Bisphenol A in everyday products: Answers to frequently asked questions

Updated FAQ of the BfR from 13 July 2023

The substance bisphenol A is used to produce the plastic polycarbonate, which, in addition to its use in house and vehicle construction, is applied in consumer products such as DVDs and smartphones, but also for containers and bottles for food. Bisphenol A can also be used in the manufacture of inner coatings for beverage and food cans. During normal use, polycarbonate and epoxy resins used for the coatings are chemically stable and will not break down again into bisphenol A. However, the substance may remain in small quantities as a residue in the plastics and may be released from them. Until the ban at the beginning of 2020, BPA was also contained in thermal papers (for example for cash register receipts or parking tickets).

Bisphenol A has been classified by the European Commission as toxic to reproduction (category 1B). Therefore, and due to its properties as an endocrine disruptor for human health and the environment, bisphenol A has been identified as a Substance of Very High Concern (SVHC) under European chemicals legislation. Endocrine disruptors are substances that cause adverse health effects by affecting the endocrine system.

People take up the substance mainly via the food, but air, dust or water are also possible sources for bisphenol A exposure. The substance has a low acute toxicity. However, it has been associated with a number of effects in animal experiments with long-term exposure. The question of whether and to what extent bisphenol A affects human health has been the subject of scientific debate for years and has not yet been conclusively clarified.

In the following, the German Federal Institute for Risk Assessment (BfR) answers questions that are frequently asked about bisphenol A.

What is bisphenol A?

Bisphenol A (chemical name: 2,2-bis(4-hydroxyphenyl)propane) is an industrial chemical used primarily as a starting material for the production of polycarbonate plastics and epoxy resins.

Where does bisphenol A occur?

Bisphenol A is used for the production of the plastic polycarbonate and epoxy resins. Polycarbonate is very hard, shatterproof, chemical-resistant and transparent. Because of these properties, it is widely used in construction and vehicle manufacturing, but also in consumer products such as DVDs or smartphones. Food contact materials such as drinking bottles, storage boxes or tableware can also be made from polycarbonate. Epoxy resins are also widely used, for example as adhesives, fibre-reinforced plastics, in printed circuit boards or paints. They can also be used as internal coatings for beverage and food cans. Polycarbonate and epoxy resins themselves are chemically stable and do not break down again into bisphenol A during normal use. However, the substance may be present in small quantities as a residue in the plastics and may be released from them. Among other things, the substance was used as a colour former in so-called thermal papers for thermal printers and fax machines (e.g. for sales slips, parking tickets and parcel labels). This use was banned in January 2020.

What are the toxicological effects of bisphenol A?
The substance has a low acute toxicity. However, it has been associated with a number of effects after long-term ingestion (exposure) in animal studies. In 2016, bisphenol A was classified as toxic to reproduction category 1B ("may impair fertility") according to the CLP Regulation. In the following year, the European Chemicals Agency (ECHA) identified it twice as a "substance of very high concern" (SVHC). This was based on the substance's reprotoxic properties and its hormone-like mode of action.

Hormones are the body's own messengers and mediate their effects by binding to certain receptors. Bisphenol A is a so-called endocrine disruptor, i.e. it showed harmful (adverse) effects in animal experiments as a result of influencing the hormone system. For bisphenol A, the most relevant is the estrogenic effect, which means that it can mimic or even interfere with the effect of female sex hormones (estrogens) by binding to corresponding receptors. However, the binding affinity of bisphenol A to the oestrogen receptor is significantly lower (by several orders of magnitude) compared to the natural hormones. Bisphenol A can also bind to the receptors of male sex hormones (androgens) and inhibit their effects. This is referred to as an anti-androgenic effect of bisphenol A.

Adverse health effects of current bisphenol A intake levels for humans have not been proven so far - corresponding population studies showed inconsistent and contradictory results. In the current opinion of the European Food Safety Authority (EFSA, 2023), none of the effects evaluated were considered to be likely based on data in humans.

