Human exposure to Bisphenol A in Europe

Bisphenol A (BPA) is a synthetic chemical that has been used in high volumes for decades and is known to harm human health. People are exposed to BPA mainly through diet due to BPA being present in a range of materials commonly used in packaging for food and beverages. This briefing presents the latest information on human exposure to BPA in Europe. It also highlights potential health risks resulting from people being exposed to unsafe levels of BPA.

Key messages

BPA is used widely around the world. As a result, people are continuously exposed to BPA as it is released from food containers and other everyday products.

BPA can harm human health due to its properties as an endocrine disruptor that can alter how the hormone system functions. It can damage the reproductive system and negatively affect the immune system.

A recent Horizon 2020 research initiative, HBM4EU, measured chemicals in people's bodies in Europe and detected BPA in the urine of 92% of adult participants from 11 European countries.

The levels of BPA measured in people's urine also exceed recently revised European safety thresholds, which raises long-term health concerns for everyone.

What is Bisphenol A and how is it used?

Bisphenol A (BPA) is a synthetic chemical used in very high volumes in the EU, with more than one million tonnes manufactured in or imported to the EU per year according to registrations under the Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (ECHA, 2023a).

BPA is mainly used in the industrial manufacturing of polymers such as polycarbonate plastics and epoxy resins, and trace levels of BPA remain in the final materials (ECHA, 2023b; HBM4EU, 2022a). These materials are used across a range of consumer products, including food packaging. For example, polycarbonates are used in reusable plastic bottles, feeding bottles and storage containers. Epoxy resins are used to coat food and beverage cans, as well as to coat the inside of pipes used to deliver drinking water (EFSA, 2023a; Geens et al., 2012; Lehmler et al., 2018).

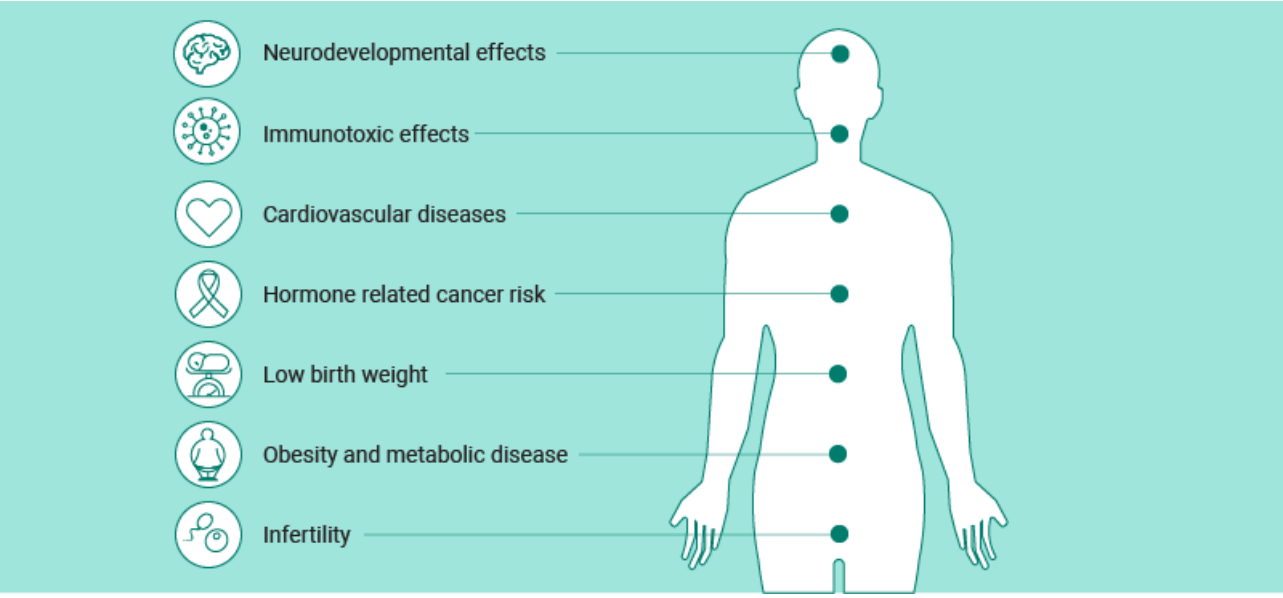
In addition, BPA is used in a wide range of other products. These include thermal paper, inks, textiles, paints and adhesives, electronic equipment, building materials such as flooring, toys, CDs, car body coatings, medical devices and dental sealants (Govarts et al, 2023).

