Bisphenol A in Everyday Products: Answers to Frequently Asked Questions

BfR FAQ of 16 December 2021

The plastic polycarbonate, which is used in house and vehicle construction, in consumer products such as DVDs and smartphones, as well as in food packaging and bottles, is made from the substance bisphenol A. Bisphenol A is also used in the production of internal coatings for beverage and food cans. Until the ban at the beginning of 2020, bisphenol A was also used in thermal papers.

In July 2016, bisphenol A was classified as toxic to reproduction by the European Chemicals Agency and, based on this classification, was identified in January 2017 as a Substance of Very High Concern (SVHC) according to the REACH Regulation. The REACH Regulation is the currently valid European chemicals law. “REACH” stands for registration, evaluation, authorisation and restriction of chemicals.

In June 2017, the substance was again identified as an SVHC due to its properties as a so-called endocrine disruptor for human health, and in 2018, it was identified as SVHC for being an endocrine disruptor for the environment. Endocrine disruptors are substances that can cause damage by acting similar to hormones.

The European Food Safety Authority (EFSA) has reassessed possible health risks associated with the use of bisphenol A and published the result in December 2021. The tolerable daily intake (TDI) of bisphenol A newly derived by EFSA is 0.04 nanograms per kilogram of bodyweight per day. The TDI value indicates the amount of a substance that can be taken up daily over an entire lifetime without any noticeable health risk. The new value is around 100,000 times lower than the provisional (temporary) health-based guidance value previously given by EFSA. For people of all ages, the intake of bisphenol A from food and other sources exceeds this new value - although the total intake in the population has been declining for years.

Numerous new studies have been published since EFSA's temporary TDI was published in 2015. The background to the lowering of the TDI by EFSA is above all evidence from studies on mice that an intake of bisphenol A by the dams (the mother animals) during gestation and in the first period after birth can lead to changes in cell counts in the specific immune system of their progeny. To what extent these effects on the immune system are detrimental to the organism concerned (mouse) and whether the results can be transferred to humans is, in the opinion of the BfR, currently still an unresolved scientific question. A causal relationship between bisphenol A intake and immunological effects in humans cannot be confirmed by studies in humans so far.

The BfR will comment on EFSA’s statement after a comprehensive review.

The use of bisphenol A in the manufacture of polycarbonate infant bottles was banned across the EU back in 2011. The ban was generally extended to polycarbonate drinking vessels and bottles for infants and young children in 2018. A limit for the transfer of bisphenol A into food was set for all other plastic food contact materials as well as for internal coatings made of epoxy resin for canned food on the basis of EFSA's TDI from 2015.

Below, the Federal Institute for Risk Assessment (BfR) answers frequently asked questions on bisphenol A.

What is bisphenol A?
Bisphenol A is the industrial chemical 2,2-bis(4-hydroxyphenyl)propane which is predominantly used as a starting substance in the manufacture of polycarbonate plastics and synthetic epoxy resins.

Where does bisphenol A occur?
Bisphenol A is used in the production of the plastic polycarbonate and epoxy resins. Polycarbonate is very hard, unbreakable, chemical-resistant and transparent. Because of these properties, it is widely used in construction and vehicle construction, but also in consumer products such as DVDs and smartphones. In addition, food contact materials, e.g. drinking bottles, storage boxes or dishes are made from polycarbonate. Epoxy resins are also widely used, for example as adhesives, fibre composite plastics, in printed circuit boards or paints. They are also used as the inner coating of beverage and food cans. Small amounts of bisphenol A can be released from polycarbonate and epoxy resins. The substance was used, among other things, as a colour former in so-called thermal papers for thermal printers and fax machines (e.g. for receipts, parking tickets and package stickers). This use has been banned since January 2020.

Which are the potential effects of bisphenol A?
The substance has a low acute toxicity. However, in animal experiments with long-term uptake (exposure), it is associated with a number of effects.

In 2015, EFSA identified damage to the kidneys and liver as the most sensitive endpoint. In animal experiments, bisphenol A was toxic to reproduction in high doses. In addition, indications of possible damage to the immune system and the metabolic system as well as indications of possible effects on the development of young rodents, such as accelerated onset of puberty and changes in the mammary gland tissue, were found.