In the human body, bisphenol A is quickly converted into a metabolic product that no longer exerts oestrogenic activity and is excreted via the kidneys.

In its re-evaluation of the health risks from the intake of bisphenol A via food of April 2023, EFSA identified changes in the number of certain cells of the immune system due to the intake of bisphenol A as the most sensitive endpoint for deriving a health based guidance value: In mouse offspring from dams administered bisphenol A during gestation and nursing, an increase in the proportion of type 17 T helper cells (Th17) was measured.

In the opinion of BfR, it is scientifically not clear, whether or not these cell number changes have an adverse effect on the overall organism. Moreover, it has to be clarified, whether the results can be transferred to humans. Based on its own analysis of scientific data, the BfR has derived a health based guidance value based on reproductive toxicity (reduced sperm count in adult rats).

How much bisphenol A do consumers ingest?
In 2015, EFSA analysed extensive data (from 2008 to 2012) to estimate the bisphenol A intake (exposure) of consumers at that time. The analysis led to the conclusion that less bisphenol A is ingested than previously assumed by EFSA. The main sources of exposure to bisphenol A were food (oral, i.e. via the mouth) and thermal paper (dermal, i.e. via the skin). According to an exposure estimate taking into account both routes of intake, adults ingested in 2015 between about 200 and 1100 nanograms (ng; one 1 billionth of a gram) of bisphenol A per kilogram (kg) of body weight per day. For children and adolescents, exposure ranged between 40 and 1400 ng per kg body weight per day. However, comparisons with the amounts of bisphenol A excretion products found in urine suggested that this estimate was probably too high by a factor of 2 to 4.

As there has been a ban on the use of bisphenol A in thermal paper since the beginning of 2020, exposure from this source is likely to have decreased significantly since then. Deducting this amount from the summed exposure calculated by EFSA in 2015, a daily intake of 130 to 410 ng per kg body weight results for adults and 40 to 870 ng per kg body weight for children and adolescents.

More recent data on exposure of the Dutch population confirm the trend of decreasing exposure to bisphenol A that was already identified by EFSA in 2015. In its 2023 opinion, EFSA did not perform an updated exposure estimate.

The BfR recommends collecting current content data in foodstuffs in order to be able to carry out an exposure estimate, as this is essential for an up-to-date risk assessment of bisphenol A. The BfR has already initiated such data generation.

How much bisphenol A can a person ingest daily without a recognisable health risk?
The tolerable daily intake (TDI) is derived for substances that occur, for example, as contaminants in food. The TDI is a guidance value that describes the amount of a substance that a person can ingest daily for a lifetime without posing a health risk. It is usually given as an amount of substance per kilogram of body weight per day.

For bisphenol A, the European Food Safety Authority (EFSA) has derived a TDI value of 0.2 nanograms per kilogram of body weight per day based on scientific data from animal studies. This value, published in April 2023, is 20,000 times lower than the provisional health based guidance value of 4000 nanograms per kg body weight per day given by EFSA in 2015.

Although the total intake of bisphenol A in the population has been declining for years, it is expected to be significantly above EFSA's new proposed TDI for people of all ages.

BfR does not support the new TDI derived by EFSA due to several scientific and methodological discrepancies (divergences) (for detailed justification see next question).

The BfR has carried out a detailed analysis of the scientific data on the toxicological effects of oral (via the mouth) exposure to bisphenol A (https://www.bfr.bund.de/cm/349/bisphenol-a-bfr-proposes-health-based-guidance-value-current-exposure-data-are-needed-for-a-full-risk-assessment.pdf). After evaluating more than 600 studies from the past 20 years, the BfR derived a TDI value of 200 nanograms per kilogram of body weight per day. This value is 20 times lower than the previous provisional TDI value of EFSA from 2015. BfR followed a conservative approach and also took into account the remaining uncertainties by means of a quantitative, statistics-based procedure.

