FAQs on bisphenol A in consumer products

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The substance bisphenol A is contained in polycarbonate products such as food and drink containers and bottles. Bisphenol A is also used in the production of internal coatings of beverage and food cans. A further source of bisphenol A is thermal paper used for printing, for example till receipts, public transport and parking tickets.

The risk assessment of this industrial chemical has been controversially debated all over the world for years. In January 2015, the European Food Safety Agency (EFSA) published a new opinion on the assessment of the health risks associated with the use of bisphenol A in food contact materials (such as containers made of polycarbonate and cans with interior coatings made of synthetic resins). In its opinion, the EFSA draws the conclusion, based on the available data, that BPA does not pose a risk to human health, since the bisphenol A quantities absorbed by consumers are significantly below what would constitute a health risk.

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

What is bisphenol A?
Bisphenol A is the industrial chemical 2,2-Bis(4-hydroxyphenyl)propane. It is mainly used as a parent substance in the production of polycarbonate plastics and synthetic resins.

Where is bisphenol A found?
The substance can be contained in objects made of polycarbonate, even those that come into contact with food. Examples are drinking bottles (in the past also baby bottles) and parts of tableware. Bisphenol A can also be contained in interior coating of beverage and food cans. In addition, it is used as a colour former in so-called thermal papers for thermal printers and fax machines.

What effects does bisphenol A have?
The substance is of low acute toxicity. However, it belongs to a group of substances that can have hormone-like (including oestrogen-like) effects. In principle, such substances can have an impact on all hormone-dependent processes, notably on the development of organisms. So far, no unequivocal evidence for the detrimental effects to human health of bisphenol A has been presented. In the human body, the substance is quickly converted into a metabolite which in itself no longer has any typical oestrogen-like effect and which is excreted via the kidneys.

What assessment conclusions does the EFSA draw in its opinion on bisphenol A?
The European Food Safety Authority (EFSA) has analysed extensive data in order to estimate exposure levels, i.e. the bisphenol A intake levels by consumers. The analysis led to the conclusion that consumers are exposed to less bisphenol A than previously assumed by the EFSA. The main sources of exposure to bisphenol A are food (oral) and thermal paper (dermal). Bisphenol A is - depending on the exposure route (orally or dermally) - metabolised at different rates in the body, thereby losing its oestrogen-like effect. Therefore, EFSA has converted the dermally absorbed quantities into oral equivalents. On that basis, the exposure contributions from all sources and via all routes can then be added up. The total value thus derived is referred to by the EFSA as the “aggregate exposure”. According to this aggregate exposure estimate, consumers take up bisphenol A at maximum levels between 1 and 1.5 micrograms (µg) per kilogramme (kg) of bodyweight per day.

In addition, the EFSA conducted an extensive literature search and evaluated several hundred epidemiological, animal and cell culture studies in order to improve the assessment of the potential health risks posed by bisphenol A. The relevance of these data for human health was evaluated by the EFSA using a so-called Weight of Evidence approach. This means that the strengths and weaknesses of experimental data are evaluated to estimate the impact of the data on a scientifically sound answer to a specific question.

The EFSA rates the likelihood that bisphenol A induces a specific health-relevant effect on a scale ranging from “very likely” to “unlikely”. “Very likely” and “likely” indicate that there is a strong correlation, whereas “unlikely” and “very unlikely” refer to a correlation which the EFSA considers as very weak.

Based on animal experiments, it is likely that high concentrations of BPA (which exceed the TDI more than one hundred-fold) are harmful to the liver and kidneys. Effects on the mammary glands of rodents from BPA are likely as well. The EFSA considers that the effects of low doses of bisphenol A on reproduction and development are “less likely”. Equally, the detrimental effects of bisphenol A on the nervous, metabolic, immune and cardiovascular systems are considered as “less likely” by the EFSA. The same applies to mutagenic and carcinogenic effects.