Influence of a number of cellular control pathways that affect the hormone concentration and the production of certain endogenous proteins is assumed to be an underlying mechanism of action. Because of this hormone-like (especially oestrogen-like) mode of action, bisphenol A has been identified by the European Chemicals Agency as a Substance of Very High Concern (SVHC) with properties causing hormonal damage (endocrine disruptor). Bisphenol A has not yet been proven to have harmful effects on human health - corresponding population studies have shown inconsistent and contradicting results. In the human body, the substance is quickly converted into a metabolic product that no longer exerts any oestrogenic effects and is excreted through the kidneys.

In its reassessment from December 2021, EFSA identified effects on the immune system through the intake of bisphenol A as the most sensitive endpoint. Studies on mice have shown that the consumption of bisphenol A by the dams (the mother animals) during pregnancy and in the period after birth can lead to changes in cell counts in the adaptive (specific) immune system of the progeny. To what extent these effects on the immune system are detrimental to the organism concerned (mouse) and whether the results can be transferred to humans is, in the opinion of the BfR, currently still an unresolved scientific question.

What does it mean that the European Chemicals Agency (ECHA) identified bisphenol A as a Substance of Very High Concern (SVHC) due to its properties as an “endocrine disruptor”?
In July 2016 bisphenol A was already classified as toxic to reproduction (Category 1B “May damage fertility” according to the CLP Regulation) and, based on this classification, was

identified as a Substance of Very High Concern (SVHC) under the REACH Regulation in January 2017. The REACH Regulation is the currently valid European chemicals law. “REACH” stands for registration, evaluation, authorisation and restriction of chemicals. Further information on SVHC identification can be found here: https://bfr.bund.de/cm/343/reach-identifizierung-der-besonders-besorgniserregenden-stoffe-svhc-bis-2020.pdf

The identification of a substance as an SVHC means that there are certain obligations for manufacturers, suppliers and sellers. In principle, substances identified as SVHCs are published in the so-called candidate list on the ECHA website. Substances on the candidate list may be subject to authorisation depending on further criteria. Then these substances may only be placed on the market or used after a fixed expiry date if the intended use is permitted and therefore safe. Further information can be found on the BfR website under “Authorisation under REACH” (http://www.bfr.bund.de/de/zulassung_unter_reach-53480.html) and in the FAQ on REACH, the European chemicals law (http://www.bfr.bund.de/cm/343/ausgewaehlte_fragen_und_antworten_zu_reach.pdf)

In June 2017, the substance was again identified as SVHC due to its properties as a so-called “endocrine disruptor” for human health. In January 2018, bisphenol A was also identified as an SVHC due to its properties as an endocrine disruptor for the environment. Endocrine disruptors are substances that have a harmful effect due to their influence on the hormone system.

Bisphenol A had already been identified as an SVHC due to its reproductive properties, which are mainly mediated via an endocrine disruptive mode of action. The additional identification based on the hormonally-damaging properties that are of relevance for humans ensures that candidates for approval must assess the risks with regard to the reproductive-toxic properties as well as with regard to all environmentally and health-relevant hormonally damaging properties.

How does the BfR assess the ECHA's decision to include bisphenol A as an “endocrine disruptor” in the SVHC candidate list?

The BfR supported the additional inclusion in the candidate list due to its properties as a so-called endocrine disruptor, since for bisphenol A, in addition to its reproductive toxicity, a suspicion exists that further effects are mediated via an endocrine disruptive mode of action (e.g. changes in the mammary gland tissue, the menstruation cycle and brain development, as well as changes in the time to onset of puberty in animal experiments). Identification as an endocrine disruptor is another argument for inclusion in the list of substances subject to authorization (Annex XIV of the REACH Regulation).

What were the assessment results of EFSA’s opinion on bisphenol A in 2015?

In 2015, EFSA evaluated extensive data to assess exposure, i.e. to estimate the bisphenol A intake of consumers. The analysis led to the result that less bisphenol A is taken up than previously assumed by EFSA. The main sources of exposure to bisphenol A were food (orally, i.e. via mouth) and thermal paper (dermally, i.e. via skin). According to an exposure estimate summed over these routes of exposure, adult consumers took up between around 0.20 and 1.1 micrograms (µg) bisphenol A per kilogram (kg) bodyweight per day in 2015. For children and adolescents, exposure was between 0.04 and 1.4 µg per kg bodyweight per day. Since the use of bisphenol A in thermal paper has been banned since the beginning of 2020, exposure from this source is likely to have decreased significantly. If this portion is deducted from the sum of exposure calculated by EFSA in 2015, the result is a daily intake of

0.13 to 0.41 µg per kg bodyweight for adults and 0.04 to 0.87 µg per kg bodyweight for children and adolescents.