The BfR assessment focused on the critical endpoints identified in the EFSA opinion from 2023 (effects on the immune system, reproductive toxicity, increased uric acid levels in blood serum). Due to the conservative approach and on the basis of assessments by other authorities, the TDI derived by the BfR is also protective against further toxicological endpoints (e.g. general toxicity, carcinogenicity, effects on brain and behaviour). After evaluating the available data, the BfR also concludes that adverse immunological effects in humans are unlikely to result from bisphenol A exposure in the range of its suggested TDI. The BfR therefore proposes to use the TDI value of 200 nanograms per kilogram of body weight per day as a health based guidance value for risk assessment.

The BfR does not consider the TDI value of 0.2 nanograms per kilogram of body weight per day derived by the European Food Safety Authority (EFSA) in 2023 to be appropriate. Why not?

The BfR considers the approach of EFSA for derivation of a new TDI and the result as inappropriate with respect to several points:

1) Selection of the critical endpoint (adversity and human relevance)

   EFSA lowered the daily tolerable intake (TDI) of bisphenol A to 0.2 nanograms per kilogram of body weight per day. This was based on data from studies on mice on the effect of bisphenol A on the immune system: In offspring of dams that were administered bisphenol A during pregnancy and during nursing, an increase in the percentage of certain immune cells (Th17 cells) in the spleen was measured. It should be noted that these (healthy) animals did not show any signs of an adverse effect. Other studies showed that bisphenol A can increase already existing inflammation in allergy models with sick animals. So far, mice are the only species in which the effects identified by EFSA have been studied.

   Th17 cells are special T-helper cells that are mainly found in mucosal barriers (e.g. in the intestine) and play an important role there in the immune defence against fungal infections. In addition to this protective function, Th17 cells are also associated with inflammatory reactions such as psoriasis. Furthermore, there are indications that the relative number of Th17 cells is increased in autoimmune diseases such as rheumatoid arthritis. However, it is still unclear what role an increased Th17 cell count plays within the respective clinical pictures, i.e. whether the increased relative Th17 cell count causes the disease or is merely associated with it (association or causality). In clinical trials, drugs that counteract Th17 cells have not been successful in treating various of these diseases.

   In healthy mice, the relative increase in Th17 cells had no adverse effect, for example no inflammatory reactions occurred. In an extensive study on rats, carried out within the framework of the US National Toxicology Program (NTP), the animals were administered bisphenol A daily over their entire lifespan - beginning in the womb and ending after two years. A variety of analyses were performed, including testing for over 530 possible effects on the immune system. No adverse (harmful) effects were found. The authors concluded that bisphenol A is “unlikely to alter immune competence in adult rats”. The highest dose of bisphenol A tested was 25 million nanograms per kilogram of body weight per day, which is 125 million times higher than the new TDI derived by EFSA.

   It is questionable whether the results from the mouse studies can be transferred to humans. Despite existing similarities between murine (mouse) and human immune systems, some important differences were identified, such as different maturation and regulatory processes in the immune system. Furthermore, the methods used for the measurements of the relative increase in Th17 cells are not standardised nor validated. There is no information on the measurement uncertainty associated with the tests and no positive controls are established. Therefore, a quality assessment of the measurements is not possible.

   Epidemiological studies (population studies) conducted so far have not shown a causal link between bisphenol A intake and immunological effects, but some of these studies have methodological shortcomings.

In conclusion, the BfR considers the critical effect "relative increase in Th17 cells" used by EFSA as a basis for TDI derivation, as well as other immunological effects discussed by EFSA, as not suitable for predicting adverse health effects in humans. Therefore, they should not be used to derive a TDI.

After evaluating the available data, the BfR concludes that adverse immunological effects in humans - if present at all - are unlikely to occur at a bisphenol A exposure in the range of the TDI of 200 nanograms per kilogram of body weight per day.

2) Selection and weighting of the literature considered

Another point of criticism of the EFSA re-evaluation by the BfR concerns the selection and quality of the studies on which the EFSA re-evaluation is based. With a few exceptions, only studies from the period between 2013 and 2018 were evaluated. Relevant studies with earlier or later publication dates were not (sufficiently) considered, even if they contained relevant information. This contradicts the internationally recognised principles of risk assessment, to which EFSA also refers.

