Frequently Asked Questions on bisphenol A in consumer products

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The chemical substance bisphenol A is contained in products made of polycarbonate, including food and drink containers and bottles. Bisphenol A is also used for manufacturing internal coatings of beverage and food cans. A further application of bisphenol A are thermal papers onto which till receipts, transportation and car park tickets are printed.

For years now, there has been an ongoing scientific debate worldwide on the risk assessment of this industrial chemical. On 17 January 2014, the European Food Safety Authority (EFSA) published a draft version of a new opinion on the assessment of the health risks from the use of Bisphenol A in food contact materials (such as polycarbonate containers and internal linings of cans) for public comment. In this draft opinion, EFSA comes to the conclusion that the risk to human health is low, as consumers are exposed to less bisphenol A than the quantities that would be potentially harmful to health.

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 resins.

Where is bisphenol A found?
The substance can be contained in products made of polycarbonate including articles that come into contact with food. Examples include water bottles (in the past also baby bottles) and tableware. Bisphenol A can also be contained in the internal lining of beverage and food cans. In addition, bisphenol A is used as colour former in so-called thermal papers for thermal printers and fax machines.

Which are the potential effects of bisphenol A?
The substance has low acute toxicity. However, bisphenol A belongs to a group of substances which can have hormone-like (e.g. estrogenic) effects. In the field of science, these substances are called “endocrine disruptors”. In principle, such substances can have effects on all hormone-dependent processes, especially on the development of organisms. Nevertheless, no detrimental health effects from bisphenol A have been demonstrated for humans so far. In the human body, the substance is quickly converted into a metabolite which itself no longer has any estrogenic effects and is excreted via the kidneys.

When will the final ESFA opinion be published?
After the consultation phase up to 13 March 2014, EFSA will process the questions and comments and, where appropriate, incorporate them in the final opinion.

What are the findings of EFSA in its draft opinion on bisphenol A?
The European Food Safety Authority (EFSA) has evaluated a wide range of data to permit estimation of exposure levels - i.e. the bisphenol A intake by consumers. The analysis showed that consumers ingest less bisphenol A than was previously assumed by EFSA. Based on the new evaluation, consumers are exposed to a maximum of approx. 1 to 1.5 micrograms (µg) of bisphenol A per kilogram (kg) of body weight every day via food (orally) and thermal paper (dermally).

In addition, EFSA has conducted a new literature review and evaluated over 450 epidemiological, animal and cell culture studies in order to permit more accurate assessment of the potential health risks of bisphenol A. As part of this process, EFSA determined the relevance of data for human health using a so-called "weight of evidence approach". This approach assesses the strengths and weaknesses of data from experimental studies in terms of their predictive power with the aim of providing a scientifically sound answer to a specific question.

EFSA ranks the probability that bisphenol A causes a specific health-related effect on a scale from "very likely" to "unlikely", where "very likely" and "likely" denote a strong relationship, and "unlikely" and "very unlikely" denote a relationship that EFSA classifies as "weak".

EFSA emphasises the health-related effects of bisphenol A on kidneys, liver and mammary gland as "likely" but assesses effects of low doses of bisphenol A on reproduction and development as well as harmful effects on nervous system, metabolism, immune system and cardiovascular system or mutagenic and carcinogenic effects as less likely.

EFSA refers to further studies currently being conducted on bisphenol A in the USA as part of the National Toxicology Program (NTP). It is expected that these studies (including a 2-year study on rats with prenatal exposure as well as other toxicokinetic studies, some of them on humans) will also help to clarify the uncertainty described by EFSA with regard to the published data on the potential health effects of bisphenol A. For this reason, EFSA has defined a temporary tolerable daily intake (t-TDI).

What is the proposed TDI in the EFSA draft?
The TDI value ("tolerable daily intake") is the quantity of bisphenol A to wich humans can be exposed daily per kilogram of body weight over the course of a lifetime without the risk of harmful effects on health.

As further studies are currently underway on the health risks of bisphenol A within the framework of the NTP, EFSA has established a temporary (t-)TDI.

In its draft opinion, EFSA proposes a t-TDI of 5 µg of bisphenol A per kilogram of body weight. This t-TDI (in other words, the daily tolerated exposure over a lifetime without any health risk) is higher than the maximum daily intake which was estimated by EFSA to be at 1 to 1.5 µg of bisphenol A per kilogram of body weight.

