French manufacturers that potentially use this substance. This work confirmed previous studies showing the great variety of uses, and therefore, products and articles, containing BPA. A second conclusion was that substitution was an issue because of the wide variety of uses that led to numerous possible alternatives (ANSES, 2011).

In another recent report, ANSES[21] (2011) reviewed recent scientific data with the aim to classify the observed effects according to a dedicated decision tree. The conclusions were based on the results of available human and animal data, which have most often been obtained at doses lower than the NOAEL of 5 mg/kg/day that was used to calculate the TDI currently used by EFSA. This report highlighted the possible existence of a non-monotonic dose-response relationship, which adds extra complexity to the interpretation of the results. The need to discuss the relevance of using toxicity reference values or Tolerable Daily Intakes for substances with non-monotonic dose-response curves was also highlighted some adverse effects in animals were considered as recognised and must be considered in a future risk assessment about this substance. These effects observed in animals are the following:

- Increase of occurrence of ovarian cysts after pre and postnatal exposures.
- Hyperplastic modification of the endometrium after pre and postnatal exposure.
- Early onset of puberty after pre- and postnatal exposures.

[20] Arch Environ Contam Toxicol (2014) 66:86–99 Is Drinking Water a Major Route of Human Exposure to Alkylphenol and Bisphenol Contaminants in France? A Colin, C Bach, Ce Rosin, JF Munoz, X Dauchy
[21] Available at : https://www.anses.fr/fr/system/files/CHIM-Ra-BisphenolA.pdf [in French]

- Altered sperm production after adult exposure.
- Histological changes in neurogenesis following pre- or perinatal exposure.
- Effects on lipogenesis following prenatal or perinatal exposures or during adulthood.
- Effects on the mammary gland: acceleration of the mammary gland's structural maturation in adulthood and development of intra-ductal hyperplastic lesions after pre- or perinatal exposure to BPA.

Some effects are considered as suspected in humans and should be taken into account for the risk assessment:

- Effects on oocyte maturation in females in infertile couples undergoing ART (Assisted Reproductive Technology).
- Effects on cardiovascular pathologies (coronary diseases) and diabetes.

In 2013, ANSES (2013b) published its assessment of the health risks of bisphenol A[22]: The risk assessment, which took into account all exposure media (but excluded specific exposure situations), shows that under certain circumstances, the exposure of pregnant women to bisphenol A could pose a potential risk to the health of the unborn child. The identified effects relate to a change in the structure of the mammary gland in the unborn child that could promote subsequent tumour development. The risk potentially affects children of both sexes.

The confidence level associated with these results was described as "moderate" by the majority of the experts, given the many uncertainties in the current state of scientific knowledge. Concerning the other three types of effects examined for the risk assessment (effects on the brain and behaviour, effect on metabolism and obesity, effect on the female reproductive system), the risk appears to be "negligible", depending on the assumptions made. The calculation of exposure via refillable polycarbonate water containers shows that water bottled in such containers is a significant source of exposure to bisphenol A. Its consumption can contribute to an increase in exposure to bisphenol A and could therefore, when combined with other sources of exposure, lead to an "additional" risk to the unborn child of an exposed pregnant woman.

The specific assessment of risks associated with the handling or use of products and/or articles intended for the general public and containing bisphenol A shows that handling thermal paper receipts leads to potential risk situations for the four types of effects considered in the risk assessment, but with a confidence level considered "limited" by the experts, due to the many uncertainties.

Following this risk assessment, restriction of BPA in thermal papers has been proposed by France. The Committees for Risk Assessment (RAC) and for Socio-economic Analysis (SEAC) recently released their joint Opinion (December 2015). The proposed restriction was approved on the 6th July 2016 by the REACH Committee and its formal adoption and publication is expected shortly.

11.4.3 Previous assessments in other contexts

In 2008, Environment Canada and Health Canada published a joint screening assessment of BPA (Health Canada, 2008a and b). The summary and the conclusions of this assessment were published in Canada Gazette Part II, Vol. 144, n° 21. Dietary intake was considered to be the major source of BPA. Other sources of exposure were

[22] Available at: https://www.anses.fr/fr/system/files/CHIM2009sa0331Ra-0.pdf [in French]. See also ANSES' Opinion on the assessment of the risks associated with bisphenol A for human health, and on toxicological data and data on the use of bisphenols S, F, M, B, AP, AF and BADGE: https://www.anses.fr/en/system/files/CHIM2009sa0331Ra-0EN.PDF

examined: dental materials' contribution was minimal while the other uses of BPA were insignificant.