The EFSA emphasises that further studies are currently conducted on bisphenol A in the USA as part of the National Toxicology Program (NTP). These studies (including a two-year study on rats with prenatal exposure and further toxicokinetic studies involving humans) aim to clarify the uncertainties described by the EFSA with regard to the published data on the potential health effects of bisphenol A. For this reason, the EFSA determined a temporary tolerable daily intake (t-TDI) value denoting the quantity that a person can take throughout their life without any adverse health effects.

What is the TDI recommended in the EFSA opinion?
The TDI value (“tolerable daily intake”) is defined as the quantity of bisphenol A that can be taken up per kilogramme of bodyweight daily over a lifetime without any harmful effects. Since further studies are conducted on the subject of health risks arising from bisphenol A in the USA as part of the National Toxicology Program (NTP), the EFSA has defined a temporary (t-)TDI.

In its opinion of 2015, the EFSA derives a t-TDI of 4 µg of bisphenol A per kilogramme of bodyweight. According to the EFSA’s estimate, the maximum daily bisphenol A intake rate of consumers in the EU is at 1 to 1.5 µg of bisphenol A per kilogramme of bodyweight. This is significantly below the t-TDI i.e. significantly below the dose which can be taken over a lifetime without any appreciable health risks.

Why does the EFSA opinion issued in 2015 recommend a reduction of the current TDI for bisphenol A?
The EFSA had conducted an assessment of the health effect of bisphenol A in 2006 and laid down a TDI value for consumers of 50 micrograms (µg) per kilogramme of bodyweight. In order to record the effects of bisphenol A, multigeneration studies were carried out in mice and rats to whom bisphenol A was orally administered over a wide dose range. In 2010, the EFSA revised this health assessment and confirmed the TDI value by additionally assessing more recent experimental studies from the years 2006 to 2010. The EFSA concluded that this data did not call for a change in the TDI.

However, in its opinion of 2010, the EFSA pointed out that recent data with so far unclear relevance for human health was now available for the risk assessment of bisphenol A. The EFSA was referring to studies on the influence of bisphenol A on the immune system, on biochemical changes in the central nervous system and on the question to what extent bisphenol A may contribute to an enhanced susceptibility to breast cancer development. These effects were described in scientific studies in the low-dose range of bisphenol A (below the TDI), although the relevance of these study results for humans was still unclear and still the subject of debates all over the world. For these reasons, the EFSA reviewed the TDI again in the years 2010 and 2015 on the basis of the latest studies.

The EFSA opinion of 2015 lays down a temporary TDI (t-TDI), as studies on the health risks associated with bisphenol A are currently underway in the USA. This t-TDI of 4 µg/kg of bodyweight (EFSA, 2015) is based on new significant data on toxicokinetics. Toxicokinetics is concerned with time-dependent changes of substrate concentrations in the organism and thus describes the absorption, distribution, conversion and excretion of substances. Thus it has been observed that at the same BPA dose, the concentration of bisphenol A in the blood is much higher in humans than in mice. This new toxicokinetic data then enabled the EFSA experts to convert the dose which in mice causes harmful effects to an equivalent oral dose for humans. When converting the results from the studies on mice to humans, a specific conversion factor was used. This means that the TDI was lowered on the basis of more realistic data for the extrapolation of the dose relationship from animals to humans.
Due to the lack of studies with suitable dose-response curves, uncertainty analyses were additionally conducted on low-dose effects. This approach was applied to establish the lowest dose above which the occurrence of such effects in animal experiments can no longer be ruled out. This dose was then taken into account when determining the t-TDI. This means that in its risk assessment of BPA, the EFSA even took into consideration study results with previously unclear relevance for human health.

What is the BfR's view on the new EFSA opinion?
BfR experts were involved in the comprehensive new assessment of bisphenol A at the European level. The assessment presented in the EFSA opinion incorporates current data on the intake of bisphenol A via food and from thermal paper as well as other, less significant, sources of exposures such as toys, cosmetic products and house dust.

In the view of the BfR, the EFSA has made an important contribution to the estimation of the effective BPA intake by consumers by compiling and weighting the possible sources of exposure as derived from extensive data from Europe. The EFSA has thereby provided the basis for a sound risk assessment of the health effects of bisphenol A. The BfR welcomes that the TDI is lowered based on recent scientific data.