Why does the EFSA draft propose lowering the current TDI for bisphenol A?
EFSA conducted its first health assessment of bisphenol A in 2006 and stipulated a TDI of 50 micrograms (µg) per kilogram of body weight as safe for the consumer. In order to investigate the potential impact of bisphenol A on the reproductive system, multi-generation studies with mice and rats have been conducted. As part of the studies, the animals were given bisphenol A over wide dose ranges. EFSA reviewed this health assessment in 2010 and confirmed the TDI value based on the additional assessment of more recent experimental studies from 2006 to 2010. EFSA came to the conclusion that the new data did not warrant any change in the TDI.

In its 2010 opinion, however, EFSA pointed out that new reports were available on bisphenol A -induced effects on the immune system, on biochemical changes in the central nervous system and on the potential sensitisation to the development of breast cancer. These effects were described in scientific studies in the low-dose range of bisphenol A (below the TDI), although the relevance of the study findings for humans is currently unclear and the subject

of debate worldwide. For this reason, EFSA reviewed the TDI once again in the period from 2010 to 2013 on the basis of more recent studies.

The t-TDI proposal of 5 µg/kg of body weight in the EFSA 2014 draft opinion is based on new, robust studies on toxicokinetics. Toxicokinetics investigates the change over time of the substance concentration in the organism and therefore describes the intake, distribution, conversion and excretion of substances. It has been estimated that with comparable intakes, the concentration of bisphenol A in the blood of humans is far higher than in the blood of mice. This new toxicokinetic data enabled the EFSA experts to convert the dose which is harmful to mice into a corresponding oral dose for humans. To this end, an appropriate conversion factor was used to extrapolate the findings from mice studies to humans. The reduction of the TDI was therefore based on more realistic data for the extrapolation of the dose-effect relationship from animals to humans.

How does the BfR view the EFSA draft opinion?
BfR experts were involved in the comprehensive re-assessment of bisphenol A on European level. Updated data on the ingestion of bisphenol A via food and thermal paper have been incorporated in the EFSA opinion.

In the opinion of the BfR, EFSA's collation and weighting of potential exposure sources based on comprehensive data from Europe makes a key contribution to the assessment of the actual intake amounts of consumers and therefore paves the way for a well-founded health risk assessment of bisphenol A. The BfR welcomes the proposal to adjust the TDI based on new scientific findings.

The BfR shares the assessment of EFSA that effects of bisphenol A on reproduction and development are less likely in the low-dose range. The BfR has already voiced this assessment in the past with regard to the effects of higher bisphenol A doses observed in reproduction studies using rodents (liver, kidneys). More recent studies in the past few years have focused more on the likelihood of changes in the mammary glands due to the exposure to bisphenol A.

The BfR is responsible for the assessment of bisphenol A in food contact materials like tableware and the inner linings of cans. What is decisive for the assessment of the BfR is the EFSA statement that the risk to human health is low as consumer exposure to bisphenol A is below the temporary TDI value (t-TDI).

What is the BfR's view of the assumption that low amounts of substances with hormone-like effects are to be considered dangerous?
The so-called low-dose effects, above all those detected only with low but not with higher doses, are disputed among toxicologists and are still in a phase of controversial scientific debate. The general rule is: “the dose determines the poison”, i.e. a reduction of the dosage should lead to decreased (or no) effects. So far no detrimental health effects of low doses of bisphenol A have reliably been identified which would call into question the EFSA assessments. However, the BfR continues to follow and critically evaluate current research in this area.

New study designs taking into account further toxicological endpoints in standard investigations may help to establish the possible relevance of low-dose effects. Since there are numerous toxicological endpoints whose relevance to human health is unclear, there is an urgent need for research in this area. For this reason, large numbers of studies on low-dose effects are currently being conducted internationally.

If newly emerging low-dose effects turn out to be relevant to human health, this would strongly impact the current risk assessment of bisphenol A. Additionally, this could have implications for the assessment of many other endocrine-active substances that are found in food as well as in plastics and other materials.

Why is the BfR looking into the issue of bisphenol A?
Among other things, the BfR has a statutory mandate to assess the risks posed by chemicals in products intended for consumers, to communicate those risks, and, where relevant, to propose measures for risk reduction. 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, 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)” amounts to 600 micrograms (µg) per kilogram of food (simulant). The SML is based on a daily intake of 10 micrograms (µg) of bisphenol A per kg of body weight during life without health risks. This value was derived by the Scientific Committee on Food (SCF) in 2002. As soon as the final new EFSA opinion (2014), which is currently only a draft, is published, the EU Commission will review the regulatory measures for bisphenol A in food contact materials.

