

Summary

Bisphenol A (BPA) is an industrial chemical which is used in many consumer products such as containers to pack and store food and drink. A growing body of evidence links the exposure of endocrine disrupting chemicals including Bisphenol A to adverse health effects and negative effects on wildlife.

In this position paper we analyse the situation for consumers with regard to Bisphenol A and call on policy makers to better protect consumers, in particular vulnerable consumers such as pregnant women and young children, from exposure to endocrine disrupting chemicals such as BPA.

We ask the European Commission to go beyond a ban of BPA in baby bottles and also to replace it in all consumer products on the condition that safer alternatives are available. It is important that action will be taken now to stimulate research and innovation on safe alternatives as industry should not continue to pretend that no substitution will be possible. We also call for changing the current risk assessment methods which look at chemical by chemical and neglect the chemical cocktail effect to which consumers nowadays are exposed.

Finally, we call for BPA to be added to the Candidate List under REACH as a Substance of Very High Concern as this is the precondition for stricter regulating its use.

Introduction

Bisphenol A (BPA) is an industrial chemical which is used in many consumer products. After traces of this chemical have been found in canned food and beverages, BPA came into the spotlight of scientists, consumer organisations, environmental NGOs and policy makers because of suspected harmful effects on human health and for the environment. BPA is considered to be an endocrine disruptor. Endocrine disruptors may disturb the hormone system and have therefore been associated with various disease patterns such as changes in behaviour (hyperactivity), diabetes, obesity and cardiovascular diseases. Moreover, it is suspected to lead to fertility problems, early puberty, endometriosis as well as prostate and breast cancer. Some studies also conclude that even small amounts of BPA may have a negative impact on the brain development of babies¹.

A healthy environment and safe products are particularly vital for the most vulnerable consumers such as children and pregnant women. Until a couple of years ago, scientists still believed that the placenta shielded cord blood would protect the unborn child from most chemicals and pollutants. However, studies which analysed the blood of newborn babies showed that their blood already contains hundreds of hazardous chemicals such as heavy metals, flame retardants, dioxins, phthalates and pesticides². Biomonitoring studies to evaluate the exposure to BPA from all sources often look at urinary concentrations of BPA. The available data from North-America, Europe and South-East Asia suggest that human exposure to BPA is widespread across the lifespan³.

These findings must be worrying as the exposure to chemicals in the womb most likely leads to serious health problems in a later stage of life. Many of the substances that have been found in newborn babies are known to cause cancer or to be toxic to the brain and nervous system. Moreover, many of the substances are suspected to disturb the hormone system of humans and animals.

In this position paper, we analyse the current situation of the use of BPA in consumer products and call on the EU Commission to take further action to reduce the exposure of consumers to endocrine disrupting chemicals including BPA.

1) Which consumer products contain BPA?

BPA has two main applications, it is used as stabilizer and hardener for clear plastic (polycarbonate) and as inner coatings of food and drink containers to protect them from corrosion (epoxy resins)⁴. Therefore BPA is often used in the following products:

- cans for beverages and food;⁵
- plastic kitchen cutlery and micro-wave crockery;⁵
- electronic devices with a plastic housing such as coffee machines;⁵
- storage media such as CDs, DVDs and Blue-ray disks;⁵

¹ Girl, disrupted. Hormone disruptors and women's reproductive health, workshop paper, Commonwealth, California.

² <http://www.ewg.org/reports/bodyburden2/execsumm.php>

³ Summary Report of Joint FAO/WHO Expert Meeting to Review the Toxicological and Health Aspects of Bisphenol A, http://www.who.int/foodsafety/chem/chemicals/BPA_Summary2010.pdf.

⁴ BPA has been invented in 1936 as a synthetic estrogen. Originally it was intended to be used as pharmaceutical. However, as the more potent estrogen Diethylstilbestrol (DES) had been synthesised in 1938, BPA has never been used for medical purposes. Since 1957 it has been used in many every day products because of its ability to harden plastic.

- cash receipts printed on thermal paper;⁵
- filling and sealing material for dentistry applications;⁵
- leisure-time equipment such as surfboards and tennis rackets;⁵
- medical equipment;⁵
- construction materials (such as floor materials, filling materials, binding agents);⁶
- paints and varnishes;⁶
- the outer plastic shield of soothers.