Neuro-behavioural effects of BPA in newborns and infants were the subject of concern regarding the results of studies in rodents. The most sensitive populations are pregnant women/fetus and infants. It was "considered appropriate to apply a precautionary approach when characterising risk to human health. Therefore, it was concluded that bisphenol A […] may constitute a danger in Canada to human life or health". These conclusions led to add BPA to the list of Toxic Substances in Schedule 1 of CEPA 1999 (Canadian Environmental Protection Act). This addition enables the Canadian authorities to use regulatory instruments available in CEPA 1999 to manage the human health and environmental risks posed by BPA. The prohibition of the importation, sale and advertising of polycarbonate baby bottles that contain BPA came into force in March 2010.

In November 2009, WHO and FAO published an information note about the current state of knowledge and their future actions regarding BPA issue. They expressed concern because of potential toxic and hormonal properties of BPA (INFOSAN, 2009).

In January 2010, the American Food and Drugs Administration (FDA) reversed its position that BPA is safe and expressed "some concern about the potential effects of BPA on the brain, behavior and prostate gland in fetuses, infants and young children" based on the NTP-CERHR[23] report (NTP-CERHR, 2008). In the same time, the FDA announced that it "will support changes in food can linings and manufacturing to replace BPA or minimise BPA levels where the changes can be accomplished while still protecting food safety and quality".

In a BPA study published on March 9, 2010, researchers from the Swiss Federal Institute of Technology, based in Zurich (von Goetz *et al*., 2010) have examined nine different consumer groups who were exposed to 17 different potential sources of BPA (various food products, beverages, house dust…). The researchers concluded that PC baby bottles were the most relevant BPA exposure source for infants and children, and that for teenagers and adults, it was the consumption of canned food.

In 2010, a joint FAO/WHO expert meeting examined the Toxicological and Health Aspects of BPA. The Expert Meeting considered BPA concentrations in food, BPA migration from food contact and dental materials and BPA concentrations in air, dust and water. The Expert Meeting concluded that the highest estimated exposure occurs for infants (0-6 months) who are fed with liquid formula out of PC bottles. For children older than 3, the highest exposure estimates are well below the infants' level and the main source of exposure is canned food (94%). For adults the highest exposure is twice the one of children older than 3. Food is the major source of exposure (limited data available). Some additional potential sources of exposure (unpackaged food and thermal paper) have been identified.

In 2011, The Japanese Research Institute of Science for Safety and Sustainability (RISS) and the National Institute of Advanced Industrial Science and Technology (AIST) published an updated hazard assessment of BPA (AIST & RISS, 2011). AIST had previously published a risk assessment document in November 2007 where it was concluded that the risks posed by BPA were below the levels of concern, so it was unnecessary to prohibit or restrict the use of BPA at this time (AIST, 2007). In their 2011 update, the BPA exposure estimate in Japanese people is found to be the highest for the 1 to 6 year old children. For this population, the calculated Margin Of Exposure (MOE) was 730 to 770 while it was 40 000 to 81 000 for adults. The risk represented by BPA was qualified as "very small" but something additional to mention is that, since approximately ten years, the Japanese can manufacturers use a method for inactivating

[23] National Toxicology Program - Center for the Evaluation of Risks to Human Reproduction

the surface of drink cans that reduce the BPA intake of 0,1-0,2µg/kg/day for average-exposure individuals (AIST, 2007).

In a report published in 2011, the National Toxicology Program and Center for the Evaluation of Risks to Human Reproduction (NTP CERHR, 2011) concluded that the highest potential for human exposure to BPA was through "products that directly contact food such as food and beverage containers with internal epoxy resin coatings and through the use of polycarbonate tableware such as those used to feed infants". The exposure via dental sealant was concluded to be "acute and infrequent event with little relevance to estimating general population exposure".

