



SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion on the presence of Bisphenol A in clothing

Commission Department requesting the Opinion: Directorate-General Justice and Consumers, Consumers, Product safety and rapid Alert System

1. Background

Bisphenol A (BPA) or 2,2-bis(4-hydroxyphenyl)propane (CAS Number 80-05-7) is an organic compound consisting of two phenolic rings connected by a single carbon carrying two methyl groups. It is an industrial chemical, with a high production volume, widely used in the production of polycarbonate and epoxy resins and as an additive in polyvinyl chloride and thermal paper.

BPA can be found in a variety of common consumer goods, such as re-usable plastic tableware and bottles for drinks, sports equipment, CDs, and DVDs. It is also used in internal coatings of water pipes and cans for food and drink to increase the shelf life and maintain the organoleptic properties of the food and drinks. BPA is employed as a dye developer in thermal paper and common in shop sales receipts, and public transport and parking tickets.

BPA is classified as toxic for reproduction (category 1b) and as skin sensitiser (category 1). It can cause alterations in postnatal growth, reproductive organ development and function, and on behaviour. Recently, it has been suggested that it might also impair the development of the immune system. These effects seem derived from its chemical structure, which resembles that of oestrogen. BPA can interfere with the endocrine system, leading to effects on the female reproductive system, the mammary gland, the metabolism and obesity. Consequently, it is listed as substance with endocrine disrupting activity.

1.1. Previous scientific opinions and existing restrictions

Because of the hazard profile of Bisphenol A, different Scientific Committees have evaluated its toxicity in the past. The European Food Safety Authority (EFSA) has regularly issued and updated scientific opinions on BPA since 2006. In 2015¹, the panel defined a temporary Tolerable Daily Intake (t-TDI) of 4µg/kg bw per day and calculated the aggregated exposure based on diet, house dust, thermal paper and cosmetics. This value is temporary because there is uncertainty on the biological effects and the exposure levels through sources other than food. Furthermore, the results of an ongoing long-term

¹ Scientific Opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs. EFSA Journal 2015;13(1):3978. <http://www.efsa.europa.eu/en/efsajournal/pub/3978>.

toxicity study on BPA are also pending and might have an impact on the TDI calculation.

Various EFSA scientific opinions on BPA have led to the restriction of its use in the manufacture of different plastic food contact materials. The use of BPA in polycarbonate infant feeding bottles is prohibited since 1 March 2011². Since 6 September 2018³, its use in polycarbonate drinking bottles or cups for infants and young children is forbidden too. At the same time, its allowed migration from epoxy resins for varnishes and coatings for the interior of food cans has been limited to a maximum of 0,05 mg/kg.

Following the t-TDI defined in 2015 and the opinions of the subgroup “chemicals” of the Expert Group on Toys, the Commission has amended Appendix C to Annex II of the Toy Safety Directive (Directive 2009/48/EC). The new maximal migration value for BPA migration from toy material is reduced to 0,04 mg/l as of 26 November 2018⁴.

In parallel to the evaluation by EFSA, the Committee for Risk Assessment (RAC) and the Committee for Socio-Economic Analysis (SEAC) of the European Chemicals Agency (ECHA) evaluated a restriction dossier on BPA in thermal paper. Their opinion lead the Commission to amend the REACH regulation (Regulation (EC) No 1907/2006) by establishing a new entry in Annex XVII with a restriction on the use of BPA in thermal paper in concentrations equal or higher to 0,02% by weight as of 2January 2020⁵.

1.2. Presence in textile articles

There is no direct restriction on the use of BPA in textiles and its absence is only taken into consideration for the potential granting of the EU Ecolabel⁶ for textiles. This is because BPA is included in the REACH list of Substances of Very High Concern (SVHC) whilst EU Ecolabel is only awarded to textiles not containing more than 0,1 % in weight of SVHC⁷.

The use of BPA has historically only been reported in polycarbonate, epoxy resins and thermal paper. Exposure scenarios or toxicity evaluations therefore never included textiles and clothing as potential source of BPA.

