

Proposal to restrict Bisphenols in the European Union

TÜV Rheinland LGA Products - Information

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Within the last years European Union restricted several application of Bisphenol A (CAS 80-05-7, 4,4'-isopropylidenediphenol) like the use in thermal paper and in toys as well as listing it as a Substance of Very High Concern (SVHC) due to its endocrine disrupting properties for humans and the environment.

The restriction proposal now published by the European Chemical Agency (ECHA) was prepared by the Germany Federal Environment Agency (UBA) in cooperation with the Federal Institute for Occupational Safety and Health (BAuA) and has been publicly discussed in two stakeholder consultations in 2020 and 2021.

The ECHA Annex XV Restriction report¹ proposes to limit the concentration of free Bisphenol A and other Bisphenols (Bisphenol B, S, F or AF) in articles to 10 mg/kg (0.001 %) in total.

However, the restriction proposal also describes exceptions, including :

- Contact with water
- Migration limit
- Covalently bonded Bisphenols
- Waste papers
- Fluoropolymers
- Products made from epoxy resins

WHAT'S IN STORE FOR US?

The proposals will be assessed by the Scientific Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) in the coming months. Once the committees have agreed, further consultations will follow.

The proposal covers not only BPA but also structurally related compounds, including Bisphenols such as B, S, F, AF and others, which are thought to have an endocrine disrupting effect.

It should be noted that the limit value of 10 mg/kg is not toxicologically derived and justified. The background is assumed effects in the environment, rather than a toxicological effect on humans.

The statement in the second stakeholder consultation was: *"The limit value of 10 ppm has proven to be target-oriented and practicable, especially for products."* As far as can be seen, this value is not derived scientifically and from an ecotoxicological point of view.

¹ <https://echa.europa.eu/en/restrictions-under-consideration/-/substance-rev/71401/term>

EXCEPTIONS IN DETAIL:

- **Contact with water** - If contact with aqueous media in any form, including cleaning, can be excluded during use.

Note - With this exception, many materials in certain uses fall outside the scope of the restriction, although there is room for interpretation here, e.g.:

- Circuit boards and electronic components of electrical appliances, machines and vehicles
- Textiles for indoor use which are not usually cleaned, e.g. upholstered furniture, carpeting
- Components in the vehicle interior
- Internal, non-accessible components of products which also do not come into contact with water.

- **Migration limit** - If not more than 0.04 mg/l of these Bisphenols are released from the article into the environment over its entire useful life.

Note - The conditions for the migration test, if required/possible, are intended to simulate the possible release of the Bisphenols into the environment and are described in an annex.

The selection of the test conditions in terms of temperature and time should be based on the regulation for plastics in contact with foodstuffs². Products that are exposed to environmental influences should be subjected to weathering prior to this migration test that corresponds to the foreseeable service life, e.g. several years for garden furniture or building materials. Obviously, there is still room for interpretation here, which is to be closed by a guideline to be prepared by the JRC.

- **Mixtures and articles** in which the Bisphenols are covalently bonded, e.g. incorporated into the polymer chain, or used as intermediates in the manufacture of polymers.
- A limit value of 150 mg/kg applies to **waste paper** for 78 months (6.5 years). It is assumed that after this time the content of Bisphenols in waste paper (mostly from sales slips and adhesive labels of mail order companies) will have decreased significantly, if then in 10 years the tax receipts are not disposed of in the waste paper. This limit value is predictably not applicable to food contact papers.
- For **fluoropolymers**, a limit value of 50 mg/kg is granted with a transitional period of 10 years. Fluoropolymers are used extensively as sealing components in hydraulics, machinery and vehicles. It should be noted that the acceptability of the use of fluoropolymers is discussed elsewhere. It should be noted that the permissibility of using fluoropolymers is discussed elsewhere.
- For products manufactured using **epoxy resins**, a limit value of 65 mg/kg applies. For mixtures, e.g. adhesives intended for consumers (non-professional users), a stricter limit value of 1 mg/kg applies.

Note - In the case of varnishes, adhesives and other mixtures which harden during processing, it is to be assumed that the limit value of 10 mg/kg refers to the resulting product. E.g. the content of Bisphenols in a lacquer is thus "diluted" by the substrate, base metal, in the case of a lacquered sheet metal.

² Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with foodstuffs

WHAT ARE RELEVANT MATERIALS AND PRODUCTS?

Materials	Products
Synthetic resins based on phenolic resins	Printed circuit boards and components on printed circuit boards
Synthetic resins, lacquers and adhesives based on epoxy resins	Abrasives bonded with synthetic resins; Cutting discs, grinding pins, abrasive papers, ...
Thermoplastic elastomers (TPE)	Panes, containers, components made of polycarbonate
Polycarbonate	Phenolic resin boards (insulation boards)
Polysulfones, polyetherketones and PVC	Components made of TPE and other polymers
Colour developer in thermal papers	Recycled materials (polymers and waste paper)

CLOTHING, TEXTILES AND LEATHER

Various test campaigns on textiles and also socks made of polyester, cotton and spandex blends have shown that levels of BPA of up to 10 mg/kg or more are possible in these textiles. Synthetic polymers (syntans) are used as after-treatment agents in polyamide dyeing and in leather as tanning and retanning agents to achieve sufficient tanning effect and colour fastness. These syntans usually contain significant amounts of Bisphenol S and F.

Substance	Polyester, cotton and blends	Spandex	Polyamide	Chrome free tanned leather
Bisphenol A	•	•		
Bisphenol S			•	•
Bisphenol F			•	•

Further information on current legal changes can also be found on our homepage at www.tuv.com or <https://www.tuv.com/regulations-and-standards/en/>.

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Infobox: You can also find more information about REACH services at <https://www.tuv.com/germany/de/reach.html>

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