21 December 2021

JBCE's contribution to2nd call for evidence on a Restriction for Bisphenol A and Bisphenols of similar concern (BPAF, BPB, BPF, BPS)

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 2nd call for comments and evidence of Bisphenol A and BosC.

1. **Proper threshold should be set based on the actual risk**

   The in conclusion of EFSA Scientific Committee Opinion on biological plausibility of nonmonotonic dose responses ("NMDR" or so-called "low dose effects") and their impact on the risk assessment says that the "no clear indications of NMDR were detected for BPA", although there were such indications for the phthalate DEHP.[1] It's the supposition of especially bad effects at especially low doses that is apparently the reason for the unusually low threshold of 10 ppm (0.001% by weight). (0.1% is usual for known carcinogens, 1% for suspected carcinogens).

   Polycarbonate and epoxy resins are widely used in a variety of industries some the most relevant ones being automotive, construction, food contact material, medical devices and EEE. Because of the various industries also the potential stressors as well as the potential release to the environment of BPA and BosC 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 S (BPS) has been used as a colour developer in the thermal paper and a development accelerator in the plates for commercial printing industries. Especially, thermal paper has a history that succeeded to replace from BPA to BPS in a long time. In the commercial printing industries, as the waste materials at printing industries have been collected and treated by appropriate professional ways, exposure to the consumer are very limited.

   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

[1] https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2021.6877f

bound. It is highly unlikely that BPAF is released into the environment at the standard operating temperature for FKMs between 200-250°C.
Similarly, the polymers based on BPA are also highly reacted. Products such as epoxy resins are cross-linked in the final manufacturing stage, such as the curing process manufacturing composites for wind energy. BPA and BPS are other examples known as raw material for polysulfone and polyethersulfone. These polymers have been used as filtration membrane for the purpose of purification of liquid and air at the many industries.
Thermoplasts like polycarbonate (PC) or polysulfone (PSf), polyethersulfone (PS), and polyether imide (PEI) are step-growth polymers which can only achieve useful mechanical strength at low residual BPA content.
JBCE strongly believes that appropriate thresholds in any REACH restriction must be based on a realistic risk assessment and to consider science and socio-economic impact assessments. Setting a limit orders of magnitude below the amount that would be needed to protect the environment would increase cost to consumers and deprive them of product performance and fill industry and enforcement laboratories with measurements that do not serve to safeguard the environment.
We expect that the thresholds should not be a common, but specific based on the potential hazard and risk for the exposure. Although industrial stakeholders are open to provide the data for this, we wish that the authorities would take into account for appropriate and sufficient period of derogation so that the industrial stakeholders and each company can investigate and provide the data.

2. **Threshold should be set which can be enforced in the face of reality**
The measurement results can be affected by type of matrix and/or additives. Therefore, it is necessary to thoroughly examine these influences first.
In addition, the variability of measurement results should be considered. It is usual that measurement results show variation. It is due to the variation between device types, the variation between devices (though they are same type) as well as the variation between operators. To account for these variations, it is necessary to set a threshold with a margin or a safety factor. Because there is no data on these variations are shown, it is not possible to discuss the threshold. Therefore, we suggest round robin tests in different laboratories using equipment from different manufacturers. Here the test should be conducted on BPA/BosC-free samples as well as samples with BPA/BosC in different concentrations. Considering the result of the test, the threshold should be determined which can be enforced in the face of reality.
Residual content can be detected using LCMS/MS, however, there is no standard method yet available. Therefore, the development of measurement method is necessary. IEC is currently preparing a related standard, however, the threshold value is not yet decided, and it is not clear whether this standard would be suitable for your suggestion of 10 ppm.

3. **Migration test (0.04 mg/l (migration limit) in total during it's service life)**
Migration testing would have to be done on the individual manufactured parts. It is unclear how the German authorities imagine such tests would be done. Would the migration limit be the sum of migration over a period of years or merely the individual results of a series of tests done on each part over the course of years.
Migration from polymers manufactured from BPA will always be very slow because their glass transition temperatures are quite high. BPA is also readily biodegradeable, so the amount in the environment at any time near such a polymer article will always be negligible.

Considering the huge number of different parts and use conditions, the laboratory capacity will be overwhelmed, and numbers of such test will be burden to article manufactures.