How does Bisphenol A harm health?

BPA is classified as a hazardous chemical in the EU due to its ability to damage fertility, and cause serious eye damage, allergic skin reactions and respiratory irritation. In addition, BPA is an endocrine disruptor that can disrupt the normal functioning of the hormone system. It can affect reproductive function, mammary gland development, cognitive function and metabolism (ECHA, 2017).

Figure 1 shows an overview of some of the health effects that can result from exposure to BPA above safe levels.

Figure 1. How Bisphenol A affects your health



Source: HBM4EU (HBM4EU, 2022b).

The tolerable daily intake (TDI) threshold was recently updated by the European Food Safety Authority (EFSA) based on evidence that BPA affects the immune system. In studies using mice, effects were observed on cells that are 'critical in cellular immune mechanisms and are involved in the development of inflammatory conditions, including autoimmunity and lung inflammation' (EFSA, 2023a). These effects occur at very low doses, which led EFSA to drastically reduce the TDI compared to a temporary TDI that had been established in a 2015 assessment (see Box 1). In addition, EFSA notes that effects linked to reproductive, developmental and metabolic toxicity can occur in similar dose ranges.

Human exposure to Bisphenol A in Europe

Due to its widespread use, the vast majority, if not all, of Europeans are exposed to BPA (Covaci et al., 2015; Geens et al., 2012; Vicente et al., 2022). The main exposure pathways for bisphenols are shown in Figure 2.

The most important exposure route for most people is through diet (Geens et al., 2012). Very small amounts of residual BPA can migrate from food contact materials into food and beverages, resulting in human exposure through ingestion. In addition, epoxy resins are used to line drinking water pipes; as a result, BPA may migrate into drinking water. Exposure may also occur from a wide range of other routes, such as certain dental sealants and medical devices, and from contact with consumer

products made from polycarbonate plastic.

Box 1. Guidance on risk from dietary exposure

EFSA is responsible for providing scientific advice to EU decision makers on the safety of food packaging and other food contact materials. To protect the public from the risks of chemical contaminants in food, **tolerable daily intakes** (TDIs) are established to reflect the amount of a substance that can be taken daily over a lifetime without significant health risk. Risk management measures should then be designed to ensure that human daily exposure to any one contaminant via diet remains below that level.

Given the use of BPA in materials that come into contact with food and drinks, EFSA is the EU agency responsible for reviewing the safety of dietary exposure to BPA. In April 2023, EFSA published its latest scientific opinion re-evaluating the risks to public health due to exposure to BPA. In a previous risk assessment from 2015, the TDI was made temporary due to data gaps and uncertainties in the evidence base, which EFSA committed to reassess when new data became available. The re-evaluation of BPA's safety considered new scientific evidence and derived a TDI of 0.2 nanograms per kilogram of body weight per day. This replaces the previous temporary TDI of 4 micrograms per kilogram of body weight per day, which had been derived by EFSA eight years earlier (EFSA, 2023b). The new TDI is thus 20,000 times lower than the former value established in 2015 — a very significant change.

Instead of performing a new exposure assessment, EFSA compared the updated TDI to estimates of human exposure to BPA from their previous 2015 assessment. They concluded that 'consumers with both average and high exposure to BPA in all age groups exceeded the new TDI, indicating health concerns' (EFSA, 2023b). Both the mean and the worst case (95^{th} percentile) dietary exposures are hundreds or thousands of times higher

than the TDI.