The BfR agrees with the assessment of the EFSA that effects from bisphenol A on reproduction and development are less likely in the low-dose range. The BfR has endorsed the assessment regarding the effects of higher bisphenol A doses from reproduction studies on rodents (liver, kidneys) in the past. The likelihood of changes in the mammary glands after bisphenol A treatment has become more topical as a result of additional studies in recent years.

The BfR is responsible for assessing bisphenol A in food contact materials such as tableware and internal coatings of cans. For the BfR, the key point is the statement of the EFSA that the risk for human health is low because consumer exposure to bisphenol A is below the temporary TDI value (t-TDI).

What is the BfR's view on the assumption that even low doses of hormone-like acting substances are to be considered hazardous?
The so-called low-dose effects, especially those that are detected only in low but not high dosages are the subject of intensive expert debates. The general rule is "the dose makes the poison", i.e. the effects should decrease as the dose is lowered. In the view of the BfR, no harmful low-dose effects from bisphenol A have been reliably identified to date that would cast doubt on the EFSA assessments. In defining the t-TDI, the EFSA has taken into account the uncertainties arising from the assessment of low-dose effects. The BfR constantly follows and critically assesses the current studies on the harmful effects of the low-dose effects of bisphenol A.

New study designs taking into account further toxicological endpoints in standard tests may be useful to reassess the possible relevance of low-dose effects. Since there are many toxicological endpoints with unclear relevance to humans, a great need for research exists in this area. In consequence, numerous studies on low-dose effects are currently being conducted internationally.

Should those effects in the low-dose range that have so far not been considered in the assessment turn out to be relevant for humans, this would not only impact the assessment of bisphenol A. Presumably, this would also concern the assessment of many other substances in foods as well as in plastics and other materials for which evidence of hormone-like effects has been presented.

In what context is the BfR concerned with Bisphenol A?
One of the legal mandates of the BfR is to assess the risks arising from the materials of consumer products, to communicate its findings and, where applicable, to propose possible measures to minimise these risks. This explains why the institute is also concerned with the assessment of bisphenol A in tableware, food cans and other products intended for consumers.

Within the framework of the REACH Regulation (EC) No. 1907/2006, the BfR is the assessment body for "Health and Consumer Protection" with regards to issues of the health aspects of bisphenol A and for assessing risk reduction measures.

The institute provides information to the authorities that by law are responsible for regulation and communicates the findings of its scientific assessment to the public. Legal regulation of the use of bisphenol A is outside the area of responsibility of the BfR.

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

It specifies the maximum amount of bisphenol A that is allowed to migrate from a food contact material made of plastic, for example packaging, into food. For bisphenol A, this "Specific Migration Limit (SML)" is 600 micrograms (µg) per kilogramme of food (simulant). The SML is based on a daily intake of 10 micrograms (µg) of bisphenol A per kg of bodyweight that can be taken over a lifetime without any appreciable health risk. The value was derived by the Scientific Committee on Food (SCF) in 2002. The regulatory measures on bisphenol A in food contact materials are currently being reassessed by the European Commission based on the new EFSA opinion (2015).

As part of precautionary consumer protection, the EU regulation also lays down that bisphenol A must not be used in the production of baby bottles made of polycarbonate.

Is the limit value for bisphenol A about to be changed within the EU?
The EFSA does not take political decisions but only assesses the state of scientific knowledge. The decision whether the recommended temporary TDI is implemented in a new limit value or possibly in other regulatory measures in the EU Regulation on plastic materials and articles intended for contact with food lies with the European Commission and the EU member states.

Do children ingest harmful quantities of bisphenol A?
The EFSA has conducted an exposure assessment for various population groups. Making a conservative (worst-case) assumption of high aggregate oral and dermal exposure, the EFSA derived a maximum daily bisphenol A intake rate of about 1.3 micrograms per kg of bodyweight for children aged between three and ten years. For younger children, the EFSA assumed a significantly lower intake. The maximum value for aggregate exposure across all age groups is 1.5 micrograms per kg of bodyweight and day. This means that for all population groups - including infants, children and women of childbearing age - the bisphenol A intake rates are below the temporary TDI value of 4 micrograms (µg) per kilogramme of bodyweight derived by the EFSA.