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

Will the limit value for bisphenol A in the EU now be changed?
EFSA does not make any political decisions but assesses the current status of knowledge. The decision whether the proposed temporary TDI will result in a new limit value or, where applicable, other regulatory measures in the EU Regulation on plastic that come into contact with food lies with the EU Commission and the member states.

Are children exposed to amounts of bisphenol A that are harmful to health?
EFSA has examined exposure levels for different population groups. Based on the cautious (worst-case) assumption of combined high oral and dermal exposure, EFSA has calculated a maximum daily bisphenol A intake of roughly 1.3 micrograms per kg of body weight for children between the ages of 3 and 10. EFSA assumed far lower intake levels among younger children. Bisphenol A intake of children and all other population groups - including women of child-bearing age - is below the temporary TDI value derived by EFSA of 5 micrograms (µg) per kilogram of body weight.

Why has the European Commission banned bisphenol A in baby bottles?
Due to the controversial debate on the effect 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 consistent legal framework within the EU, the European Commission consequently 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 within the EU member states. The ban has been in effect since March and June 2011 respectively.

Since the use of bisphenol A is regulated at the European level, the European Commission is the competent authority for laying down restrictions on the use of the substance.

Are there alternatives to baby bottles made of polycarbonate?
There are various plastic alternatives to polycarbonate; baby bottles made of polypropylene and polyethersulfone are available, for example, which are advertised as BPA-free products. BPA stands for bisphenol A. The first scientific studies show that polypropylene bottles can release significantly more substances into food than polycarbonate. These substances were generally assessed on the basis of results from toxicological standard tests. However, the toxicological properties of these substances were not investigated as intensively as those of bisphenol A.

Parents who would like to avoid plastic bottles altogether can use glass bottles instead. 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 tested 18 baby soothers of different manufacturers and brands made of latex and silicone for bisphenol A. The aim was to find out how much bisphenol A is released when the soothers are used. Only in one dummy was a release of bisphenol A detected, amounting to 0.02 micrograms (µg) per soother and hour. This value is considered safe in terms of its health effects. None of the other 17 dummies released any bisphenol A. These test results are consistent with results of the Austrian Agency for Health and Food Safety (AGES) and various surveillance laboratories.

Why do the internal coatings of food and beverage cans contain bisphenol A?
As a contaminant resulting from the manufacturing process, bisphenol A is found in epoxy resins (epoxide resins) which are also used in internal linings of food and beverage cans. Such coating is necessary to prevent corrosion of the tin and release of metals which would cause contamination of the food as well as discolouration and impairment of the flavour.

Bisphenol A-free coating systems are up to now limited to a few applications and in some cases still await an evaluation of their health effects.

How can I tell whether internal linings of food and beverage cans contain bisphenol A?
It is not mandatory to label cans which are coated with epoxide resins.

Why can bisphenol A be contained in till receipts, transportation and car park tickets?
A further application of bisphenol A is so-called thermal paper. Thermal paper is used for thermal printing systems which are integrated in cash registers, ticket offices, parking meters as well as printers for receipts and bank statements, where the substance is used as a colour former.

What is the bisphenol A content in these thermal papers?
According to tests done by various laboratories, thermal papers contain between 0.5 and 3.2 per cent of free bisphenol A which is not bound in the material and which can therefore easily be released.

Does bisphenol A exposure from thermal papers pose a health risk for consumers?
Recent exposure estimates for dermal exposure to bisphenol A from thermal paper have prompted EFSA to view this source of exposure as the second most important source after food. Based on EFSA estimates, this exposure path might account for around 7 to 15% of average total exposure in children above the age of 3 and adults. The uncertainty as to the amount of bisphenol A that actually enters the body via the skin from thermal paper is, however, far greater than is the case with food products. This exposure path plays no role at all in children below the age of 3. For reasons of precautionary consumer protection, it should be ensured that children do not play with till and other receipts, nor with tickets made of thermal paper. In particular in case of small children, it cannot be ruled out that they put these papers in their mouth during playing, so that they could orally ingest bisphenol A from the paper.