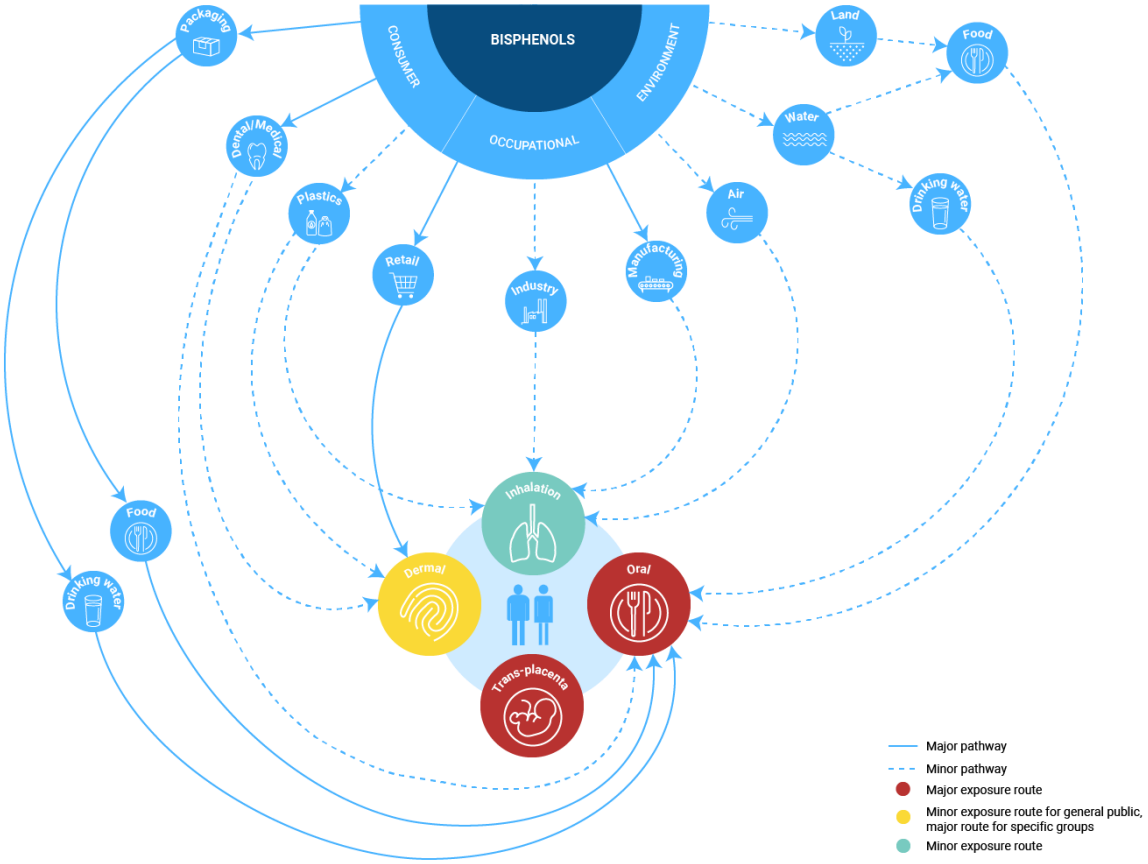
EFSA's 2015 exposure assessment drew on a range of information to model the exposure of different age groups to BPA, capturing how both dietary and non-dietary sources contribute to exposure. Canned food was identified as the most important exposure source for all age groups. Thermal paper was the second largest source of external exposure in all age groups above three years of age (EFSA, 2015).

The 2015 exposure assessment for BPA may no longer accurately represent current exposure: dietary intake may have since been reduced following newer restrictions on some BPA uses, in place in the EU since 2015. However, given the large exceedance of the TDI, EFSA concluded that there is a current health concern from dietary BPA exposure, even considering the uncertainties in the exposure assessment (EFSA, 2023a).