The BfR also sees partly fundamental differences in the assessment of the quality of the evaluated studies and accordingly the reliability of the data generated in them. For example, the mice from the key study on which the TDI is based were kept in polycarbonate cages. Since bisphenol A is a starting material in the production of polycarbonate, in the opinion of the BfR, a relevant background exposure of the animals is very likely and also documented in the literature for similar experiments. In addition, the animals were fed "standard feed", which was neither tested for its bisphenol A content nor specifically selected with regard to a low bisphenol A content. As comparable studies have shown, this also very likely results in a relevant additional bisphenol A intake of the study animals, which is why the actual dose administered is unclear. The study is therefore not suitable for a quantitative risk assessment in the opinion of the BfR.

3) Derivation of the conversion factor mouse - human

Hazard characterisation is mostly based on experimental data from animal studies. Humans and animals may differ with regard to the uptake of a substance into the blood, its distribution and metabolism in the body, and its excretion. Therefore, the administered critical doses in animal experiments are converted into corresponding intake levels for humans via appropriate conversion and assessment factors.

EFSA bases the calculation of the conversion factor (mouse-human) on a study on the time course of bisphenol A blood levels after a single dose in mice. However, far too few measurement points could be generated on too few animals (1 to 2 animals; no statistical meaningfulness) and only over a very short measurement period (one hour instead of 24 hours after dosing). From the BfR's point of view, the study is therefore unsuitable for determining a conversion factor. This study is contrasted with two other studies that come to clearly different results. These studies are based on sufficient measurement points over a period of 24 hours, in a statistically sufficient number of animals.

> In the BfR's view, just the use of the above-mentioned study, which in the BfR's view is unsuitable for determining the mouse-human conversion factor, means that the TDI calculated by EFSA is too low by a factor of 10 to 100.

The large discrepancy between the TDI of the BfR and EFSA results from the choice of a different endpoint for the TDI derivation and a different conversion factor mouse - human as well as from a different methodological, guideline-compliant approach applied by the BfR to determine remaining uncertainties. The scientific divergences in the TDI derivation by BfR and EFSA are summarised in a document and are publicly available. (https://www.efsa.europa.eu/sites/default/files/2023- 04/bfr-efsa-art-30.pdf).

The European Medicines Agency (EMA) has also drafted a divergence paper with EFSA. The EMA essentially criticises the same points as the BfR.

What conclusions does the BfR reach in its statement in 2023?
The German Federal Institute for Risk Assessment (BfR) has conducted a detailed analysis of scientific data on the health effects of the intake of bisphenol A via food and drinking water (https://www.bfr.bund.de/cm/349/bisphenol-a-bfr-proposes-health-based-guidance-value-current-exposure-data-are-needed-for-a-full-risk-assessment.pdf).

After evaluating over 600 studies from the last 20 years, the BfR derived a TDI value of 200 nanograms per kilogram of body weight per day. The BfR followed a conservative approach and also took into account existing uncertainties by means of a quantitative, statistics-based procedure. The assessment focused on the critical endpoints identified in the opinion of the European Food Safety Authority (EFSA) from 2023 (effects on the immune system, reproductive toxicity, increased uric acid levels in blood serum). Existing assessments by other authorities also consider other toxicological endpoints. Based on these assessments, the TDI derived by BfR is also protective against these endpoints (e.g. general toxicity, carcinogenicity, effects on brain and behaviour). After evaluating the available data, BfR also concludes that adverse immunological effects in humans are unlikely to result from a bisphenol A exposure in the range of the TDI. The BfR therefore proposes to use the TDI value of 200 nanograms per kilogram of body weight per day as a health reference value for risk assessment.