In 2010, the United States Environmental Protection Agency (US EPA, 2010a; US EPA, 2010b) launched a program to identify safer substitutes for BPA in the manufacture of thermal paper. The final report should be published in May 2012. A recently published study (Liao and Kannan, 2011) confirmed the fact that, among all kind of papers, the highest concentrations of BPA were found in thermal papers but it also underlined that not negligible amounts of BPA were found in some recycled napkins and toilet papers due to contamination during the paper recycling process. The study also showed that the value of the general population's exposure due to this route was minor compared with exposure through diet. But the authors also concluded that this exposure had to be studied and with particular attention to occupationally exposed individuals whose median daily intake is 74 times higher than the general population.

In 2011, the Danish Environmental Protection Agency (Danish EPA) published a report about the migration of BPA from cash register receipt and baby dummies. This report has taken into account the actual recognised NOAEL of 5 mg/kg/day and estimated consequently a DNEL of 0.029 mg/kg bw/d. It concludes that there are no risks neither for consumers (RCR=0.19) nor for cashiers (RCR=0.79) with the cash register receipts. It also concludes that there is no risk with baby dummies (RCR=0.281).

The Swedish Chemicals Agency has initiated a survey on bisphenol A in toys and children articles. The contracted laboratory identified that toys made of polycarbonate, PVC, polyurethane and epoxy may contain BPA. Of 80 analysed articles only 20 of them were made of any of these plastic materials. In toys made of polycarbonate up to 600 ppm could be detected. However migration studies showed that there was no leakage of BPA (SE MSCA comments on this report, April 2012).

In 2016, the Dutch National Institute for Public Health and the Environment (RIVM) published a report on recommendations for risk management of BPA. This report advises the Dutch government to reduce BPA exposure in the short term wherever possible. According to RIVM, special attention needs to be devoted to protecting small children, pregnant women and women who breastfeed.

The RIVM further concludes that the risk characterisation ratios (RCRs) for consumers, patients and workers may require revision in the light of the new insights into the immune system effects of BPA. With regard to the environment, BPA is found in all surface water and sediment. The RIVM concludes that there is a risk for benthic organisms in line with earlier conclusions presented by the EU RAR (EC, 2008). More clarity on the contribution of various sources of BPA to its concentration in sediment is expected in the course of 2016 following the substance evaluation of BPA under the REACH regulation, which is being performed by Germany.

Different recommendations (general, for reduction of environmental risks and for reduction of human health risks) are proposed. In particular, Bureau REACH (RIVM) intends to inform other Member State competent authorities (MSCAs) under REACH and the ECHA on the effects of BPA exposure on the immune system. With this information, the ECHA could take action to initiate a Compliance Check requesting the DNELs for workers and consumers to be updated. This information will also be disseminated by

Bureau REACH in the Risk Management Expert Meeting (RiME), via commenting on ongoing risk management analyses.