Some workers may be more exposed to BPA than the general public (Bousoumah et al., 2021). As an example, BPA was previously used in thermal receipt papers; as a result, cashiers were highly exposed to BPA via skin contact due to frequently handling receipts (Björnsdotter et al., 2017). A restriction introduced under REACH banned the use of BPA in thermal paper in 2020.

BPA degrades rapidly in surface water. However, degradation may be slow under certain environmental conditions. Furthermore, BPA is not considered to be highly bioaccumulative in living organisms (JRC, 2022). Therefore, the environment including via water, air or food (via contaminated soil rather than food contact materials) is not considered a major exposure route. However, people may be exposed to BPA indoors due to BPA leaching out of polycarbonate plastic products and contaminated dust.

Figure 2. Overview of exposure sources and routes for bisphenols



Source: HBM4EU (HBM4EU, 2022c)

Box 2. European human biomonitoring initiative — HBM4EU

Human biomonitoring is a tool for identifying and measuring chemicals in the human body by testing samples of blood, urine and/or hair. The purpose is to understand what chemicals are in the human body, at what levels and how they might impact health. Human biomonitoring measures total internal exposure from multiple exposure pathways that are regulated under distinct legislative silos. The European human biomonitoring initiative, HBM4EU, was conducted from January 2017 until June 2022 under Horizon 2020. It generated Europe-wide, harmonised human biomonitoring data on the occurrence of chemicals in the European population and associated impacts on health. Bisphenol A and two other bisphenols used as substitutes for BPA (bisphenol S and bisphenol F) were measured in urine from 2,756 adults from across 11 countries, namely Croatia, Czechia, Denmark, France, Finland, Germany, Iceland, Luxembourg, Poland, Portugal and Switzerland, representing north, east, south and west Europe. The urine samples were collected between 2014 and 2020. HBM4EU results on bisphenols are summarised in a HBM4EU policy brief.

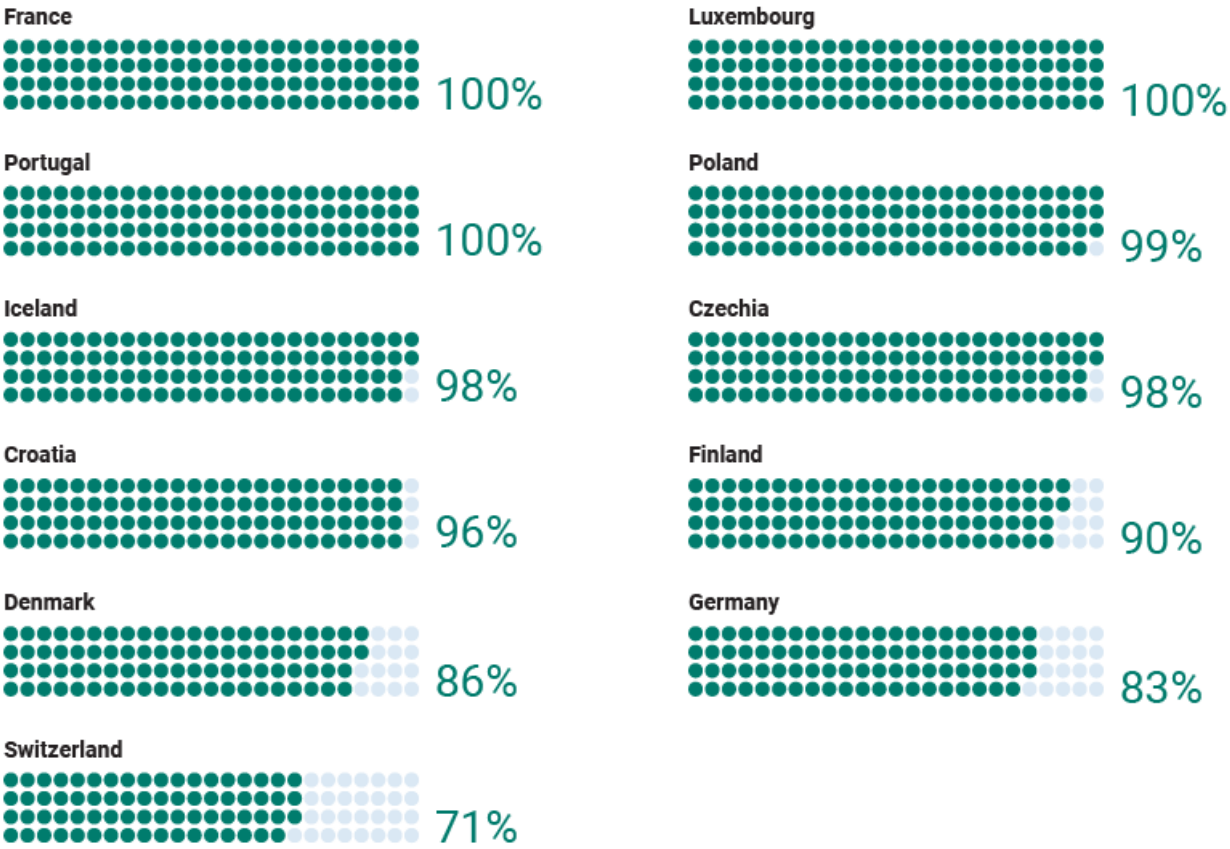
In a recent human biomonitoring initiative, HBM4EU, BPA was detected in 92% of adult participants from across 11 European countries (Govarts et al, 2023).