In 2006, 3.8 million tonnes of BPA had been produced world wide. About 1.15 million tonnes have been produced in the EU of which around 70% in Germany⁷.

One major problem seems to be that BPA is leaking into food and drink even when consumers use products under normal conditions. The German test magazine “Öko Test” reported for instance that BPA was leaking into milk and tea after BPA containing baby bottles had been cleaned in the dishwasher or heated in the microwave⁸.

As the use of BPA in baby bottles has been of major concern, the EU Commission and Member States decided to prohibit the manufacturing of BPA containing baby bottles from 1 March 2011 based on the precautionary principle. The importation and placing on the market of BPA containing baby bottles will become illegal as of 1 June 2011⁹. We welcome this step. However, as consumers, in particular vulnerable consumers such as pregnant women and children, have to be better protected, we call on the Commission to take further action to reduce exposure to endocrine disrupting chemicals including BPA.

The exposure to BPA coming from food and drink is estimated highest for infants 0-6 months of age who are fed with liquid formula out of BPA containing polycarbonate bottles¹⁰. In some countries such as Denmark, Bisphenol A has therefore not only been banned in baby bottles but also in food packaging which is used to pack food for children under the age of three¹¹.

⁵ Umweltbundesamt (2010): Bisphenol A – an industrial chemical with adverse effects, <http://www.umweltdaten.de/publikationen/fpdf-l/3992.pdf>

⁶ Møller; Helweg, Christian; et al. (2004): Evaluation of Alternatives for Compounds under Risk Assessment in the EU, Bisphenol A, <http://www2.mst.dk/udgiv/publications/2004/87-7614-181-0/pdf/87-7614-182-9.pdf>.

⁷ Umweltbundesamt (2010): Bisphenol A – an industrial chemical with adverse effects

⁸ Öko-Test (2011): Volle Pulle, <http://www.oekotest.de/cgi/index.cgi?artnr=96712;bernr=07;co=>

⁹ Commission Directive 2011/8/EU regarding the restriction of use of Bisphenol A in plastic infant feeding bottles, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:026:0011:0014:EN:PDF>

¹⁰ Summary Report of Joint FAO/WHO Expert Meeting to Review the Toxicological and Health Aspects of Bisphenol A, p. vii.

¹¹ Press release of the Danish Ministry of Food, Fisheries and Agriculture: Danish ban on bisphenol A in materials in contact with food for children aged 0-3, 26.03.2010, http://www.fvm.dk/News_display.aspx?ID=18488&PID=169628&year='+thisYear+'&NewsID=6014

2) What are scientists saying about the effects of BPA on humans and the environment?

The levels of endocrine disruptors, including BPA, causing effects in humans and the environment are very controversially debated among scientists.

2.1 EFSA opinion

In September 2010, the European Food Safety Authority (EFSA) published an updated opinion on BPA in food contact material¹². In its opinion, EFSA did not recommend lowering the currently existing Tolerable Daily Intake (TDI) values of BPA in food contact material. BEUC reacted with concern as:

- o EFSA points out that effects reported by some studies deserve further consideration.
- o The 'cocktail effect' of chemicals is not taken into account¹³.

2.2 Joint FAO/WHO report reviewing the toxicological and health aspects of Bisphenol A

In November 2010, a joint FAO/WHO Expert Meeting reviewed the toxicological and health aspects of BPA¹⁴. Similar to the EFSA assessment, the expert group of the FAO/WHO doubts a health effect for conventional end-points¹⁵. However, the experts also pointed out that for some emerging new end-points (such as sex-specific neurodevelopment, anxiety, impaired sperm parameters and changes in mammary glands and prostate of rats) studies showed low-dose effects. Moreover, the group acknowledged difficulties to assess the findings due to considerable uncertainties and called for future research to close these knowledge gaps.

2.3 Research Studies looking at reproductive disorders

Related to a growing awareness about the negative health effects of endocrine disrupting chemicals on fertility, an increasing number of scientific studies investigate the role of endocrine disruptors including BPA on reproductive health.

