POSITION PAPER

Japan Business Council in Europe

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JBCE'S POSITION ON REACH ANNEX XV REPORT CONSULTATION OF BISPHENOLS WITH ENDOCRINE DISRUPTING PROPERTIES FOR THE ENVIRONMENT AND THEIR SALTS (BPA AND BOSC)

INTRODUCTION

Being a cross-sector association with member companies operating in different industries and stages in the supply chain (electronics, chemicals, polymer, automotive, machinery, semiconductor, wholesale trade, precision instruments, pharmaceutical, steel, nonferrous metal, textiles, ceramics, and glass products), JBCE welcomes the opportunity to contribute to the discussion regarding REACH Annex XV report in the context of the consultation on the restriction on the manufacture, placing on the market and use of Bisphenols with endocrine disrupting properties for the environment and their salts.

KEY MESSAGES

On a general note, we understand that the proposed restriction proposal on BPA and BosC is in line with the target of having "a zero-pollution ambition for a toxic-free environment" which was proposed in the "Chemicals Strategy for Sustainability -Towards a Toxic-Free Environment-(CSS)". However, despite agreeing and supporting its concept and purpose to protect human health and the environment, we would like to point out that **the currently proposed restriction raises various issues which need to be addressed in terms of scientific reasoning and socio-economic impact**, as highlighted by various companies across different impacted sectors represented by JBCE.

Our main points of concern are listed below, and further explanation and evidence is provided in the Annex.

1. **Thresholds should not be common but specifically based on realistic risk assessments that consider the actual hazard, exposure levels, science and socio-economic impact assessments.**
2. **Enforceable thresholds should be set** because the measurement results can be affected by the type of matrix and/or additives and the variability of measurement results should be considered. To account for these effects and variations, it is necessary to set a threshold with a margin or a safety factor.
3. **Migration testing is not feasible for very complex products** consisting of a very large number of parts (e.g. electrical and electronic equipment). In addition, considering the high number of different parts and conditions of use, **the laboratory capacities will be**

overwhelmed and the amount of tests to be performed will be a burden for article manufacturers.

4. **Migration limits should reflect the actual use of the product** because the release potential of BPA/BosC from weathering should be different depending on how the articles are used during their service life. Instead of applying uniformly the same weathering tests to all products, tests taking into consideration 1) the environment the test object will be exposed to during its service life and 2) through what media BPA/BosC may be released into the environment should be introduced.
5. **Further fact-finding on alternatives is necessary**. While some of the possible alternatives listed by the German authorities may be viable for certain specific applications, there are many applications where this is quite unlikely.
6. **Allow for sufficient time to prepare for restrictions for the relevant industry sectors .** In the complex supply chain, there is a concern that 10 ppm cannot be tracked by even downstream industrial stakeholders. In addition, even if a potential alternative substance for BPA/BosC could be identified, it still needs to be proven whether the final products perform at the same level after the design change.
7. **Spare parts: the "repair as produced" principle should be introduced**. If spare parts are not exempted, the lifetime of EEE will be shortened. As a result, the volume of waste of EEE will rapidly increase, which is undesirable from the viewpoint of circular economy. In addition, reuse of used parts/used equipment should be exempted from the restriction without expiry date in order to make the EU society more sustainable.

ABOUT JBCE

Founded in 1999, Japan Business Council in Europe (JBCE) is a leading European organization representing the interests of 100 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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ANNEX

2. DETAILS

2-1: Proper threshold should be set based on the actual risk

- The conclusion of EFSA's 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 "*no clear indications of NMDR were detected for BPA*", although there were such indications for the phthalate DEHP[1]. It is 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)[2].

- **Polycarbonate (PC) and epoxy resins** are widely used in a variety of industries, some of the most relevant ones being automotive, construction, food contact material, medical devices and EEE. Because of the various industries, potential stressors and potential release to the environment of BPA and BosC, a differentiated evaluation based on a proper risk assessment is required.

- **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 BPA to BPS in a long time. In the commercial printing industries, as the waste materials inprinting industries have been collected and treated by appropriate professional ways, exposure for the consumer is very limited.

- **Bisphenol AF (BPAF)** has been 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 as well as 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 200-250°C.