To assess whether the BPA levels measured in the urine of European residents are of concern, it was first necessary to establish a human biomonitoring guidance value (HBM-GV). An HBM-GV is an established concentration in a human biological matrix (in this case, urine) below which adverse human health effects are not expected. For the analysis presented in this briefing, the new TDI for BPA set by EFSA has been translated into an HBM-GV using a methodology established under HBM4EU (Apel et al., 2020). The calculations were performed using the same methodology and assumptions used to derive an HBM-GV for BPA from the previous temporary TDI from EFSA (Ougier et al., 2021). The new EFSA TDI of 0.2 ng/kg bw/day translates into an HBM-GV of 11.5 ng/L

of total urinary BPA for adults. This can be used to assess whether current levels of exposure to BPA give rise to a potential public health concern in the European population.

When comparing the HBM-GV for BPA against internal exposure data collected under HBM4EU, 92% of the sample population showed levels of BPA in urine that exceeded 11.5 ng/L of total urinary BPA. In the 11 individual countries that participated in the biomonitoring initiative for BPA, the level of exceedance varied between 71% and 100% (Figure 3). Population exposure to BPA in Europe is therefore too high and constitutes a potential health concern. It should be noted that the limit of quantification of the analytical methods used to monitor BPA in human urine is above the HBM-GV. This means that the reported exceedances are minimum numbers; the probability exists that actually, all 11 countries have exceedance rates of 100% exposed above safe levels.

Figure 3. Share of adults in 11 European countries with BPA levels in urine exceeding the HBM-GV, 2014 to 2020



Source: Based on human biomonitoring data from the HBM4EU Dashboard (HBM4EU, 2022d)

The HBM4EU human biomonitoring data support EFSA's conclusion that there is a health concern for EU residents from exposure to BPA (EFSA, 2023). Human biomonitoring provides actual measurements of total internal exposure resulting from multiple sources of exposure. The biomonitoring data on BPA levels in human urine show that exposure is still too high, despite the different regulatory measures that have been introduced since 2015.