More recent data on the exposure of the Dutch population to bisphenol A confirm the trend established by EFSA in 2015 of decreasing exposure of the population to bisphenol A. In its opinion from 2021, EFSA did not carry out an exposure assessment.

In 2015, EFSA pointed out that further studies were carried out in the USA as part of the National Toxicology Program (NTP) on bisphenol A, including a two-year study in rats with prenatal exposure and toxicokinetic studies, amongst others, on humans. These studies should also help to clarify the uncertainties described by EFSA in 2015 regarding the published data on the potential health effects of bisphenol A. For this reason, in 2015 EFSA derived a provisional (temporary) tolerable intake (t-TDI) that can be consumed daily for a lifetime without incurring any health risks. The studies have now been completed, evaluated and incorporated into the current EFSA reassessment.

What are EFSA's assessment results in its opinion on bisphenol A in 2021?
In December 2021, EFSA derived a new tolerable daily intake (TDI) of bisphenol A based on new studies. This is 0.04 nanograms (ng) per kilogram (kg) of bodyweight per day. The TDI value indicates the amount of a substance that can be taken up daily over an entire lifetime without any noticeable health risk. The new value is around 100,000 times lower than the provisional (temporary) health reference value given by EFSA in 2015. For most people, the intake of bisphenol A from food and other sources exceeds this new value - although the total intake in the population has been declining for years (for currently estimated intake levels see below). The background to the lowering of the TDI by EFSA is above all evidence from studies in mice that the ingestion of bisphenol A by dams (mother animals) during pregnancy and in the period immediately after birth can lead to changes in the cell count in the specific immune system of the offspring. The respective cells are particularly important for the immune defence against bacteria, but there is also evidence that they could be associated with autoimmune diseases such as rheumatoid arthritis. In the opinion of the BfR, the extent to which the findings observed in the mouse studies are detrimental to the animals and whether the results may be transferable to humans is scientifically unclear, as are the suspected underlying mechanisms of action. In contrast, an extensive study in rats performed as part of the US National Toxicology Program (NTP) showed virtually no effects of BPA on the immune system. Neither has a causal relationship between bisphenol A intake and immunological effects in humans been confirmed yet by epidemiological studies in humans (population studies).

What is the BfR's view of the assumption that low amounts of substances with hormone-like effects are to be considered dangerous?
So-called low-dose effects, especially those that have only been demonstrated at low, but not higher, dosages (so-called non-monotonous dose-response relationships), form the subject of intense and controversial discussion among experts. “Low” usually means a dosage in the range of the real exposure or below. In general, “the dose makes the poison”, i.e. the effects should decrease with lower doses. Accordingly, a distinction should be made between effects at low doses with “monotonic” (steadily increasing) dose-effect relationships and - if this can actually be demonstrated - low-dose effects with non-monotonic dose-effect relationships. In October 2021, the European Food Authority EFSA found no evidence of non-monotonic dose-effect relationships for the substance bisphenol A (https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2021.6877). Accordingly, the current derivation of the tolerable daily intake (TDI) is also not based on low-dose effects with a non-monotonic dose-response relationship.

A large number of studies on low-dose effects have been and are still being carried out internationally. New study designs that include additional, molecular-mechanistic endpoints in standard investigations could help to check the possible relevance of the effects observed at low doses. However, it must also be shown that such endpoints are causally related to adverse tissue and organ defects. Since these often represent physiological endpoints in a specific animal model, it is not definite that these are transferable to humans. Accordingly, there is a great need for research on this.

