Position paper

4th October 2023

Bisphenol A in food is a health risk: a possible contamination via micro- and nanoplastic in soil and irrigation water

The latest European Food Safety Authority (EFSA) re-evaluation on bisphenol A identifies it as a health concern for consumers across all age groups, with the potential to have harmful effects on the immune system. As a consequence, EFSA has lowered the tolerable daily intake (TDI) for BPA to 0.2 nanograms (0.2 billionths of a gram) per kilogram of body weight per day, replacing the previous temporary level of 4 micrograms (4 millionths of a gram) per kilogram of body weight per day. While this is a step forward in protecting consumers and the environment from dangerous chemicals, this is not enough.

In reaction to EFSA's new opinion, SAFE welcomed the long-awaited recognition of bisphenol A as a health concern, but also expressed disappointment over the lack of a stricter approach:

> **Floriana Cimmarusti**, founder of SAFE, said: "Over the years multiple *studies have demonstrated the negative health effects of exposure to bisphenol A. EFSA's new opinion is welcomed but is not enough, and it comes late. Several Member States have introduced bans on bisphenol A in food packaging for years now; ECHA already identified bisphenol A as an endocrine disruptor in 2017. Only in 2023 we are getting the recognition by the European Food Authority of bisphenol A as a health risk".*

SAFE will continue advocating to phase out bisphenol A from all consumer products as soon as possible, as well as banning the chemical from products with which children come in direct and close contact.

Background

Bisphenol A (BPA) is a chemical substance used in the manufacture of certain plastics, including food contact materials. It is used in polycarbonate plastic, a transparent and rigid type of plastic used to make food storage containers and reusable beverage bottles. BPA is also used to produce epoxy resins found in protective coatings and linings inside metal food and beverage cans, and on metal lids for glass jars and bottles.

BPA in foodstuff containers can migrate into food and drinks they contain, resulting in exposure of BPA for consumers[1]. Moreover, BPA can also contaminate water through the release of micro- and nano-plastics, leading to a consequent contamination of soil.

Over the years, scientific evidence has grown linking the exposure of BPA to adverse health effects and negative effects on the environment. The danger of BPA was first noticed with animal studies. In rats prenatally exposed to BPA, scientists have observed an increase in estrogen feedback as well as

[1] https://echa.europa.eu/it/registry-of-restriction-intentions/-/dislist/details/0b0236e1853413ea

development of precocious puberty via inhibition of tyrosine hydroxylase activity in rostral preoptic periventricular neurons[2].

Today, many epidemiological studies correlate BPA measurements in urine and blood with observed differences in fertility, brain development, metabolism, cardiovascular function, and other conditions.[3] Scientific studies also identify BPA as an endocrine disruptor (ED). Endocrine disruptors are substances that interfere with humans' hormonal 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 of these conclude that even small amounts of BPA may have a negative impact on the brain development of babies.[4]

Environmental Contamination by BPA

One of the major sources of contamination of food is water. Animals drink water, plants use it for photosynthesis and their life cycle. The presence of BPA in water in surface and deep-water bodies has not yet been assessed at the European level, because the obligation to analyse its presence has only been in force since 2021 and there have been delays in setting up monitoring plans in the Member States and the choice of analysis methods.

One of the routes by which BPA contaminates water[5] is through the release of micro- and nano-plastics. These small particles are also present in the air and can be transported for thousands of kilometres.[6]

Micro and nano plastics are also present in agricultural soils (many plastics are in fact used in agriculture) and can be absorbed by plants or leached into surface and groundwater.

Between November 2021 and December 2022, analyses were conducted in the Italian Alpine region of South Tyrol on the presence of microplastics in the main rivers and in some high-altitude streams. The presence of microplastics was found in all monitored rivers and streams, although the overall concentration was not high and was comparable with similar river environments in Italy or Europe, while

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[2] Rubin, BS., Lenkowski, JR., Schaeberle, CM., Vandenberg, LN., Ronsheim, PM., Soto, AM. *Evidence of altered brain sexual differentiation in mice exposed perinatally to low, environmentally relevant levels of bisphenol A*. Endocrinology, 147 (2006): 3681–3691

[3] A. Martínez-Ibarra, L.D. Martínez-Razo, K. MacDonald-Ramos, M. Morales-Pacheco, E.R. Vázquez-Martínez, M. López-López, M. Rodríguez Dorantes, M. Cerbón. *Multisystemic alterations in humans induced by bisphenol A and phthalates: Experimental, epidemiological and clinical studies reveal the need to change health policies*, Environmental Pollution, 271 (2021)

[4]Julia Barrett, Shelby Gonzalez, Heather Sarantis, Julia Varshavsky, *Girl, disrupted. Hormone disruptors and women's reproductive health*, workshop paper, Commonweal, California (2009).