- **Polysulfone (PSU)** has resists to both hydrolysis and chemicals. It has been used for electronic devices such as connectors and printed circuit boards, membrane purification for water, beverages, food, and even medical applications (i.e. dialysis). Since BPA is a raw material for the synthesis of polysulfone polymer, it might be present as very small amounts of impurities because BPA are also highly reacted. As this would depend on the manufacturing and purification process by polymer suppliers, downstream users can unfortunately not control it. The conditions of the derogation for polysulfone should be appropriately taken into account for the opinions of polymer suppliers (e.g. #3790).

- **Thermoplastics like PC or PSU, polyethersulfone (PS) and polyether imide (PEI)** are step-growth polymers which can only achieve useful mechanical strength at low

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

[2] 0.1% is usual for known carcinogens, 1% for suspected carcinogens

residual BPA content.

- Appropriate thresholds in any REACH restriction must be based on a realistic risk assessment and consider science and socio-economic impact assessments. Setting a limited order of magnitude below the amount that would be needed to protect the environment would increase costs for 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 common but specifically based on the potential hazard and risk linked to the exposure. Although industrial stakeholders are open to provide the data for this, we hope 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 data.

2-2: Enforceable thresholds should be set

- The measurement results can be affected by the 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 (although 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 how 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, an enforceable threshold should be determined.

- Residual content can be detected using LCMS/MS, however, there is no standard method yet available. Therefore, the development of measurement methods 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.

2-3: Migration test (0.04 mg/l (migration limit) in total during its service life)

- Migration testing is supposed to be done for individual manufactured parts. It is not feasible to perform migration test for very complex products consisting of a very large number of parts (e.g. electrical and electronic equipment). It is unclear how the German authorities[3] imagine such tests would be done. Would the migration limit be the sum of migration over a number of years or merely the individual results of a series of tests done on each part over the course of years.

[3] https://www.echa.europa.eu/documents/10162/9256e73b-0aa1-68ee-5afd-61391613b91c

- Migration from polymers manufactured from BPA will always be very slow because their glass transition temperatures are quite high. BPA is also readily biodegradable, so the amount in the environment at any time near such a polymer article will always be negligible.

- Considering the high number of different parts and conditions of use, the laboratory capacities will be overwhelmed, and the amount of tests to be performed will be a burden for article manufactures.

2-4: 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.

- Instead of applying uniformly the same weathering tests to all products, tests taking into consideration 1) the environment the test object will be exposed to during its service life and 2) through what media BPA/BosC may be released into the environment should be introduced.

2-5: Alternatives

While some of the possible alternatives listed by the German authorities[3] could be viable in certain specific applications, there are many applications where this is quite unlikely.

i) Polycarbonate

- The mechanical toughness of PC coupled with its 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.

ii) Epoxy resins

- 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.

- The Annex XV report specifically describes DGEBA as an example of epoxy resin containing bisphenol A as a partial structure. However, adhesive and glue manufacturers often create formulations based on the supplier's product name, and rarely compose adhesive formulations based on better understanding of the molecular structure.

- The decomposed materials from epoxy resin will depend on the curing conditions (i.e. heat, UV, temperature, time). Even if the raw material suppliers can control the BPA and BosC less than 10 ppm, the thresholds or migration limits in epoxy resins might exceed the thresholds after curing and/or processing to the products and articles by downstream stakeholders. It is difficult for both upstream and downstream to predict and analyse this impact. Furthermore, it is very difficult for the electronic product manufacturers to understand for this. Epoxy resins are difficult to substitute (e.g., acrylic, urethane adhesives) due to their mechanical properties which have good balance of toughness, and adhesiveness due to their stability and sterilization resistance from the initial stage of curing. They are also used commonly as adhesives for medical applications. When used in medical devices, their safety has been confirmed by strict safety regulations and standards which follow the usage environment (MDR: Medical Device Regulation, IVDR: In Vitro Diagnostic Regulation).

iii) Fluoroelastomers

- BPAF is used 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 moulding 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.