What were the findings of the large-scale US study program published in October 2021 as part of the National Toxicology Program (NTP)?
The CLARITY-BPA (Consortium Linking Academic and Regulatory Insights on BPA Toxicity) program is designed to study the full spectrum of potential health effects of bisphenol A ingestion. The program was initiated by the US National Institute of Environmental Health Sciences (NIEHS) of the National Toxicology Program (NTP) and the Food and Drug Administration (FDA) and consisted of two components. On the one hand, there was a two-year study on the potential toxicity of BPA in rats (core study) that complied with the relevant OECD test guideline, and on the other hand, additional endpoints were investigated in these animals as part of research studies at various universities. The pregnant females were dosed with bisphenol A from the sixth day of gestation. The offspring ingested the substance in the womb, then through breast milk and then through the feed for a period of up to two years. The different groups of animals were exposed to different levels over a very wide range of doses.
https://ntp.niehs.nih.gov/ntp/results/pubs/rr/reports/rr18_508.pdf

Apart from the highest dose, the core study found no biologically relevant health effects from exposure (ingestion) to BPA. Accordingly, the study authors came to the conclusion “that the core study data do not suggest a plausible hazard of BPA exposure in the lower end of the dose range tested.”

Is bisphenol A causally related to the formation of so-called “chalky teeth”?
“Chalky teeth” is a colloquial term for a defective development of the tooth enamel in children. Scientifically, the disease is called “molar incisor hypomineralisation” or MIH for short. The BfR dealt with this topic in 2018 (https://www.bfr.bund.de/cm/349/connection-between-chalky-teeth-in-children-and-the-uptake-of-bisphenol-a-not-likely.pdf) and came to the conclusion that there is no established connection between the intake of bisphenol A via food contact materials and the development of MIH in children, and that a direct connection between Bisphenol A and MIH in humans is unlikely.

Is there a connection between the consumption of bisphenol A and an increased risk of allergies or the occurrence of asthma?
In some studies in mice, the intake of bisphenol A in the period before birth was associated with an increased risk of sensitisation to allergens. This led to an increased incidence of allergic asthma in the mice. The possible mode of action that leads to this observed effect is unknown. In the opinion of the BfR, the extent to which these observations from an experimental mouse study with intentional sensitisation and allergy triggering are relevant for humans is still yet to be answered scientifically. A causal relationship between bisphenol A intake and an increased risk of allergies or the occurrence of asthma in humans has not yet been confirmed by studies in humans.

In what context is the BfR looking into the issue of bisphenol A?
The BfR has, among other things, the legal mandate to assess the substance-related risks of consumer-related products, to communicate them and, if necessary, to submit options for action to minimise them. Against this background, the institute is also concerned with the assessment of bisphenol A in tableware, cans and other consumer products.

In the context of REACH Regulation (EC) No. 1907/2006, the BfR is, in its capacity as the assessment centre for “Health and Consumer Protection”, responsible for questions relating to the health aspects of bisphenol A and for assessing risk reduction measures.

The institute informs the government authorities who have a statutory regulation mandate and the public about the results of its scientific assessment. However, the change or creation of legal regulations on the use of bisphenol A do not fall within the area of responsibility of the BfR.

What are currently the legal limit values in Germany and the EU?
In Germany and the EU, the limit values as laid down in the Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food apply.

This regulation stipulates the maximum permissible quantity of bisphenol A that may migrate from food contact materials made of plastic, e.g. packaging, into food. This “Specific Migration Level” (SML) for bisphenol A currently amounts to 50 micrograms (µg) per kilogram (kg) of food (simulant). The SML is based on the preliminary tolerable daily intake (t-TDI) derived by EFSA in 2015.

For reasons of consumer health protection, this regulation also stipulates that bisphenol A may not be used for the manufacture of polycarbonate infant feeding bottles and of polycarbonate drinking cups or bottles which, due to their spill proof characteristics, are intended for infants and young children.

Varnishes and coatings that are applied to materials and objects and that may come into contact with food (for example, the inner coating of tin cans) are not subject to the Plastics Regulation. For them, an SML of 50 µg per kg of food is specified in Regulation (EU) 2018/213. A corresponding transfer of bisphenol A to the following foods is not permitted: infant formula, follow-on formula, processed cereal-based food, baby food, food for special medical purposes developed to satisfy the nutritional requirements of infants and young children or milk-based drinks and similar products specifically intended for young children.