What does the divergence in EFSA's assessment process mean in 2023?
Both the European Medicines Agency (EMA) and the German Federal Institute for Risk Assessment (BfR) have different views on aspects of the methodology used compared to the European Food Safety Authority (EFSA). It is a common situation and integral part of the scientific process, that scientists have different views on approaches and methods. In scientific discussions, attempts are made to explain and/or resolve potential differences. The remaining differences and positions are explained in a joint document by both parties. This divergence paper is published to make the disagreements and arguments transparent to the public as well as to risk management (e.g. legislators). The divergence paper between BfR and EFSA can be found here: https://www.efsa.europa.eu/sites/default/files/2023- 04/bfr-efsa-art-30.pdf.

In this context, BfR and EFSA emphasise that discussions about methodology and results are part of gaining scientific knowledge. They contribute to the further development of risk assessment methods and thus to a better classification of possible health risks in the long term. The public presentation of divergent views gives political decision-makers the opportunity to take the state of scientific knowledge into account when making decisions in the context of risk management.

What does it mean that the European Chemicals Agency (ECHA) has 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 impair 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 European chemicals legislation currently in force. "REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals.

The identification of a substance as SVHC means that there are certain obligations for manufacturers, suppliers and sellers. In principle, recognised SVHC substances 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 set expiry date if the intended use is authorised and thus safe. Further information can be found on the BfR website under "Authorisation under REACH"
https://www.bfr.bund.de/en/reach___the_new_european_chemicals_legislation-9749.html
and in the FAQ (only in German) on the European chemicals legislation REACH.
(http://www.bfr.bund.de/cm/343/ausgewaehlte_fragen_und_antworten_zu_reach.pdf)

In June 2017, the substance was re-identified as an SVHC due to its properties as an 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 cause a harmful effect due to their influence on the hormone system.

In summary, bisphenol A was identified as a SVHC due to its reproductive toxic properties, which are mainly mediated via an endocrine-disrupting mechanism of action. The additional identification based on endocrine disrupting properties relevant for humans ensures that applicants for authorisation have to assess the risks with regard to the reproductive toxic properties as well as with regard to all endocrine disrupting properties relevant for the environment and human health.

How does BfR assess ECHA's decision to include bisphenol A as an "endocrine disruptor" in the SVHC candidate list?
The BfR has supported the additional inclusion in the candidate list based on the properties as a so-called endocrine disruptor, since for bisphenol A, in addition to its reproductive toxicity, it is suspected that further effects are mediated via an endocrine-disruptive mechanism of action (e.g. changes in mammary gland tissue, the menstrual cycle and brain development, as well as changes in the time to onset of puberty in animal experiments). Identification as an "endocrine disruptor" constitutes a further argument for inclusion in the list of substances subject to authorisation (Annex XIV of the REACH Regulation).

How does the BfR assess the assumption that even small amounts of hormone-like substances pose a health risk?
The so-called low-dose effects, especially those that have only been proven at low, but not higher doses (so-called non-monotonic dose-response relationships), are discussed intensively and controversially in expert circles. In this context, "low" usually refers to a dosage in the range of the real exposure or below. In general, "the dose makes the poison",

i.e. effects should decrease at lower doses. Accordingly, a distinction should be made between effects at low doses with "monotonic" (steadily increasing) dose-response relationships and - if actually detectable - low-dose effects with non-monotonic dose-response relationships. For the substance bisphenol A, the European Food Safety Authority (EFSA) had found no evidence of non-monotonic dose-response relationships in October 2021. (https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2021.6877).

A large number of studies on low-dose effects have been and are still being conducted. New study designs that include further, molecular-mechanistic endpoints in standard investigations, as well as so-called "New Approach Methodologies" (NAMs) could help to verify the possible relevance of the effects observed at low doses. However, it must also be shown that such effects are causally related to adverse effects at the tissue and/ or organ level. Since these are often physiological endpoints in a specific animal model, their transferability to humans is not necessarily given. Accordingly, there is still a need for research in this area.

