

New rules on bisphenol A in food contact materials

A new European Commission regulation updating the rules concerning the use of bisphenol A (BPA) in food contact materials was published on 14 February 2018 and will apply as of 6 September 2018. The rules aim at better protecting children under three years of age, by extending the ban on the use of BPA to include, in addition to infant feeding bottles, drinking cups or bottles intended for infants and young children.

Background

Bisphenol A (BPA) is a chemical substance used in the manufacture of certain plastics, including food contact materials, such as polycarbonate plastic (used for example in reusable drinking bottles, plates, mugs and storage containers) and epoxy resins (used in varnishes and coatings inside metal food and drink cans, and as a coating on metal lids for glass jars and bottles). BPA can leach into food from the material, resulting in exposure to BPA for consumers.

[Regulation \(EC\) No 1935/2004](#) lays down general requirements for food contact materials at EU level. The regulation also provides that specific measures can be set for certain types of materials, but so far, specific EU measures have only been adopted for four materials (plastics, ceramics, regenerated cellulose film, and active and intelligent materials).

The use of BPA is currently authorised in the production of plastic food contact materials ([Regulation \(EU\) No 10/2011](#)), but banned, on the basis of the precautionary principle, in polycarbonate infant feeding bottles ([Regulation \(EU\) No 321/2011](#)). As is the case with other authorised substances, the use of BPA is subject to a specific migration limit (the amount of the substance that is allowed to migrate from the food contact material into the food), currently set at 0.6 mg of BPA per kg of food (mg/kg).

Some Member States have already introduced restrictions on the use of BPA. Denmark and Belgium have banned BPA in food contact materials for infants and young children; Sweden has banned BPA in coatings and varnishes in FCMs intended for infants and young children; and France banned BPA in all food contact materials (except industrial equipment such as pipes and tanks) as of 1 January 2015. Differences between national laws affect the proper functioning of the internal market for food contact materials and pose challenges to third-country exporters. For example, imported canned fruit and vegetables are often brought to a centrally located EU Member State and distributed to other EU countries from there. Special production and distribution chains are now having to be established in order to comply with individual national rules.

Recent opinions and decisions concerning BPA

After four times updating its scientific advice between 2006 and 2011, the European Food Safety Authority (EFSA) completed a full [re-evaluation](#) of BPA in 2015, leading to a 'scientific opinion' on the subject. In addition to dietary exposure, EFSA estimated non-dietary sources, such as exposure through the skin due to contact with thermal paper (used in receipts) and cosmetics. It concluded that there is no health concern for BPA at the estimated levels of dietary exposure. However, also taking into account other possible sources of exposure, a new temporary Tolerable Daily Intake (t-TDI) of 4 µg/kg bodyweight per day was established, pending the anticipated outcome of a long-term toxicity study on BPA being undertaken in the United States (called [CLARITY-BPA](#)).

In June 2017, the Member State Committee of the European Chemicals Agency (ECHA) decided unanimously, with two Member States abstaining from the vote, to identify BPA as a [substance of very high concern](#) (SVHC) due to its endocrine-disrupting properties 'for which there is scientific evidence of probable serious effects to human health'. PlasticsEurope, the association of plastics manufacturers, [filed a lawsuit](#) in the General Court



in September 2017 against ECHA over its decision, alleging that the Agency had infringed the principle of legal certainty by applying inconsistent and unforeseeable criteria to assess the endocrine-disrupting properties for human health of BPA, and that it failed to take into account all relevant information, in particular the ongoing CLARITY-BPA study.

European Commission action

The European Commission has taken the view that the specific migration limit for plastic materials should be updated following EFSA's 2015 opinion. The limit will, therefore, be lowered from 0.6 mg to 0.05 mg of BPA per kg of food (mg/kg) for plastic materials, and the same limit will apply for varnishes and coatings intended to come into contact with food. Currently BPA-based coatings are used in around 80 % of metal cans.

The Commission argues that, taking into account the extent of the scientific uncertainties and the nature of the potential adverse effects pointed to by new studies, further precautionary steps should be taken as regards more vulnerable population groups, in particular infants and young children, where 'developmental effects could be irreversible and would last a life-time'. The Commission points out that it is authorised to take preventive measures as regards the use of BPA on the basis of the precautionary principle, applicable in a situation in which there is scientific uncertainty, even if the risk, notably to human health, has not yet been fully demonstrated. As a result, the Commission decided to bring in a new measure, under the 'Regulatory Procedure with Scrutiny', extending the ban on the use of BPA to polycarbonate drinking cups or bottles specifically intended for infants and young children, up to three years of age (as defined in [Regulation \(EU\) No 609/2013](#)).

Under the Commission's [new regulation](#), no migration of BPA will be permitted, above the detection limit of 0.01 mg/kg, from varnishes and coatings applied to materials specifically intended to come into contact with food intended for infants and young children (infant formula, follow-on formula, processed cereal-based food, baby food or milk-based drinks and similar products specifically intended for young children). In addition, the regulation defines rules for checking compliance with the restrictions.

The Commission proposal was supported by the majority of Member States' experts in the standing committee on Plants, Animals, Food and Feed on [25 September 2017](#). The resulting Commission regulation on the use of BPA in food contact materials was published in the *Official Journal of the European Union* on 14 February 2018, after neither the Parliament nor Council objected to it by the deadline of 28 January 2018. It will enter into force on the 20th day following its publication, and apply as of 6 September 2018.

European Parliament position

In its [resolution](#) of 6 October 2016 on the implementation of the Food Contact Materials Regulation, the Parliament noted that multiple EFSA re-evaluations over the last decade have not effectively addressed all health concerns, and called for a ban on BPA in all food contact materials. Furthermore, the Parliament called on the Commission to ensure better coordination between legislation on chemicals and food contact materials, and to prioritise the drawing-up of specific EU measures for paper and board, varnishes and coatings, metals and alloys, printing inks and adhesives. The Parliament also stressed that alternatives should not include bisphenol S (BPS) as a substitute for BPA, as BPS may have a toxicological profile similar to BPA.

On 11 January 2018, a draft [motion](#) for a resolution objecting to the new Commission regulation, on the grounds that it did not go far enough and failed to ensure a high level of protection of human health and vulnerable groups, such as pregnant women and their unborn children, was rejected in the Parliament's Committee on the Environment, Public Health and Food Safety (ENVI).

Outlook

The Commission has recently finished (December 2017) a public consultation on [evaluating](#) the current legislation on food contact materials, with the evaluation due to be completed in 2019. To support the Commission's assessment work, the Joint Research Centre published a [study](#) (2016) on the market situation of food contact materials not harmonised at EU level. In December 2017, EFSA [announced](#) that it had finalised its strategy for the next re-evaluation of the toxicity of BPA, with a working group to be set up in 2018. The new EFSA opinion could be expected by the end of 2019. The results of the CLARITY-BPA project in the USA are expected to become available in early 2018. In January 2020, a restriction on the use of [BPA in thermal paper](#) will come into effect through the [REACH \(Registration, Evaluation, Authorisation and Restriction of Chemicals\) regulation](#), which will reduce BPA in packaging made of recycled material.

This is an updated edition of an 'At a glance' note originally published in January 2018.