Why has the European Commission banned bisphenol A in baby bottles?
Due to the controversial discussion on effects of bisphenol A in the low-dose range, the EU member states Denmark and France banned the substance in baby bottles in 2010. The ban was imposed solely for reasons of precautionary consumer protection. In order to create a uniform legal situation within the EU, the European Commission subsequently banned the use of bisphenol A in the production of baby bottles and the placing on the market of baby bottles manufactured with bisphenol A within the EU member states. These measures are in place since March and June 2011 respectively.

Since the use of bisphenol A is regulated at the European level, the European Commission is the authority in charge of imposing restrictions on the use of the substance.

Are there alternatives to baby bottles made of polycarbonate?
There are various plastic alternatives to polycarbonate, for example, baby bottles made of polypropylene and polyethersulfone are available on the market and advertised as “BPA-free”. BPA stands for bisphenol A. Initial scientific studies indicate that many more substances are transferred to food from polypropylene than polycarbonate bottles. These substances have generally been assessed on the basis of test results from toxicological standard procedures. However, the toxicological properties of these substances have not been investigated as closely as those of bisphenol A.

Parents who would like to avoid the use of plastic baby bottles as a matter of principle can use glass bottles instead. However, the risk of breakage and injury has to be taken into account.

Can bisphenol A also be contained in pacifiers made of latex or silicone?
No bisphenol A is needed for the production of these materials. However, the substance can be contained in pacifiers with polycarbonate shields. According to the current state of knowledge, it is not to be expected that substances are transferred from the polycarbonate shield of the pacifier, provided that it is used as intended.

In 2009, the BfR conducted its own laboratory analyses to test for bisphenol A in 18 pacifiers of different manufacturers and brands made of latex and silicone. The goal was to establish how much bisphenol A is released during use of the pacifiers. Only in one pacifier was a bisphenol A release of 0.02 micrograms (µg) per pacifier and hour detected. This value can be regarded as safe. None of the other 17 pacifiers released any bisphenol A. These study results accord with the findings of the Austrian Agency for Health and Food Safety (AGES) and various control laboratories.

Why do the internal coatings of food and beverage cans contain bisphenol A?
As part of the production process of epoxy resins, bisphenol A is found as a contaminant. These epoxy resins are then used to coat the inside of food and beverage cans. This coating is necessary to prevent corrosion of the tin and the release of metals which would lead to contamination and discolouration of the food and to an adverse effect on its flavour.

Bisphenol A-free coating systems for this application are available only to a very limited extent and some are currently still awaiting assessment in terms of their health effects.

How can I tell whether the inside coating of food and beverage cans contain bisphenol A?
No obligation to label cans coated with epoxy resins is currently in force.

Why can bisphenol A be contained in till receipts, transport and parking tickets?
A further source of bisphenol A is so-called thermal paper. Thermal paper is used in thermal printing systems used in cash registers, transport ticket tellers, parking ticket machines and printers for receipts and bank statements. In this application, the substance is used as a colour former.

How much bisphenol A is contained in these thermal papers?
According to studies conducted by various laboratories, thermal papers contain between 0.5 and 3.2 percent of bisphenol A which is not firmly bound in the material and which can therefore easily be released.

Does bisphenol A from thermal papers pose a health risk to consumers?
Recent exposure estimates for the dermal exposure to bisphenol A through thermal paper have induced the EFSA to rank this source of exposure as the second-most important one after food. In the estimate of the EFSA this source of exposure can constitute a significant part of the overall exposure (aggregate exposure) of children over the age of 3, adolescents and adults. However, the uncertainty as to how much bisphenol A is actually transferred from the thermal paper to the skin and then absorbed through the skin is much higher than for foods. For children under three years of age, this source of exposure is irrelevant. However, it should be ensured that children do not play with till and other receipts, nor transport tickets made of thermal paper. For smaller children in particular, it cannot be ruled out that they put these papers in their mouth during play and that they may thus orally ingest bisphenol A from the paper.