² Commission Directive (EU) 2011/8 of 28 January 2011 amending Directive 2002/72/EC as regards the restriction of use of Bisphenol A in plastic infant feeding bottles

³ Commission Regulation (EU) 2018/213 of 12 February 2018 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials

⁴ Commission Directive (EU) 2017/898 of 24 May 2017 amending, for the purpose of adopting specific limit values for chemicals used in toys, Appendix C to Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards bisphenol A

⁵ Commission Regulation (EU) 2016/2235 of 12 December 2016 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards bisphenol A

⁶ Commission Decision (EU) 2014/350 of 5 June 2014 establishing the ecological criteria for the award of the EU Ecolabel for textile products (notified under document

⁷ Commission Decision (EU) 2017/1392 of 25 July 2017 amending Decision 2014/350/EU establishing the ecological criteria for the award of the EU Ecolabel for textile products

During the last two years, BPA has however been detected in clothing articles and some exposure studies were carried. In 2017 and 2018, two limited peer-reviewed articles identified BPA in infant socks⁸ and women's pantyhose⁹, on samples taken locally outside the European Union. Only recently, (April 2019) have the presence and endocrine disrupting activity of BPA being measured in samples of socks for infants and young children taken from the European market¹⁰.

These recent results are of concern as clothing articles are in direct and prolonged contact with the skin: This concern is strengthened, due to not only the high content levels of BPA measured and the estrogenic and anti-androgenic activities detected, but because young and vulnerable children usually put clothes in their mouth and suck it. The latter potentially increases exposure through ingestion and not only through dermal contact. Similarly, the risk on pregnant women is worrying due to the potential effect on the unborn child.

Furthermore, the study of Freire *et al.* also detected the presence of several parabens, which are suspected to have a potential endocrine disrupting activity and thus may contribute to further increase the effect of BPA alone.

Thereby and in the absence of any legislation regulating the presence of BPA in clothing articles intended for infants and young children, as well as, for pregnant women, it is critical to evaluate the potential risk derived from such presence.

1.3. Legal obligations

The presence of BPA's is regulated only under the following legal instruments, i) the Cosmetic Products, ii) the Plastic Food Contact Materials and iii) REACH Regulations, as well as, iv) the Toy safety Directive. None of these instruments defines restrictions for the presence or release of BPA in clothing or textile articles. Consequently, the safety and protection of the health of consumers against such a potential risk is covered by the General Product Safety Directive (GPSD, 2001/95/EC).

Under article 13, paragraph 1 of the GPSD the Commission is entitled to request the Member States to take measures against a product for which the Commission becomes aware that it poses a serious risk to the health and safety of consumers. To do, the Commission has to consult the Member States as well as the competent Community Scientific Committee. Such an opinion would additionally support the Commission in developing potential preventive measures ensuring the protection EU consumers.

2. Terms of reference

The Scientific Committee on Consumer Safety is kindly requested to provide a scientific opinion on "The safety of the presence of BPA in clothing articles". The main purpose of the

⁸ Xue, J., Liu, W., Kannan, K., 2017. Bisphenols, benzophenones, and bisphenol A diglycidyl ethers in textiles and infant clothing. *Environ. Sci. Technol.* 51 (9), 5279–5286. PMID: 28368574. <https://doi.org/10.1021/acs.est.7b00701>.

⁹ Li, A.J., Kannan, K., 2018. Elevated concentrations of bisphenols, benzophenones, and antimicrobials in pantyhose collected from six countries. *Environ. Sci. Technol.* 52, 10812–10819. PMID: 30137966. <https://doi.org/10.1021/acs.est.8b03129>.

¹⁰ Freire, C., Molina-Molina, J.M., Iribarne-Durán L.M., Jiménez-Díaz, I., Vela-Soria, F., Mustieles V., Arrebola, J.P., Fernández, M.F., Artacho-Cordón, F., Olea, N. Concentrations of bisphenol A and parabens in socks for infants and young children in Spain and their hormone-like activities. *Environ Int.* 127, 592–600. PMID: 30986741. <https://doi.org/10.1016/j.envint.2019.04.013>.

scientific opinion is to provide scientific support to assist the Commission in assessing the risk of the presence of BPA in clothing articles and the potential need for legislative amendments in the chemicals legislation and/or enforcement measures under the General Product Safety Directive.

In particular, the SCCS is asked to:

1. To review the available data on the presence and activity of Bisphenol A in clothing articles, taking into consideration the adopted opinions on tolerable intake limits and the legislative framework in other products (food contact materials, toys and printed paper)
2. To determine whether the exposure levels to BPA due to the use of clothing articles raises health concerns for consumers and, if possible, to provide indications on limit values for BPA content/release from clothing articles
3. To identify whether vulnerable consumers such as infants and young children (who might put such articles in their mouth) or pregnant women are in particular risk. On the basis of the risk assessment, could it be indicated what level of exposure to BPA from textiles can be accepted in such groups.

3. Timeline

Preliminary opinion – tentatively March 2020

Final opinion – tentatively summer (September) 2020

The SCCS approved this mandate during Plenary meeting on 30-31 October 2019.