

12 February 2021

JBCE's contribution to the Call for Evidence

4,4'-isopropylidenediphenol (Bisphenol A) and structurally related bisphenols of similar concern for the environment

As a cross-sector association with member companies operating in different industries and stages in the supply chain, JBCE welcomes the opportunity to contribute to the public consultation on call for comments and evidence of Bisphenol A and structurally related bisphenols.

1. Proper risk assessment for BPA and structural similar substances restriction

Polycarbonate and epoxy resins are widely used in a variety of industries the most relevant ones being automotive, food contact material, and EEE.

Because of the various industries also the potential stressors as well as the potential release to the environment of BPA and structural similar substances requires differentiated evaluation based on a proper risk assessment.

The BPA-use in thermal paper which posed by far the most relevant exposure has already been restricted. In addition, conservative precautionary migration limits for BPA in food contact materials and cosmetics already exist. We believe that the exposure to humans and the environment through any other application than the above is quite minimal.

Bisphenol AF (BPAF) as an example, is used for fluoroelastomers (FKM) as a cross-linking agent to produce pre-compounds and full compounds which contain FKMs. The cross-linking reaction between BPAF and FKM is a solid reaction. The FKM which is treated with BPAF is used in parts for automotive, and oil, gas and chemical processing. BPAF has almost completely reacted and incorporated in final FKM products and is therefore chemically bound. It is highly unlikely that BPAF is released into the environment at the standard operating temperature for FKMs between 200-270°C.

This type of FKM products treated with BPAF allow stable extrusion and molding processes for all kinds of technical rubber articles like O-rings, seals and fuel/turbo charge hoses which contribute to the safety in variety of sectors to prevent from leakage.

Therefore, JBCE would like to emphasize the need of a proper risk-based assessment which considers the specific applications and the specific potential exposure to humans and the environment.

2. Sufficient time to prepare for restrictions by the relevant sectors of industry is necessary

There are many industrial sectors that manufacture parts and assemble them over entire complex supply chains. Therefore, there will need to be enough time for companies in these sectors to prepare, in case BPA and structural similar substances are restricted despite the proper risk assessment. Even if a potential alternative substance for BPA could be identified, it is not always the case, that it can become a real and viable alternative. It still needs to be proven whether it shows the same level of performance after design change. It needs to be considered that many industrial sectors of course must comply with chemical and environmental regulations, but in addition also with sector-specific stringent product-related regulations as well as performance and safety standards. Special consideration is, for example, necessary for medical devices as well as monitoring, control and analytical devices, which require the Notified Body approval in the EU and equivalent approvals globally. If the preparation time for the compliance with new restrictions is too short, these devices with long design cycles cannot be placed on the EU market. In such cases the interrupt of supply will have a negative impact on continuous market reliability of the respective sector fields. Moreover, it would give negative influence on the environment, due to the disposal of the non-compliant inventory.

3. Proper threshold should be set based on the actual risk

Draft of EFSA Scientific Committee Opinion on biological plausibility of nonmonotonic dose responses and their impact on the risk assessment says that the "low dose effects" or "non-monotonic dose response" (NMDR) have NOT been shown for BPA.¹ It's the supposition of especially bad effects at especially low doses that is apparently the reason for the unusually low threshold of 0.02%. (0.1% is usual for known carcinogens, 1% for suspected carcinogens). JBCE strongly believes that appropriate thresholds in any REACH restriction needs to be based on a profound risk assessment and to consider science and socio-economic impact assessments.

4. Harmonised analytical standard for the proper enforcement

In order to receive reliable analytical results, the detection limit needs to be 10 times below the threshold (0.002% level of detectivity). As far as JBCE knows, there is no such standard analytical method to measure a whole kind of BPA and structural similar substances simultaneously. As the first step it would be necessary to establish standard analytical methods for each BPAs and structural similar substances. Here it must be also considered that even for the same substance the optimal method to extract the substance from sample material can significantly differ. Consequently, there are a variety of optimised analytical methods established in each industrial sector. For example, Japanese Food Sanitation Act which restricts hazardous substances used for food contact material, has specified the analytical methods for BPA detection and extraction from an article. There is a different standard method for detecting BPA released to the environment in Japan. Therefore, JBCE strongly believe that the lack of proper harmonised analytical standards will result in

¹ <https://www.efsa.europa.eu/sites/default/files/consultation/consultation/draft-opinion-NMDR.pdf>

improper enforcement that subsequently results in confusion through the global supply chain.

5. Proper method should be taken into consideration for the purpose to detect the concentration during service life

In the background note, the registry of intention for the restriction is as follows:

- A) Restricting the use as an additive and the content in articles (0.02% by weight)*
- B) Restricting content of residues (unreacted monomer) in articles – also for imported goods (0.02% by weight)*
- C) Restricting the use of mixtures with content of 0.02% by weight for industrial and professional uses where strictly controlled conditions cannot be assured, e.g. in nonautomated processes and for consumer uses.*
- D) Introducing release rates for BPA from articles (products and subassemblies) during service life (weathering, leaching due to cleaning action) preventing release into the environment and/or (direct) migration to organisms*

In terms of D), scientific data which demonstrate the potential impacts on the human health and the environment due to release from articles should be provided in advance. It is difficult to say a restriction of articles according to D) is appropriate without indication of the conditions to measure it and without sufficient explanation. From A) to C) are about the concentration in the mixture or in the article, however, D) is about the emission during service life. We believe that the analytical method should be different for the concentration in article and for the emission from the article during its service life.

6. Possible analytical equipment

- Gas Chromatography Mass Spectrometry (GC/MS)
- Triple Quadrupole Gas Chromatography Mass Spectrometry (GC/MS/MS)
- Liquid Chromatography (LC)
- Liquid Chromatography Mass Spectrometry (LC/MS)
- Triple Quadrupole Liquid Chromatography Mass Spectrometry (LC/MS/MS)

7. Alternatives (BPAF only)

Currently we have not identified an alternative to BPAF, particularly not for the use in the automotive sector. There is a patent application for an alternative, but the same performance with BPAF grades has not been confirmed as of yet.

There are several research works to explore alternatives particularly for the use in the automotive sector, such as diamine cured system and peroxide curing system. These however cannot replace the BPAF curing system, since it is reported that the materials produced with those methods do not have the same level of functions, such as heat resistance and compression set.

Overall, in our view no alternative to BPAF as a cross-linking agent to FKM made with BPAF has been identified on the market so far.

JBCE and its members support to promote for human health and environment in a realistic manner and on the basis of profound evaluation, and are willing to contribute to bring these ideas forward together with the European Institutions and other interested stakeholders.

ABOUT JBCE

Founded in 1999, the Japan Business Council in Europe (JBCE) is a leading European organization representing the interests of about 90 multinational companies of Japanese parentage active in Europe. Our members operate across a wide range of sectors, including information and communication technology, electronics, chemicals, automotive, machinery, wholesale trade, precision instruments, pharmaceutical, textiles and glass products.

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