What were the findings of the large-scale US National Toxicology Program (NTP) study programme published in October 2021?
The CLARITY-BPA programme (Consortium Linking Academic and Regulatory Insights on BPA Toxicity) was developed to investigate the full range of potential health effects of bisphenol A ingestion. The programme 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. Firstly, there was a two-year study on the potential toxicity of BPA in rats (core study), which conformed to the relevant OECD test guideline, and secondly, additional endpoints were investigated in these animals as part of grantee studies at various universities. Bisphenol A was administered to the pregnant females from the sixth day of gestation. The offspring was exposed to the substance in the womb, then via breast milk and then via feed over a period of up to two years. The exposure regime covered a wide range of bisphenol A concentrations (2.5 – 25,000 µg/kg bw/d).
https://ntp.niehs.nih.gov/ntp/results/pubs/rr/reports/rr18_508.pdf

The core study found no biologically relevant health effects from exposure (ingestion) of BPA, except at the highest dose. Accordingly, the study authors concluded "that the core study data do not indicate a plausible hazard from BPA exposure at the lower end of the dose range tested." This also applies to effects on the immune system. The authors consider it unlikely that the immune competence of adult rats is altered by exposure to bisphenol A.

Is bisphenol A causally related to the formation of so-called "chalk teeth"?
Chalk teeth" is the colloquial term for a disturbed formation of the tooth enamel in children. Scientifically, the disease is called "molar incisor hypomineralisation" or MIH for short. In 2018, the BfR looked into this topic (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 proven 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 is unlikely for humans.

Is there a connection between the intake of bisphenol A and an increased risk of allergies or the occurrence of asthma?
In some studies in mice, bisphenol A intake was associated with an increased inflammatory response in asthma models. These asthma models involve the intentional, artificial induction of an immunological response independent of bisphenol A exposure. The possible

mechanism of action by which bisphenol A increases asthma-related inflammation is currently unknown. To what extent these observations from an experimental mouse study with a very artificial allergy model are relevant for humans is, according to the BfR, currently still an open scientific question. A connection between bisphenol A intake and an increased risk of allergy or occurrence of asthma in humans has not yet been confirmed by epidemiological studies (population studies).

In what context does the BfR deal with the issue of bisphenol A?
Among other things, the BfR has the legal mandate to assess the substance-related risks of consumer products, to communicate them and, if necessary, to submit options for action to minimise them. Against this background, the Institute is also involved in the assessment of bisphenol A in consumer products.

Within the framework of the REACH Regulation (EC) No 1907/2006, the BfR is responsible as the "Health and Consumer Protection" assessment body for questions on health aspects of bisphenol A and for the assessment of risk reduction measures.

The Institute informs the authorities designated by the legislator for regulation and the public about the results of its scientific assessment. Changing or creating legal rules for the use of bisphenol A does not fall within the BfR's remit.

What limits apply in Germany and the EU?
For the release of bisphenol A from plastic food contact materials, the limit value of Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food apply in Germany and in the EU.

This regulates the amount of bisphenol A that may be transferred from a plastic food contact material, e.g. packaging, into the food. This "Specific Migration Limit" (SML) for bisphenol A is currently 50 micrograms (µg) per kilogram (kg) of food (simulant). The SML is based on the provisional tolerable daily intake (t-TDI) derived by EFSA in 2015. This was 4 micrograms per kilogram of body weight per day.

This regulation also stipulates, for reasons of consumer health protection, that bisphenol A may not be used in the manufacture of polycarbonate infant bottles and in the manufacture of polycarbonate drinking vessels and bottles intended for infants and young children due to their leak-proof design.

Varnishes and coatings that are applied to materials and articles that may come into contact with food (for example, interior coatings of food cans) are not covered by the Plastics Regulation. For them, Regulation (EU) 2018/213 sets an SML of 50 µg per kg of food. However, a 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 Toys Directive (Directive 2009/48/EC), a specific migration limit for the release of bisphenol A from toy materials was derived on the basis of the temporary TDI value of EFSA from 2015 (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 liter (sweat or saliva simulant).