In the EU Toy Safety Directive 2009/48/EC, a specific limit value for the migration of bisphenol A from toy materials has been established using the temporary TDI value derived by EFSA in 2015 (Commission Directive (EU) 2017/898). According to this, the migration limit for toys intended for use by children under 36 months or in other toys intended to be placed in the mouth is 40 µg per litre (sweat and/or saliva simulant).

Will the limit value for bisphenol A from food contact materials now be changed in the EU?
EFSA does not make political decisions, but assesses the state of knowledge - just like the BfR. The decision on regulatory measures lies with the EU Commission and the member states. In 2018, Regulation (EU) 2018/213 reduced the Europe-wide specific migration limit (SML) for bisphenol A from plastic materials or varnishes and food contact coatings to 50 micrograms per kilogram of food. The EU Commission calculated this value on the basis of the tolerable daily intake (t-TDI), which EFSA had derived in its 2015 opinion. EFSA also

found that there are, in addition to food contact materials, other significant uptake sources. Therefore, the SML is calculated in such a way that the t-TDI can be exhausted up to a maximum of 20 % through food contact materials.

Does bisphenol A intake result in an elevated health risk for consumers?
In its reassessment in 2021, EFSA did not perform an updated estimate of the daily intake of bisphenol A via food and drinking water, but used the exposure estimate for various population groups from its 2015 opinion. According to this exposure estimate, children and adolescents ingest between 0.03 and 0.86 micrograms (µg) bisphenol A per kilogram (kg) bodyweight from food and drinking water every day. Toys only contribute marginally to the bisphenol A intake of children. For adult consumers, exposure from food and drinking water is between 0.12 and 0.39 µg per kg bodyweight per day.

The bisphenol A intake in all population groups - including infants, children and women of childbearing age - is several orders of magnitude higher than the newly derived TDI value of 0.04 nanograms per kg bodyweight per day (= 0.00004 micrograms per kg bodyweight per day). Even if you consider that, among other things, due to regulatory measures, bisphenol A intake in all population groups has probably decreased since 2015, still a significant exceedance of the TDI results for all population groups. Accordingly, EFSA concluded that there is a health concern from dietary BPA exposure for all age groups.

Whether the BfR agrees with this assessment will be decided after a comprehensive review of the current EFSA assessment.

Why has the European Commission banned bisphenol A in baby bottles?
Due to the controversial discussion about the effect of bisphenol A within the low dose range, initial indications of possible additional effects of the substance, e.g. on the immune system and the development of children, and because infants are to be seen as a particularly sensitive consumer group, the European Commission has prohibited the use of bisphenol A in the manufacture of infant feeding bottles as well as bringing infant feeding bottles made with bisphenol A into circulation within EU member states. According to the EU Commission, the ban was issued for reasons of consumer health protection and has been in effect since 2011. In 2018, the ban was generally extended to the use of “polycarbonate drinking cups or bottles which, due to their spill proof characteristics, are intended for infants and young children”.

Since the use of bisphenol A is regulated at the European level, the European Commission is responsible for applying restrictions on the use of the substance.

Are there alternatives to baby bottles made of polycarbonate?
There are various plastic alternatives to polycarbonate, e.g. infant feeding bottles made from polypropylene that do not use bisphenol A in their production, and which are advertised as “BPA-free” products (BPA stands for bisphenol A).

Parents who generally do not want to use plastic drinking bottles have the option of glass bottles. However, the risk of breakage and injury must be taken into account.

Can bisphenol A also be contained in baby dummies made of latex or silicone?
No bisphenol A is required for the manufacture of these materials. However, the substance may be contained in the plastic shield. Based on current knowledge, a transfer of substances from the plastic shield into the actual dummy is not to be expected under normal conditions of use.

In 2009, the BfR examined 18 soothers from different manufacturers and brands made of latex and silicone for bisphenol A through its own laboratory analyses. The aim was to determine how much bisphenol A is leaching off the soothers during use. A release of bisphenol A totalling 0.02 micrograms (µg) per soother and hour was determined in only one soother. No bisphenol A was released from any of the other 17 soothers. These test results agree with the results of the Austrian Agency for Health and Food Safety (AGES) and various monitoring laboratories.

Why do the internal coatings of food and beverage cans contain bisphenol A?
Bisphenol A is found, as a contaminant resulting from the manufacturing process, in epoxy coatings (epoxy resins) which are used in internal coatings of food and beverage cans. Such a coating is necessary to prevent the sheet metal from corroding and metals from loosening, which would contaminate the food as well as cause discolouration and impaired taste.