[5] Dehaut, A.; Cassone, A.L.; Frère, L.; Hermabessiere, L.; Himber, C.; Rinnert, E.; Rivière, G.; Lambert, C.; Soudant, P.; Huvet, A.; et al. Microplastic in sea food: Benchmark protocol for their characterization. Environ. Poll. **2016**, 215, 223–233. [CrossRef] [PubMed]

[6] Enyoh, C.; Verla, A.; Verla, E.; Ibe, F.; Amaobi, C. Airborne microplastics: A review study on method for analysis, occurrence, movement and risks. Environ. Monit. Assess. **2019**, 191. [CrossRef]

it was lower than the concentrations found in large rivers. This shows that microplastics can also be found in sparsely populated and non-industrialised areas such as the Alpine regions of the EU.

BPA accumulates in the soil, where interaction phenomena also take place, especially in soils rich in iron, cadmium and lead, and many studies have pointed out that BPA dispersed in the environment (water and soil) is biodegraded by a wide variety of bacterial strains, and in timescales ranging from 12 to 20 days its dangerousness is high.

The passage and accumulation of BPA in plants through the soil has been repeatedly demonstrated in the literature.

Plant roots are vital organs, formed after a long adaptation to the conditions of the soil in which the plant is grown. They allow water and nutrients to be absorbed by the plant and are, therefore, in direct contact with the BPA that may be present in the soil. In a study by Hai et al. (2013), the growth of some soybean plants in BPA-contaminated soil was studied. By analysing the length, surface area, volume and weight (wet and dry) of the root, their growth status could be determined, showing the effect of BPA on the root growth of soybean seedlings. When these are treated with low concentrations of BPA (1.5 mg/l), root growth is improved; when the concentration is increased (17.2 - 50 64 mg/l), growth is inhibited. Furthermore, in the same study, it was shown that the effects of BPA on root growth caused a nutritional change relative to the amount of nitrogen intake (Hai et al., 2013).

In a study by Lu et al.(2014)[7], the distribution and uptake of BPA in some food crops, lettuce (Lactuca Sativa) and tomato (Lyco-persicon esculentum), were analysed. The contaminant was diluted in irrigation water with a concentration of 50 µg/l by reference to the concentrations present in reclaimed water in the environment, which is often used in agriculture due to the lack of clean water. In this experiment, two possible exposure scenarios were analysed, that of the leaves and that of the roots. The results show not only the importance of the route of exposure, but also the more or less equal distribution of the contaminant in the edible parts of the plant, especially if the exposure occurred through contact with the leaves, e.g. through irrigation.

Dodgen et al. (2013)[8] analysed the uptake and accumulation of BPA and other emerging pollutants from pharmaceutical and personal care products (PPCPs) in lettuce (Lactuca Sativa) and cabbage (Brassica oleracea) plants in a hydroponic environment. The accumulation of these compounds, in particular BPA, in food cultures, in the present case leafy vegetables, is relevant for the possibility of unintentional human exposure. In the study, the nutrient solution was contaminated with 46.4 ng/l BPA and was found 21 days after planting. A significant accumulation of BPA within the plant under consideration, especially in the roots, was deduced from the study.

[7] Lu, J., Wu, J., Stoffella, P. J., & C., W. P. (2014). Uptake and distribution of bisphenol A and nonylphenol in vegetablecrops irrigated with reclaimed water. Journal of Hazardous Materials, 283 (2015) 865–870

[8] Dodgen, L., Li, J., Parker, D., & Gan, J. (2013). Uptake and accumulation of four PPCP/EDCs in two leafy vegetables. Environmental Pollution, 150-156.

European Union action

At EU level, the use of BPA is currently authorized in the production of plastic food contact materials (FCMs) under Regulation (EU) No 10/2011, amended by Regulation (EU) 2018/213. It establishes migration limits for plastic materials intended to come into contact with food, as well as limits for materials specifically intended to come into contact with foods for infants and young children (infant formula, processed cereal-based food, baby food or milk-based drinks and similar products specifically intended for young children). BPA is only banned in polycarbonate infant feeding bottles (Regulation (EU) No 321/2011).

After four times updating its scientific advice between 2006 and 2011, EFSA completed a full re-evaluation of BPA in 2015. It concluded that there is no health concern for BPA at the estimated levels of dietary exposure. However, considering other possible sources of exposure, EFSA established a new temporary TDI of 4 micrograms (4 millionths of a gram) per kilogram of body weight per day.

In 2017, the European Chemicals Agency (ECHA) identified BPA as a substance of very high concern (SVHC) due to its endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health. Consequently, BPA has been added to the Candidate List under REACH.