Will the limit value for bisphenol A from food contact materials be changed in the EU after EFSA's re-evaluation in 2023?
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 coatings for food contact to 50 micrograms per kilogram of food. The EU Commission set this value based on the tolerable daily intake (t-TDI) derived by EFSA in its opinion from 2015. EFSA had also determined that there are significant other uptake sources in addition to food contact materials. Therefore, the SML was derived in such a way that the t-TDI can be exhausted by the food contact materials to a maximum of 20%.

Do the bisphenol A intake levels result in an increased health risk for consumers?
In its 2023 re-evaluation, 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 different population groups from its 2015 opinion. According to this exposure estimate, children and adolescents ingest between 30 and 860 nanograms (ng) of bisphenol A per kilogram (kg) of body weight per day via food and drinking water. Toys contribute only marginally to children's bisphenol A intake. For adult consumers, exposure via food and drinking water ranges between 120 and 390 ng per kg body weight per day.

Thus, the bisphenol A uptake is in all population groups - including infants, children and women of childbearing age - several orders of magnitude higher than the new TDI derived by EFSA. Even if one considers that, amongst others due to regulatory measures, the bisphenol A intake in all population groups is likely to have decreased since 2015, there is still a clear exceeding of the new TDI for all population groups. Accordingly, EFSA sees a health risk from daily bisphenol A intake in all population groups.

After detailed analysis and evaluation of the scientific data, the BfR has derived a higher TDI value. It is 200 nanograms per kg body weight and day. In order to be able to assess the health risks that may be associated with bisphenol A intake, current data on the exposure of the population are necessary. For this reason, the BfR recommends conducting such an exposure assessment and has already initiated a generation of new data.

Why did the EU Commission ban bisphenol A in baby bottles?
Due to the controversially discussed questions about the effects of bisphenol A in the low-dose range, initial indications of possible further effects of the substance, e.g. on the immune system and the development of children, and because infants are to be regarded as a particularly sensitive consumer group, the European Commission has banned the use of bisphenol A in the manufacture of baby bottles and the placing on the market of baby bottles manufactured with bisphenol A in the EU Member States. According to the EU Commission, the ban was issued for reasons of consumer health protection and has been in force 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".

As the use of bisphenol A is regulated at European level, the EU Commission is responsible for setting restrictions on the use of the substance.

Are there alternatives to polycarbonate baby bottles?
There are various plastic alternatives to polycarbonate, e.g. infant feeding bottles made from polypropylene are offered, for the production of which no bisphenol A is used and which are advertised as "BPA-free" (BPA stands for bisphenol A).

Parents who generally want to avoid plastic drinking bottles have the option of using glass bottles. However, the risk of breakage and injury must be taken into account.

Can bisphenol A also be present in baby dummies made of latex or silicone?
Bisphenol A is not necessary for the production of these materials. However, the substance may be contained in the plastic shield of the dummy. According to current knowledge, a transfer of substances from the plastic shield into the teat is not to be expected under normal conditions of use.

In 2009, the BfR tested 18 latex and silicone soothers of different manufacturers and brands for bisphenol A in its own laboratory analyses. The aim was to determine how much bisphenol A is released by the teats during use. Only in one teat was a release of bisphenol A of 0.02 micrograms (µg) per teat and hour determined. All other 17 soothers did not release any bisphenol A. These test results are in agreement with the results of the Austrian Agency for Health and Food Safety (AGES) and various monitoring laboratories.

Why do inner coatings of food and drink cans contain bisphenol A?
Bisphenol A occurs as an impurity from the manufacturing process in epoxy coatings (epoxy resins), which are, amongst others, used to coat the inside of food and beverage cans. Such a coating is necessary to prevent the sheet metal from corroding and dissolving metals that would cause contamination of the food as well as discolouration and adverse taste effects.

Materials and objects that come into contact with food should be designed in such a way that, as far as possible, no substances are transferred from them to the food. If this nevertheless occurs, Article 3 of Regulation (EC) No 1935/2004 states that the materials and articles must be manufactured in accordance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer constituents to food in quantities likely to constitute a hazard to human health.