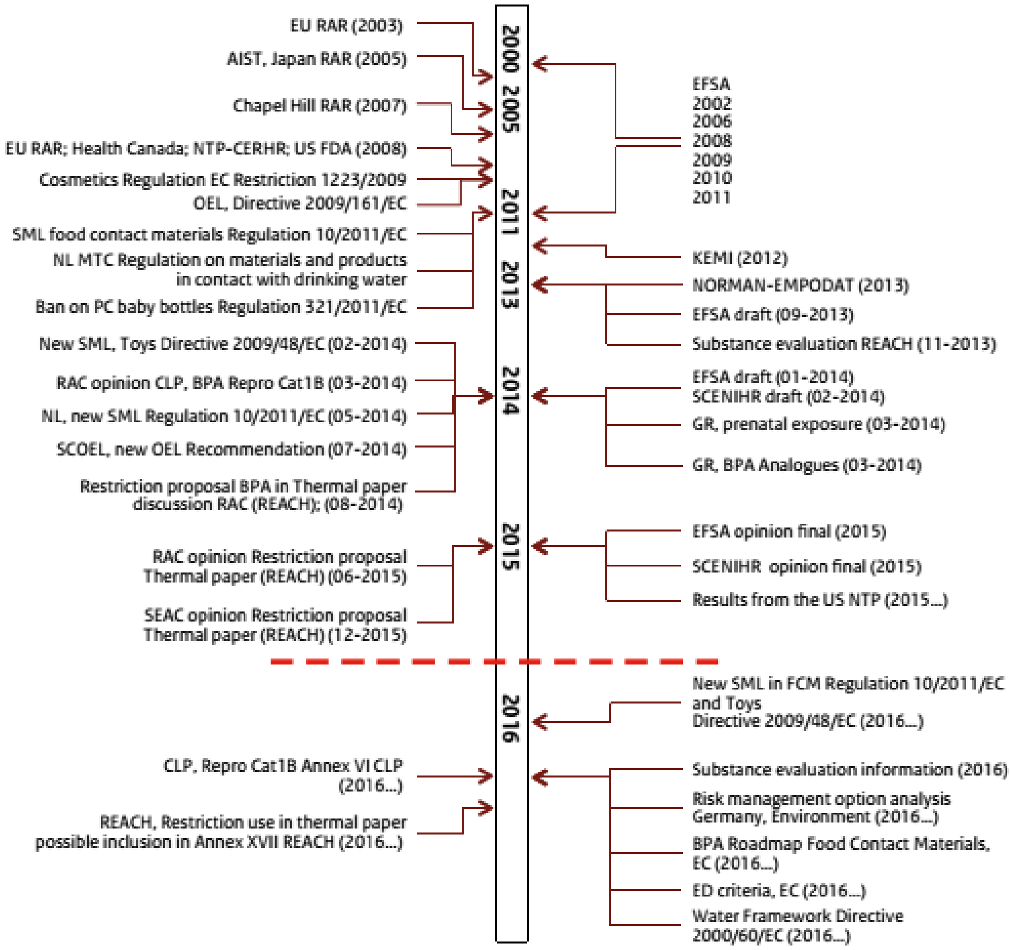


Figure 1: Chronological overview of regulatory measures and key risk assessments on BPA, implemented and under development (RIVM 2016)

REFERENCES

References for Part I

ECHA (2014). Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of Bisphenol A; 4,4'-isopropylidenediphenol. Adopted 14 march 2014. ECHA. Available at http://echa.europa.eu/documents/10162/777918ff-33b5-46ff-be89-2bdc406d34fa (accessed on 6 June 2016).

Commission Regulation (EU) 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. Available at http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2016.195.01.0011.01.ENG (accessed on 25 August 2016).

References for Part II

AFSSA (2008a). Opinion of the French Food Safety Agency regarding bisphenol A in polycarbonate baby bottles likely to be heated in microwave ovens. Request no. 2008-SA-0141, 24 October 2008.

AFSSA (2008b). Opinion of the French Food Safety Agency regarding the exposure assessment of bisphenol A in water intended for human consumption and possible resulting health risks. Request no. 2008-SA-0141A, 21 November 2008.

AFSSA (2009). Note from the French Food Safety Agency regarding the publication by Stahlhut et al. (2009) on urinary elimination of bisphenol A in humans. Request no. 2009-SA-0177, 07 July 2009.

AFSSA (2010a). Opinion of the French Food Safety Agency on the critical analysis of the results of a developmental neurotoxicity study of bisphenol A together with other recently-published data on its toxic effects. Request no. 2009-SA-0270, 29 January 2010.

AFSSA (2010b). Opinion of the French Food Safety Agency regarding clarification of the AFSSA opinion on bisphenol A issued on 29 January 2010. Request no. 2010-SA-0041, 7 June 2010.

AFSSA (2010c). Opinion of the French Food Safety Agency regarding exposure to bisphenol in the French population and maximum levels of bisphenol A in foods. Request no. 2010-SA-0040, 2 March 2010.

AIST (2007). Bisphenol A risk assessment document – summary - AIST risk assessment document series n°4.

AIST & RISS (2011). Updated hazard assessment of bisphenol A.

ANSES (2011). Health effects of bisphenol A – Knowledge about the uses of bisphenol A.

ANSES (2012). Analysis of the most appropriate risk management option for bisphenol A. January 2012

ANSES (2013a). Substitution of bisphenol A: an inventory of alternatives to BPA, identification of the hazards of potential substitutes for bisphenol A. March 2013

ANSES (2013b). Risk assessment of Bisphenol A (BPA) on human health. March 2013.

ANSES (2014). Annex XV Restriction Report – Proposal for a restriction – 4.4'-isopropylidenediphenol (bisphenol A; BPA). May 2014.

ANSES (2016) Analysis of the most appropriate risk management option for bisphenol A. May 2016

Canada Gazette (2010). Order amending Schedule I to the Hazardous Products Act (bisphenol A). P.C. 2010-256 March 11, 2010.