Research in Denmark¹⁶ found a dramatic decline in sperm count over the last decades¹⁷. At the same time, the number of testicular cancer had risen sharply. The data also showed an increasing number of genital abnormalities such as undescended testicles and shortened urinary tracts. Because the changes occurred over such a short period of time, the researchers were convinced that only environmental factors could

¹² 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, <http://www.efsa.europa.eu/en/efsajournal/doc/1829.pdf>

¹³ BEUC press release: BEUC calls for Bisphenol A to be banned, <http://www.beuc.eu/BEUCNoFrame/Docs/1/GEJQHEDPJKPEFCODLAHJDHPDWD9DB1CY9DW3571KM/BEUC/docs/DLS/2010-00582-01-E.pdf>

¹⁴ http://www.who.int/foodsafety/chem/chemicals/bisphenol_release/en/index.html

¹⁵ An endpoint in clinical studies refers to a disease, a symptom, or sign that constitutes one of the target outcomes of the research.

¹⁶ For more information about the work of the Department of Growth and Reproduction, located at Rigshospitalet in Copenhagen see: <http://www.reproduction.dk/index-filer/Page457.htm>

¹⁷ Højgaard, Liselotte; Makarow, Marja (2010): Male reproductive health. Its impacts in relation to general wellbeing and low European fertility rates, European Science Foundation, Science Policy Briefing 40.

explain this change, not genetic factors¹⁸. Because of this research, awareness of policy makers in Denmark is high for the health threats linked to endocrine disruptors. Bisphenol A has for instance been added to the list of unwanted chemicals of the Danish Environment Protection Agency.

The workshop report “Girl disrupted”¹⁹, published by a group of American scientists, also points out that the number of male and female reproductive disorders is increasing. Trigger for many of the disorders seem to be hormonal disruption in key developmental stages of the embryo. A negative impact on the hormonal system in such an early stage of life seems to lead to serious health effects in a later stage of life. One area of concern is linked to so called low-dose effects. It seems that a contact with very small amounts of endocrine disrupting chemicals may already unbalance the hormonal system in particular when the exposure takes place in a critical stage of development.

3) More research is needed to identify safe alternatives to BPA

3.1 BPA used in food contact material

BPA is present in the protective coating on the inside of tin cans. The coating is applied to prevent the metal from corroding, thus protecting the tin from contamination by bacteria from the outside and thus protecting the consumer from food poisoning.

Since all products need to be safe, the existence of safer alternatives needs to be carefully investigated. BPA cannot be substituted by a single other substance since it is being used in several different applications with several functional requirements. Therefore, the functionality and safety of any replacement material needs to be carefully assessed. It is recommended to look at the product as a whole and not to limit the safety assessment to one or a few substances substituting BPA²⁰.

The US Food and Drug Administration (FDA) points out that:

“Because reliable can lining materials are a critical factor in ensuring the quality of heat processed liquid infant formula, safe replacement of such materials requires not only that they both be safe for food contact but also allow for processing that is fully functional in protecting the safety and quality of the infant formula itself”.²¹

The U.S. FDA points moreover out that cooperation with industry is necessary to identify alternative substances which could reduce exposure and that it is important that no harmful changes be made in food packaging or consumption, whether by industry or consumers, that could jeopardize either food safety or reduce access to and intake of food needed to provide good nutrition, particularly for infants²².

¹⁸ See Theo Colborn, Dianne Dumanoski and John Peter Myers (1996): Our stolen future. Are we threatening our fertility, intelligence, and survival? A scientific detective story, p.9.

¹⁹ Girl, disrupted. Hormone disruptors and women’s reproductive health, workshop paper, Commonwealth, California.

²⁰ Møller; Helweg, Christian; et al. (2004): Evaluation of Alternatives for Compounds under Risk Assessment in the EU, Bisphenol A, <http://www2.mst.dk/udgiv/publications/2004/87-7614-181-0/pdf/87-7614-182-9.pdf>.

²¹ Update on Bisphenol A for Use in Food Contact Applications; U.S. Food and Drug Administration, January 2010, <http://www.fda.gov/newsevents/publichealthfocus/ucm197739.htm>.

²² ibidem

Some alternatives to BPA for use in plastic bottles and food containers seem to be available. However, safety data are incomplete or missing. Moreover, some possible alternatives do not have the same performance and therefore cannot be used to replace BPA, e.g. for interior can linings because of their likelihood to deteriorate when coming in contact with food²³.