A limit of 50 micrograms per kilogram of food has been set for the transfer of bisphenol A from varnishes and coatings in contact with food under Regulation (EU) 2018/213. Studies by the Bavarian State Office for Health and Food Safety (https://www.lgl.bayern.de/publikationen/doc/band10_bpa_lm_verpackungen.pdf) for example, show that this limit is complied with by most of the canned foods tested.

Are there alternatives to BPA-coated food cans?
Bisphenol A-free systems are available for coating food cans. However, the alternatives are not equally technically suitable for some applications and in some cases still require further health evaluation.

Alternatives to epoxy resin-based coating systems are polyester-based systems. There are also mixed forms, e.g. with phenolic resins, or multilayer systems in which the epoxy resin layer is not in direct contact with the food. Epoxy resins using other bisphenols, such as tetramethylbisphenol F, can also be considered as bisphenol A-free. The BfR does not have any figures on the market shares of the individual coating systems in Germany or Europe.

How can I tell if the inner coatings of food and drink cans contain bisphenol A?

There is no labelling obligation for cans coated with epoxy resins.

How can consumers reduce their intake of bisphenol A?
In all population groups, diet is the main source of bisphenol A intake. According to EFSA data from 2015, foods stored in epoxy-coated cans are the main contributors to bisphenol A intake. For foods not stored in such cans, the largest exposure contribution results from meat and meat products. Consumers who want to reduce their intake of bisphenol A are best advised to eat food freshly cooked. A clear correlation between the type of food in the can and the bisphenol A concentration contained could not be found in random sample studies so far. Comparative studies with food simulants at different temperatures and contact times indicate that the content of bisphenol A in the food could essentially depend on the method of preservation.

When buying plastic cans, drinking bottles and plastic tableware, look for the label "BPA-free". However, other bisphenol alternatives (such as bisphenol S), some of which have been less well studied, may be contained. Labels such as "Bisphenol-free" must not contain any bisphenols. Consumers who generally want to avoid plastic drinking bottles have the option of switching to glass bottles. However, the risk of breakage and injury must be taken into account.

The plastic polycarbonate (abbreviated: PC), which is amongst others made from bisphenol A, does not have a recycling code that applies specifically to this plastic. PC is grouped together with a variety of other plastics not containing bisphenol A (e.g. polyamide or polylactide) under recycling code 7 (other). Accordingly, the printed recycling code 7 does not indicate the presence of PC.

According to EFSA data from 2015, bisphenol A is present in almost all types of food. Foods that are not stored in cans coated with epoxy resin exhibit lower concentration compared to foods from epoxy resin-coated cans. However, even the consumption of these comparatively less contaminated foods results in an exceedance of the TDI newly derived by EFSA by several orders of magnitude.

Can bisphenol A be present in receipts, tickets or parking tickets?
Until the ban at the beginning of 2020, BPA was also used in thermal papers. Thermal paper is used in thermal printing systems installed in cash registers, ticket counters, parking ticket machines or printers for receipts and bank statements. There, the material is used as a colour former. The use in thermal papers in concentrations of more than 0.02% has been banned since 2020. In principle, this corresponds to a ban on use, as concentrations below 0.02% do not lead to the desired technological effect.

Is bisphenol A present in recycled paper?
Thermal paper, from which, for example, sales slips, parcel labels or parking tickets are made, does not belong in the waste paper but in the residual waste.

Due to the use of bisphenol A in thermal paper until the end of 2019, bisphenol A could still end up in waste paper. In addition, printing inks, adhesives or plastics in combination with paper may also contain bisphenol A - albeit in much smaller quantities than thermal paper. When recycled paper fibres are used in the manufacture of new products made of paper, residues of bisphenol A could also end up in 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/de/bfr_empfehlungen_zu_materialien_fuer_den_lebensmittelkontakt-447.html?list_documents_sort_by=title&list_documents_order_by=asc). BfR Recommendation XXXVI entitled "Papers, cardboard and paperboard 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 or 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. For the risk assessment of bisphenol S and bisphenol F, the tolerable daily intake for bisphenol A is therefore currently used.

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