4. **Migration limit should reflect the actual use of the product**
The test for the release potential of BPA/BosC from weathering should be different depending on how articles are used during their service life. The examples given in "Supplemental material on migration - release potential of BPA/BosC during service life" assume a scenario in which the test object is degraded by exposure to sunlight and exposed to rain, resulting in environmental runoff of BPA/BosC. However, this is not the case, for example, if the test object is used indoors or used encapsuled. The suggested migration limit of 0.04mg/l is proposed in accordance with the existing migration limit for BPA in the EU Toy Safety Directive. This assumes a scenario in which small children put toys into their mouths, where BPA is leached out. Again, this scenario does not fit for the test object which is used indoors or used encapsuled. Therefore, instead of uniformly applying the same weathering tests to all products, tests should be introduced depending on what kind of environment the test object will be exposed to during it's service life, and through what media BPA/BosC may be released into the environment.

5. **Alternatives**

While some of the possible alternatives listed by the German authorities could be viable in certain specific applications, there are many applications where this is quite unlikely. For example, the mechanical toughness of polycarbonate coupled with it's clarity is unsurpassed. Uses that depend on this combination of properties and performance level have no alternative. None of the listed alternatives are as thermally stable as PSU, PES or PEI.

Epoxy resins are specially tailored for individual applications, where the composition is optimized for compatibility with the other components of the formed part as well as the curing process in part manufacture and the required properties of the formed part. Replacement with some alternative would be a long, iterative process that would have to be repeated with each individual part. In demanding applications such as composites for medical devices, automotive, aerospace or wind energy, long qualification processes would be required to ensure that the final product meets performance and safety requirements. In the end, it may be found that there is no alternative that meets requirements.

One example of the difficulty in finding alternatives is with BPAF as a curing agent in fluoroelastomers. 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. 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. Bisphenol crosslinking is the most widely used system for FKM, given its superior scorch stability and mould release characteristics, low mould staining, and fast crosslinking, as well as superior heat resistance and sealing properties of the crosslinked compound. These FKMs are designed to perform to the highest requirements in extreme environments.

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.

The automotive sector is by far the most important sector for above-mentioned FKM products. They are designed to achieve the highest requirements in extreme environments. This includes high temperatures in a combination of contact with fuel, diesel and manufactured substances. The very low permeation rate of the precompounds allows components to meet current environmental regulations, which without BPAF would not be possible. Last but not least, it is important to mention that BPAF itself was never used as an alternative to BPA.

Currently commercial printing stakeholders focus on to replace conventional printing plates of alkaline chemical development by process-free printing plates, which are not necessary the chemical process and will not contain bisphenol type developers from the viewpoint of environment and sustainability. Although the industrial stakeholders are promoting a process-free plates for sustainability, it takes sufficient time to replace the conventional plates and spreads widely because the commercial printing market are broad and scattering. In case that the printing industries explore the alternatives of development accelerator for bisphenol related substances on conventional thermal and alkaline process, it needs sufficient time for transition with considering the procedure on feasibility studies, manufacturing, market testing, and certification in the market. This may cause even delaying the development of process-free plates and overall eco-friendly production activities due to further investment on R&D resources.

6. 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. Since communication in the supply chains is maintained based on the requirement of Article 33 in REACH which specifies the threshold of 0.1% in an article, there is a concern that 10 ppm cannot be tracked by even downstream industrial stakeholders. Therefore, there would need to be enough time for companies in these sectors to prepare. Even if a potential alternative substance for BPA/BosC 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.

As the above mentioned, polysulfone and polyethersulfone which have been used as filtration membrane for the purpose of purification of liquid and air at the many industries. Some of the products have been used for the purification of food and beverage for a long time. These applications are well-managed and certified as applying independent regulations. If the industrial stakeholders face the necessity on further certification of polymers by additional restriction, they also need to apply again for the certification of each application. That will cause a very long transition period.

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.

7. **Spare parts: “repair as produced” principle should be introduced**
   JBCE strongly believes that spare parts for EEE placed on the market before the implementation of the restriction should be excluded from the restriction without expiry date. If spare parts are not exempted, the lifetime of EEE will be shorten. Consequently, the volume of waste of EEE will rapidly increase, which is undesirable from the viewpoint of circular economy. Therefore, “repair as produced” principle should be introduced.

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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