Box 3. Bisphenols and regrettable substitution

As concerns about the health impacts of BPA emerged, alternative chemicals bisphenol S (BPS) and bisphenol F (BPF) have been used as substitutes. BPS has many of the same uses as BPA (e.g. plastics, food contact materials and thermal paper). It is now replacing BPA in thermal papers across Europe (ECHA, 2020) and it is authorised for use as a food contact material in the EU (EU, 2011a). According to Pivenko et al. (2018), paper materials in Europe are estimated to contain 200 tonnes of BPS.

Under HBM4EU, the substitutes BPS and BPF were detected in urine from 67% and 62% of adult participants, respectively, from 10 different European countries (HBM4EU, 2022a). Regarding BPS, exposure levels varied significantly by country, with between 0.5% and 19.2% of the national sample populations exceeding the health-based human biomonitoring guidance value established under HBM4EU (Ougier et al., 2021; EEA, 2022). BPS levels were higher throughout 2014 to 2021 compared to levels detected from 2010 to 2012, reflecting this substance's increased use (which is of concern, given the known associated health risks) (HBM4EU, 2022b). In 2022, BPS was included on the REACH Candidate List as a substance of very high concern due to its endocrine disrupting and reproductive toxic properties (ECHA, 2022a). According to the Member State Committee established under the European Chemicals Agency (ECHA), BPF fulfils the WHO criteria as an endocrine disruptor in the environment (UBA, 2023). However, although BPF is also suspected of having endocrine disrupting properties in humans, it has not yet officially been identified as an endocrine disruptor in humans at the EU level. This shows the importance of evaluating and regulating bisphenols as a group rather than as individual substances to avoid regrettable substitutions. Such a group assessment has recently been conducted by ECHA and Member State authorities. They recommended that more than 30

bisphenols need to be restricted due to their potential endocrine disrupting or reprotoxic effects (ECHA 2022b).

Measures to protect people from harmful exposure to bisphenols

A number of regulatory measures have been put in place at the EU level to reduce people's exposure to BPA in particular and bisphenols in general. Bisphenol A was identified as a substance of very high concern (SVHC) under the REACH Regulation in 2016 (due to its reprotoxic properties) and in 2017 (due to its endocrine disrupting properties in humans and the environment). Table 1 gives an overview of the different measures that have been introduced in the EU.

Table 1. Regulatory measures to limit exposure to bisphenols in the EU

Year	Measure	Reference
2011	Ban in plastic infant feeding bottles.	EU, 2011b
2016	Harmonised classification of BPA as a reproductive toxicant cat. 1B, which imposed a number of restrictions for use in chemical mixtures intended for consumers.	EU, 2016a
2018	Restriction on the amount of BPA (0.04 mg/l) that is allowed to leach out of toys for children under three years of age, and in any toys that are intended to be placed in a child's mouth.	EU, 2018a
2018	Ban in plastic bottles and coated packaging containing food for babies and children under three years of age.	EU, 2018b
2018	Reduction of migration limit of BPA in plastic food contact materials to 0.05 mg/kg food and application to coated FCMs.	EU, 2018b
2020	Restriction for use in thermal (printing) paper under REACH.	EU, 2016b

Proposals for additional regulatory measures to further restrict the uses of and limit exposure to BPA and other bisphenols are under consideration in the EU. Under the REACH Regulation, a new proposal has been submitted by the German authorities to restrict the use of BPA and other bisphenols (BPB, BPS, BPF and BPAF) with endocrine-disrupting properties for the environment. The proposal is to restrict placing mixtures and articles on the market if their concentration is equal to or greater than 10 ppm (0.001% by weight) (ECHA, 2022c). The restriction proposal was submitted to ECHA in October 2022. However, following the public consultation the German Federal Institute for Occupational Safety and Health announced, that the proposal would temporarily be withdrawn due to the need for a revision of the dossier (BAuA, 2023). Although the purpose of this restriction proposal is to protect the environment from harmful exposure to endocrine disrupting bisphenols, it will also result in reduced exposure to humans if adopted.