- In addition, BPAF is also subjects of restriction proposal of PFAS. We are really concerned that the two restriction proposals will have different transition periods and that they will cause confusion for not only the EU market but also the global supply chain. This kind of duplicate regulations and/or contradiction should be avoided.

iv) Development accelerators in photosensitive materials on offset printing plates for commercial printing

- Photosensitive phenolic resins have been coated on certain commercial offset printing plates. Phenolic chemicals as by-products of low molecules from phenolic resins act as alkaline development accelerators. Since these phenolic chemicals have concerns on safety and environmental issues, it is also known in the printing industry to use bisphenols as additives instead of these phenolic chemicals. Thanks to using these bisphenols as additives, harmful emission can be suppressed. Additionally, alkaline waste liquid after developing process can be greatly reduced, which is more favourable for environment. Considering the printing plate as an article, the bisphenol content will be less than 200 ppm, depending on the thickness of the aluminium plate. For chemical substances, the distribution of each element is usually analysed by Time-of-Flight Secondary Ion Mass Spectrometry (TOF-SIMS) and / or mapping with an electron probe microanalyzer (EPMA). However, since many materials with similar structures are included in the residue, analysis aimed for the migration amount of only the target bisphenols will be very difficult.

- Currently commercial printing stakeholders focus on replacing conventional printing plates of alkaline chemical development by process-free printing plates, which are not necessary for the chemical process and will not contain bisphenol type developers from the viewpoint of environment and sustainability. Although the industrial stakeholders are promoting process-free plates for sustainability, it takes sufficient time to replace the conventional plates and spread widely because the commercial printing market is wide and scattered. In case printing industries explore the alternatives of development accelerator for bisphenol related substances on conventional thermal and alkaline processes, it needs sufficient time for transition and to consider 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.

v) Toner in Multifunction printers (MFPs) and Single function printers (SFPs) application

- According to the stakeholders on printers, copying machines, and multifunctional printers and devices (MFPs/MFDs), BPA might be present as an impurity in the polyester resin which contained in their consumable product (toner). However, unfortunately the impurity cannot be controlled as a toner manufacturer which is not involved in the production of resin. The resin manufacturers have provided information on the amount of BPA present as an impurity from several dozen ppm to 200 ppm. Since the limit value of 10 ppm on the conditions of restriction cannot be managed for toner, we would like to insist that 200 ppm could be appropriate as a technically feasible value.

- Additionally, there is a history that polyester resins made from BPA contribute to improve energy-saving performance and to lower emission performance. If polyester resin having bisphenol structure could not be used for toner products, it would be difficult to meet current environmental standards such as stringent TEC (Typical Electricity Consumption) values and CO2 emissions. This means going backwards from environmentally friendly product development. Even though the industry strives to improve or replace bisphenol type polyester resins, currently there are no alternatives.

- Regarding Paragraph 2 under "Conditions of Restriction", not only when BPA is used as an intermediate for polymer production, but also when it is used as a starting material for polymer production including raw materials for monomers, it should be exempt from the restrictions if there is no case to contact with aqueous media during its service life or if its migration during its service life is below the limit. To clarify, the term "intermediate" should be modified to "starting material or intermediate" for polymer manufacturing.

2-6: Necessity to allow for sufficient time to prepare for restrictions by the relevant sectors of industry

- There are many industrial sectors that manufacture parts and assemble them over entire complex supply chains. Industrial stakeholders are using BOM Check and chemSHERPA which are supply chain platforms for articles and equipment. These platforms help industrial stakeholders to figure out the information of chemical substances containing equipment and components. Since these are covering above statutory thresholds or components above 0.1 wt%, 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 the final products perform at the same level after design change. The sector-specific stringent product-related regulations as well as performance and safety standards should be considered. 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.

- A long transitional period is especially important for professional use products with long design cycles such as medical devices and analytical devices which model is not frequently changed. For such devices we strongly recommend applying “legacy approach” the devices whose Declaration of Conformity is issued before the implementation of the new restriction. It can avoid negative impact on continuous market reliability by interruption of supply. Moreover, it would avoid negative influence on the environment, due to the disposal of the non-compliant inventory.

2-7: 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 shortened. 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.

- In addition, reuse of used parts/used equipment should be exempted from the restriction without expiry date in order to make the EU society more sustainable.