In October 2022, Germany submitted a proposal to ECHA to restrict the placing on the market of mixtures and articles containing bisphenol A, other bisphenols, and bisphenol derivatives with endocrine-disrupting properties for the environment. This is to avoid regrettable substitution of BPA with other bisphenols of concern, including derivatives (i.e. those that exhibit similar concern for the environment based on their structural similarity and hazardous properties for the environment). ECHA is currently assessing this proposal and will make a decision later this year (as a tentative timeline).

In 2018, EFSA started evaluating BPA in light of recent toxicological data. This work has materialized in the new re-evaluation of BPA published last week, where the agency has identified BPA as a health concern for consumers across all age groups. As a consequence, the TDI has been lowered to now 2 nanograms (0.2 billionths of a gram) per kilogram of body weight per day. Nonetheless, a stricter approach needs to be taken to properly protect EU citizens across the EU.

SAFE urges the European Commission to take a stricter approach and phase out BPA from all consumer products to properly ensure the safety of European citizens' food and health across the EU.

Policy asks

SAFE has continuously advocated to phase out BPA from consumer products as soon as possible, as well as banning BPA from products with which children come in direct and close contact. In light of the new EFSA opinion, we would like to highlight the following elements that should be taken into account by the European Commission when assessing next steps.

Harmonised protection to all EU consumers

For some years now, some Member States have already introduced restrictions on the use of BPA. Denmark and Belgium have banned BPA in FCMs for infants and young children. Sweden has banned BPA in coatings and varnishes in FCMs intended for infants and young children. France banned baby bottles

made with BPA and even went further by introducing, in January 2015, a law banning the use of BPA in all food packaging.

Differences between national laws pose threats to European consumers, as they are not receiving the same protection. SAFE calls for harmonized EU rules phasing out BPA from all consumer products placed in the EU market, as well as banning BPA in all food contact materials intended for infants and young children.

Better coordination between REACH and FCMs legislation on endocrine disruptors

Currently, EU requires that FCMs must not transfer their chemical components into food in quantities that might endanger human health.[9] However, this provision fails to properly protect consumers.

Among the FCMs, plastic packaging is associated with more than 4.000 different chemicals, including at least 148 substances which represent a high risk for human health and the environment. In addition, plastic packaging may contain non-intentionally added substances (NIAS) arising from impurities, products' degradation and from various contaminants, most of which are simply not known.[10]

As mentioned above, in 2017 ECHA identified BPA as a substance of very high concern due to its endocrine-disrupting properties causing adverse effects on human health, particularly damaging damage and disrupting the hormonal systems of both people and animals. BPA has therefore been added to the Candidate List of substances of very high concern under the REACH legislation. As a consequence, companies manufacturing or importing articles containing these substances in a concentration above 0,1% weight of the article, have legal obligations – they are required to inform consumers about the presence of the substance and how to use it safely.

The Commission should ensure better coordination between REACH and FCMs legislations to guarantee that harmful substances phased out under REACH are also phased out in FCMs. Consequently, it is crucial that the two agencies involved in assessing chemicals under both laws, ECHA and EFSA, strengthen their cooperation to ensure consumers' maximum protection against harmful and dangerous chemicals.

EU chemicals legislation 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.[11] It must 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.

[9] Article 3(1) of Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food, OJ L 337, 13.11.2004, p.4-17

[10] Food Packaging Forum, *Plastic packaging contains thousands of chemicals, including hundreds of hazardous substances,* (2018)

[11] CHEM Trust, *Chemicals cocktail: the neglected threat of toxic mixtures and how to fix it,* (2022)

SAFE calls for the incorporation of a Mixture Assessment Factor (MAF) to be incorporated in all EU chemical regulations – risk assessment and risk management approaches need to adequately be updated to take into account the added effect of chemicals.

Proper protection from environmental contamination by BPA.

As explained above, one way in which BPA is easily transmitted into food is through its release from micro- and nano-particles in irrigation water and soil. Particularly in soil, certain bacterial strains present there are known to degrade microplastics, favouring the release of BPA and its derivatives.

The assessment of transmission through this route has not yet been undertaken and poses a risk to human health. SAFE therefore calls on the Commission to take immediate action to:

- ✓ Obtain data from Member States on micro- and nano-plastic contamination of irrigation water;
- ✓ Pursuant to Article 115 of Reg. (EU) 625/2017 and in application of the general plan for crisis management referred to in Article 55(1) of Regulation (EC) No 178/2002, ask Member States to set up contingency plans to determine the contamination in food of BPA in particular for fruit and vegetables;
- ✓ Ask EFSA for a risk assessment of environmental contamination of food and feed by BPA.

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