Bisphenol A-free coating systems are up to now limited to a few applications and in some cases not yet evaluated with respect to possible health effects.

How can I tell whether internal linings of food and beverage cans contain bisphenol A?
There is no labelling requirement for cans coated with epoxy resins.

How can consumers reduce their consumption of bisphenol A?
Diet is the main source of bisphenol A intake in all population groups. According to EFSA data from 2015, it is predominantly food that is stored in cans coated with epoxy resin that contributes to bisphenol A intake. In the case of foods not stored in such cans, the greatest contribution to exposure comes from meat and meat products. Consumers who want to reduce their consumption of bisphenol A should ideally consume fresh food. A clear connection between the type of contents of food cans and the bisphenol A concentration in the food has not yet been established in random sample studies. Comparative studies with food simulants at different temperatures and contact times indicate that the bisphenol A content in the food could essentially depend on the preservation method.

When buying plastic containers, drinking bottles and plastic dishes, consumers should look out for the words “BPA-free”. However, they may contain other bisphenol A alternatives (such as bisphenol S), some of which have not been well evaluated. If labelled with “bisphenol-free” or similar, products should contain no bisphenols at all. Consumers who generally do not want to use plastic drinking bottles have the option of glass bottles. However, the risk of breakage and injury must be taken into account. Plastic polycarbonate (abbreviated: PC) does not have a recycling code that is specific to this plastic. PC is grouped together with a large number of other plastics (e.g. polyamide or polylactide) under recycling code 7 (other). Correspondingly, it is not possible to infer the presence of PC from the recycling code 7 label.

According to EFSA data from 2015, bisphenol A is contained in almost all types of food - albeit in comparatively lower concentrations in foods that are not stored in cans coated with epoxy resin. However, consumption of these comparably less contaminated foods also results in the significantly lower TDI, re-derived by EFSA in 2021, being exceeded by several orders of magnitude.

Can bisphenol A be found in receipts, train tickets or parking tickets?
Until the ban at the beginning of 2020, bisphenol A was also used in thermal papers. Thermal paper is used in thermal printing systems that are built into cash registers, ticket offices, parking ticket machines or printers for receipts and bank statements. There the material is used as a colour former. Use in thermal papers in concentrations of over 0.02 % has been prohibited since 2020. In principle, this corresponds to a ban on use, as contents below 0.02 % do not facilitate the desired technological effect.

Does recycling paper contain bisphenol A?
Thermal paper, which is used for receipts, parcel stickers or parking tickets, for example, does not belong in the waste paper, but in the residual waste.

Due to the continued use of bisphenol A in thermal paper until the end of 2019, bisphenol A could still end up in the waste paper for recycling. When using recycled paper fibres in the manufacture of new paper products, residues of bisphenol A could also get into the new products.

For food contact materials of certain material groups for which there is no specific regulation at European level, the BfR maintains the “Recommendations on food contact materials” (https://www.bfr.bund.de/en/bfr_recommendations_on_food_contact_materials-1711.html). BfR Recommendation XXXVI entitled “Paper and board for food contact” lists a guidance value of 50 micrograms per kilogram of food for the maximum release of bisphenol A from paper, produced using recycled fibres, into food. The value corresponds to the specific migration limit (SML) from the European Plastics Regulation.

Are bisphenol S and bisphenol F alternatives to bisphenol A?
Bisphenol S and bisphenol F have so far been studied less extensively for their possible harmful effects. The modes of action for both substances are assumed (and/or suggested by initial studies) to be similar to those for bisphenol A. It is not yet clear whether the potency is also comparable to that of bisphenol A. Accordingly, for bisphenol S and bisphenol F a daily intake, for which adverse health effects are not to be expected, is not yet known. The tolerable daily intake for bisphenol A is therefore currently used for risk assessments of bisphenol S and bisphenol F.

Further information on the subject from the BfR website

Bisphenol A
https://www.bfr.bund.de/en/a-z_index/bisphenol_a-129760.html

You can also find all BfR Opinions and all issues of the BfR science magazine BfR2GO in our app.

BfR “Opinions app”

This text version is a translation of the original German text which is the only legally binding version.