In addition, authorities from France and Sweden submitted a proposal under REACH to restrict over 1,000 skin-sensitising chemicals in clothing, footwear and other articles with similar skin contact. The proposal was evaluated by ECHA's scientific committees in 2020 (ECHA, 2023c). Bisphenols that have been classified as skin sensitisers would be covered under this restriction if adopted by the Commission in its current form.

Finally, the European Commission recently published their intention to propose a ban on the intentional use of BPA to manufacture food contact materials such as plastics or coatings (EU, 2023a; EU, 2023b).

Uncertainties and reflections

Publications

Bisphenol A is undoubtedly one of the best-studied industrial chemicals in the world. Thousands of scientific publications and numerous regulatory assessments deal with its health and environmental impacts. For the last two decades it has also been one of the most controversial substances, giving rise to frequent discussions and divergences in opinions between experts. The 2023 opinion from EFSA revising the TDI for BPA is no exception. Simultaneously with its publication, two joint reports were published in which the European Medicines Agency (EMA) and the German Federal Institute for Risk Assessment (BfR) expressed divergent scientific opinions regarding how the TDI value was derived for BPA (EMA, 2023) (BfR, 2023). However, the EFSA assessment has also received support; for example, a number of scientists have agreed with the methodology applied by EFSA. In particular, they supported the inclusion of academic studies and the use of an intermediate endpoint (effects on cells that are linked to the development of immune-dependent allergies such as asthma) to derive the TDI (Zoeller et al., 2023).

The HBM-GV for BPA in urine was originally derived under the EU-funded project HBM4EU, based on the previous temporary TDI from EFSA. It was updated for the first time in this briefing to reflect the new TDI in the 2023 EFSA opinion. How these values were derived and the methodology used have been discussed between the different countries in the HBM4EU project with the purpose of harmonising the approach (Apel, 2020). However, the HBM-GVs and the methodology have not been officially adopted at EU level and the HBM-GV for BPA is therefore not an official regulatory limit value. Yet it is the best currently-available measure for assessing the health risks associated with urinary concentrations of BPA.

Unlike many other chemical pollutants of concern, BPA does not persist in the environment or bioaccumulate in living organisms to a significant extent. Therefore, the major exposure pathway for most people is consumer exposure to products containing BPA, and not via the environment. This also means that regulatory measures to limit the use of BPA should bring down human exposure relatively quickly. This is especially true with regards to exposure from disposable food contact materials and other products with a short lifecycle. Other types of products containing BPA have a longer lifecycle, and for these products, the effect of regulatory measures in reducing human exposure will be slower. This includes non-disposable food contact materials, consumer products made of polycarbonate, PVC products where BPA has been used as an additive and epoxy linings in drinking water networks.

The urine samples under HBM4EU were collected between 2014 to 2020. Whilst the newest samples from 2020 still exceed the HBM guidance value, it appears that there is a trend towards a decrease in urinary BPA levels and a slight increase for bisphenol S. At present, however, the data are insufficient to draw a conclusion from with certainty. The new EU Horizon Europe partnership for the assessment of risk from chemicals (PARC) has included bisphenols as priority substances to be further examined in human biomonitoring studies in children, teenagers and adults. This will provide further data in the coming years on the occurrence of BPA and other bisphenols in Europeans. As a result, it will enable researchers and authorities to measure the efficiency of existing and future regulatory measures on BPA.

Publications

Despite two decades of significant focus from national and EU authorities and the introduction of numerous regulatory measures, biomonitoring data show that exposure to BPA is still far too high and constitutes a potential health concern. This underlines the importance of better protecting Europeans from exposure to harmful chemicals. A number of important new actions are underway as described in the European Commission's **Chemicals Strategy** and **Zero Pollution Action Plan**. For BPA itself, the European Commission has expressed its intention to propose a ban on the use of BPA and other bisphenols in food contact materials. This proposal is expected to be ready by the first quarter of 2024 (EU, 2023a).

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