

# Bisphenol A vs EU REACH: Brief note to ESA projects on regulatory status of BPA

The substance 4,4'-isopropylidenediphenol (CAS 80-05-7, EC 201-245-8) – also known as Bisphenol A, BPA – is targeted by various regulatory actions in the EU (including but not limited to the EU REACH Regulation) due to its hazard profile.

# Space applications

BPA can currently be found in a multitude of space-related applications. In particular, BPA containing **epoxies** are widely used in epoxy adhesives for structural and nonstructural bonding over a wide temperature envelope. In addition, BPA and BPF based epoxy composites are critical for satellites and launchers. In satellites, composites form the backbone of both platform and payload structures, support structures, solar arrays, tanks, as well as being used in reflectors and antennas. Similarly, launchers require composites in their fairings, adapters, stage and interface structures, skirts, tanks, etc. According to REACH Article 33(1) declarations received BPA is also present above 0.1% w/w in a number of **electronic components** for space applications.

#### EU REACH Candidate List

BPA has been included in the EU REACH Candidate List of substances of very high concern (SVHCs) for Authorisation for the following reasons / intrinsic properties (<u>link to entry</u>):

- Toxic for reproduction, Category 1B (REACH Art. 57(c)) ECHA decision of 4.1.2017 (link)
- Endocrine disrupting properties (Article 57(f) human health) ECHA decision of 6.7.2017 (link)
- Endocrine disrupting properties (Article 57(f) environment) ECHA decision of 3.1.2018 (link)

EU/EEA suppliers of articles containing candidate-listed substances in a concentration **above 0.1 % w/w** have reporting obligations under REACH Article 33(1) towards the recipients of the article and to the ECHA SCIP Database (<u>link to ECHA SCIP page</u>).

# ECHA recommendation for inclusion in the Authorisation List

On 1.10.2019 ECHA has recommended BPA for inclusion in the Authorisation List (REACH Annex XIV) given the aforementioned properties (<u>link to recommendation</u>).

However, the European Commission is not obliged to follow this recommendation and decided to **postpone** the inclusion of BPA in Annex XIV, because a dossier is under preparation to restrict the use of Bisphenol A and structurally related bisphenols of similar concerns for the environment (Commission Regulation (EU) 2022/586 of 8 April 2022, recital (17), link).

#### **REACH Restrictions in place**

BPA is currently restricted for placing on the market in thermal paper (Entry 66 of REACH Annex XVII).

In addition, given its CLP harmonized classification a reproductive toxicant category 1B, BPA shall not be placed on the market, or used, as a substance, as constituent of other substances or in mixtures, <u>for supply</u> <u>to the general public</u> when the individual concentration in the substance or mixture is <u>equal to or greater</u> <u>than 0.3 %</u> (Table 3.7.2 in CLP Annex I); this use is hence *'restricted to professional users'* (<u>Entry 30 of</u> <u>REACH Annex XVII</u>, Commission Regulation (EU) 2017/1510 of 30.8.2017 amending the Appendices to

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Annex XVII to REACH as regards CMR substances (available <u>HERE</u>). This means that **professional and industrial use of BPA is NOT restricted / NOT legally affected** by this restriction.

## Outlook on possible additional future restrictions or other regulatory constraints

*Germany* has been pursuing a restriction of BPA and structurally related bisphenols (including derivatives) of similar concern given their **endocrine disrupting properties for the environment** (see ECHA Registry of Restriction Intentions). The intended restriction would target the placing on the market of mixtures and articles containing these substances above certain concentrations, but be subject to certain derogations. After the 6-month public consultation on the initial restriction proposal of 7.10.2022 (link), to which also Eurospace (supported by the MPTB/Space Restrictions Task Force) participated (see link to Eurospace alert of May 2023), Germany concluded that a revision of the proposal is necessary. Therefore, the proposal is currently "temporarily" withdrawn until further notice (see BAuA website). Germany intends to re-submit an updated proposal to ECHA once they have considered the information submitted during the consultation and reworked the scope of the restriction proposal.

Furthermore, the *European Commission* and *ECHA* are currently assessing the need for further regulatory action, including restrictions, SVHC-identification or harmonized classification and labelling for bisphenols and taking into account the work on the aforementioned German restriction dossier. Depending on the outcome of these discussions, the Commission could request ECHA to prepare a restriction dossier that may complement the restriction of some bisphenols for environmental risks due to **concerns for human health as well as to cover additional bisphenols**. The timing to progress any such restriction (or other measure) has not been decided yet (Source: Rolling List of (groups of) substances for restriction updating Annex I to the Restrictions Roadmap under the Chemicals Strategy for Sustainability SWD(2022) 128 final, revised version 1.7.2024).

It should also be noted that Bisphenol A (or bisphenols as a group) is being restricted in some EU product laws with consumer focus, such as in food packaging and toys.

# Workplace limit values

BPA also has the following binding Occupational Exposure Limit (OEL) according to Directive 2004/37/EC (Carcinogens, Mutagens or Reprotoxic substances Directive - CMRD), as amended by Directive (EU) 2022/431 of 9.3.2022 (LINK). Employers are obliged to minimise worker exposure as far as possible, and must arrange for medical surveillance of workers exposed.

Name of Agent	EC Number	CAS	Long-term Exposure Limit (LTEL) Values			Short-term Exposure Limit (STEL) Values		Expressed As	Carcinogen Category	Physical form	Dermal Sensitisation	Respiratory Sensitisation	Skin Designation	Effective Date
Name			f/ml	mg/m3	ppm	mg/m3	ppm							
4.4'- Isopropylidenediphenol Bisphenol A	201- 245- 8	80- 05- 7		2 mg/m3						Inhalable fraction				

ECHA, acting on the request of the European Commission, is currently pursuing a further lowering of the existing OEL to  $0.2 \text{ mg/m}^3$  (see Table 1 in ECHA Scientific Report of 19.12.2023 – <u>LINK</u>). ECHA's Committee for Risk Assessment is required to adopt its opinion by 23.02.2025 (see <u>LINK</u> to ECHA process page). The revision process will then continue with the European Commission.



## **Continued use**

As a conclusion, **<u>Bisphenol A is still allowed to be used in the production of space hardware today and</u> <u>in the foreseeable future</u> where there are no viable alternatives. It is thus expected that uses of BPA without alternatives may legally continue in the EU space industry as long as necessary. Employers should ensure compliance with applicable national workplace limit values transposing the corresponding EU Directives. Compliance with reporting obligations (REACH Art. 33(1), WFD/SCIP) should also be ensured.** 

## **European Space Sector activities addressing BPA**

A dedicated Space Sector Task Force (**Restrictions Task Force (RTF)**) under the MPTB is closely monitoring the regulatory evolutions for BPA and other bisphenols to support continued use (link)

## **Contact for further questions**

For remaining questions, please contact <u>reach.officer@esa.int</u>.

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