CETIM (2012). Remplacement des polycarbonates. March 2012 (Unpublished)

Danish EPA (2011). Migration of bisphenol A from cash register receipts and baby dummies. Survey of chemical substances in consumer products n°110 2011.

EC, February 2010. European Union Risk Assessment Report – 4,4'-isopropylidenediphenol (bisphenol A) – complete risk assessment in one document.

ECHA – European Chemicals Agency. June 2016

ECHA (2015). Opinion on an Annex XV dossier proposing restrictions on Bisphenol A. Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted 5 June 2015) and SEAC's opinion (adopted 4 December 2015).

EFSA (2015). Scientific Opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs. EFSA Journal 2015;13(1):3978.

EFSA (2011). Agreed joint report of EFSA and ANSES according to Article 30 of the Regulation (EC) No 178/2002 on bisphenol A. Parma, 30 November 2011.

EFSA (2010). Scientific opinion on bisphenol A: evaluation of a study investigating its neurodevelopmental toxicity, review of recent scientific literature on its toxicity and advice on the Danish risk assessment of bisphenol A. EFSA Journal 2010; 8(9): 1829 [116 pp.].

EFSA (2008). Toxicokinetics of bisphenol A – Scientific opinion of the panel on food additives, flavourings, processing aids and materials in contact with food. EFSA Journal 2008; 759.

EFSA (2006). Opinion of the scientific panel on food additives, flavourings, processing aids and materials in contact with food on a request from the Commission related to 2,2-bis(4-hydroxyphenyl)propane (Bisphenol A). Question number EFSA-Q-2005-100 adopted on 29 November 2006. The EFSSA Journal (2006) 428, 75p.

Fache M, Auvergne R, Boutevin B, Caillol S (2015). New vanilin-dreived diepoxy monomers for the synthesis of biobased thermosets

FAO/WHO (2010). Toxicological and health aspects of bisphenol A. Report of Joint FAO/WHO Expert Meeting and report of Stakeholder Meeting on bisphenol A.

Health Canada (2008a). Health risk assessment of bisphenol A from food packaging applications. Bureau of chemical safety, food Directorate, health products and food branch.

Health Canada (2008b). Proposed risk management approach for Phenol, 4,4'-(1-methylethylidene)bis (bisphenol A).

INERIS (2010). Données technico-économiques sur les substances chimiques en France : Le bisphénol A. Rapport d'étude. NO.INERIS-DRC-10-109972-01125C. – October 2010.

INFOSAN (2009). Bisphenol A (BPA) – Current state of knowledge and future actions by WHO and FAO. INFOSAN information note No. 5/2009 – Bisphenol A.

Liao C. and K. Kannan (2011). Widespread occurrence of bisphenol A in paper and paper products: implications for human exposure. Environmental Science and Technology 2011, 45, 9372-9379.

NTP-CERHR (2008). Monograph of the potential human reproductive and developmental effects of bisphenol A. National Toxicology Program, Center for the Evaluation of Risks to Human Reproduction, Expert Panel evaluation of bisphenol A.

Report of Joint FAO/WHO Expert Meeting, 2-5 November 2010 and Report of Stakeholder Meeting on Bisphenol A, 1 November 2010. Toxicological and health aspects of bisphenol A.

RIVM (2016). Bakker J et al. Bisphenol A: Part 2. Recommendations for risk management. RIVM report 2015-0192, 84p. Published on RIVM website http://www.rivm.nl/Documenten_en_publicaties/Wetenschappelijk/Rapporten/2016/maart/Bisphenol_A_Part_2_Recommendations_for_risk_management (accessed on 7 June 2016)

SCOEL (2014). Recommendation from the Scientific Committee on Occupational Exposure Limits for Bisphenol-A. SCOEL/SUM/113. June 2014. (accessed on 7 June 2016)

US EPA (2010a). List of known or expected functional BPA alternatives for use in thermal paper to be evaluated in the DfE alternatives Assessment. US EPA Action plan on BPA.

US EPA (2010b). Bisphenol A Action Plan. 29 March 2010.

Von Goetz N., M. Wormuth, M. Scheringer and K. Hungerbühler (2010). Bisphenol A: how the most relevant exposure sources contribute to total consumer exposure. Risk Analysis 30.3 (2010), 473-487.