- In food contact material where BPA can be easily replaced with substances of lesser concern, this should be done immediately based on the precautionary principle.
- More research is needed to assess the safety of alternative materials. The safety assessment needs to take into account potential endocrine disrupting properties of alternatives and should be based on the whole product such as the food storage container, not the single substances which are used to replace BPA. The alternatives need to be safer and must provide for at least the same properties as BPA in order to ensure safe storage of food and protect it e.g., from contamination through corrosion.
- In the case of baby bottles, consumers could use glass bottles as alternatives. Moreover, some companies promote nursing bottles manufactured with polyethersulphone which are labeled as “BPA”-free.

3.2 BPA in cash receipts, toners and printing ink

BPA is used in toners and printing ink for office copiers, fax machines and printers. It is also contained in cash receipts which are printed on thermal paper. According to a study, holding a BPA containing cash receipt in hands for five seconds leaves roughly 1 µg BPA on the skin of the forefinger and the middle finger if the skin was dry and about ten times more when the fingers were wet or greasy²⁴. This may lead to problems for workers and consumers likewise. When touching the receipt and unpacked food such as vegetables thereafter, BPA may make its way into the food and be ingested.

In France, the retailer Carrefour announced in January 2011 to remove BPA from their cash receipts²⁵.

- Based on the precautionary principle Bisphenol A should be banned from printing ink based on safer alternatives.

4) Risk assessment methods need to include the cocktail effect

The effects of chemicals on humans and the environment are traditionally evaluated on the basis of single substances, chemical by chemical. Consequently, also the risk management measures are usually based on single substances leaving out the chemical cocktail effect. However, it is known that the combined effect of chemicals is greater and more toxic than the effect of single substances. It has to be stressed moreover that chemicals which are not harmful on their own may have harmful effects when combined with other substances which also do not have an effect on their own. This means zero plus zero plus zero does not equal zero.

²³ Ibidem.

²⁴ Sandra Biedermann, Patrik Tschudin and Koni Grob: Transfer of bisphenol A from thermal printer paper to the skin, *Analytical and Bioanalytical Chemistry*. Volume 398, Number 1, 571-576. Abstract: <http://www.springerlink.com/content/d5j507113141120h>

²⁵ See ChemicalWatch: Leading French retailer phases out BPA in till receipts, 31 January 2011, <http://chemicalwatch.com/6415/leading-french-retailer-phases-out-bpa-in-till-receipts>.

- As the current risk assessment and risk management approaches are inadequate they need to be updated to take into account the added effect of chemicals.

5) Conclusion: What should be done by policy makers?

An increasing number of scientific studies conclude that BPA is an endocrine disruptor which has a negative impact on humans and the environment. The negative health effects which are associated with BPA are related to the reproductive system (decreased fertility, early puberty, early menopause, and endometriosis) as well as (breast and prostate) cancer, cardiovascular diseases, obesity, diabetes, behavioral effects such as hyperactivity and negative effects on brain development.

As scientific studies also underline the low-dose effects of endocrine disrupting chemicals, action has to be taken based on the precautionary principle to reduce exposure. All measures need to consider the global exposure to BPA from all exposure routes and all sources. Moreover, preventive measures need to consider the added effect of different chemicals (the so-called cocktail effect).

Regulatory action is first and foremost needed at EU level to address bisphenol A in consumer products. Ambitious national measures such as in Denmark where BPA is banned in food contact material for food for children under the age of three show that action based on the precautionary principle is possible.

We recommend that Bisphenol A should be added to the candidate list under REACH as a Substance of Very High Concern (SVHC). This is a precondition for BPA to be regulated more strictly at a later stage.

To sum up, we call for:

- Banning BPA from products with which children come in direct and close contact.
- Phasing out BPA from all consumer products based on the condition that there are safer alternatives available. We need to make major progress within the next 2-3 years.
- Carrying out more research to drive forward innovations for safer alternatives.
- Carrying out more research to understand the complexity of the endocrine system and to investigate the negative health effects of endocrine disruptors including BPA.
- Changing current risk assessment models which only look at chemicals substance by substance ignoring the chemical cocktail effect to which consumers are exposed.
- Adding BPA to the Candidate List under REACH as a Substance of Very High Concern. Finally, BPA should be put on the authorisation list to ensure that producers have to ask for permission to use BPA.

End.