Comments to the public consultation on the Annex XV report for Bisphenols

25 January 2023

Introduction

Policy makers have pledged to get rid of some of the most harmful substances in non-essential uses - and bisphenols are part of them.[1] We therefore highly welcome the German proposal to restrict this group of chemicals, many of which have been confirmed as endocrine disruptors to the environment and human health. The importance of restricting the group as a whole is all the more relevant as evidence of regrettable substitution of BPa with other bisphenols of concern is piling up.

In our view the risk posed by bisphenols can only be addressed by:

- Targeting all bisphenols known or suspected to be endocrine disruptors for the environment[2];
- Looking at emissions throughout all life stages, not merely the service life;
- Banning the presence of bisphenols, beyond their capacity to migrate;
- Allowing derogations only for essential uses without suitable alternatives immediately available.

In the report submitted by Germany, the restriction conditions as described are clear but they likely fail to serve the goal of the restriction, which is reducing the unacceptable risk from the environment's exposure to bisphenols. **We provide arguments and evidence for this assessment in the following general comments:**

1. Scope

1.1. Limitation to environmental hazards

The present dossier **exclusively assesses the environmental hazards of bisphenols, potentially losing sight of the well-documented hazards and risks posed to human health,** with their various effects, various dose levels and types of risks, and various exposure routes.

In this contribution, we criticise the exaggeratedly high threshold levels for residual bisphenol in polycarbonate, and we highlight the risk that implicit regulatory endorsement of such high

[1] Restriction Roadmap - DocsRoom - European Commission (europa.eu)
[2] In that regard, a recent ECHA assessment of regulatory needs for Bisphenols confirms the need restrict at least 34 bisphenols (Dec 2021). 1bd5525c-432c-495d-9dab-d7806bf34312 (europa.eu)

levels can lead to effectively increasing residue levels in materials and therefore human exposure - as well as increased environmental exposure - during the end of life stage.

On that basis, we urge the dossier submitter and RAC to take into account human health concerns in the context of the hazard assessment. At the very minimum, the restriction must ensure that risks to human health do not increase as a (likely unintended) result of regulatory action.

1.2. Limited number of bisphenols

Endocrine-disrupting properties throughout a broad range of bisphenols have long been described in the academic literature.[3] Notably, comparisons between effects of different substitution patterns on the phenyl rings have established strong structure-activity relationships for hazard characterisation. **It is therefore surprising and regrettable that the dossier submitter limits the proposal to a handful of bisphenols,** although the link between structural similarity and expected hazard similarity is recognised (e.g. in section 1.1.2. on p. 17). ECHA's recent "assessment of regulatory needs" report on bisphenols[4] lists a substantially broader array of bisphenols. The dossier submitter could have, and should have, used a structural descriptor for the scope, without limiting the scope to identified SVHCs.

Moreover, unclarity remains with regard to non-covalently bound derivatives. Additive uses of (in scope)[5] bisphenols, i.e. uses where bisphenols are present molecularly in the mixture or article, are covered by condition 1 of the restriction (p. 5 of the dossier), subject to the substance scope and derogations in condition 3. Bisphenols covalently bound to the matrix, or used as intermediates in the manufacture of polymers, are exempted by virtue of condition 2. This condition would apply to reacted diisocyanate, diglycidyl or diacrylate derivatives of the bisphenols. However, it is not clear what the dossier submitter intends to do with non-covalently bound derivatives, such as an acetate-capped BPA diether EC 242-859-2, a phosphate-functionalised BPA EC 425-220-8. These substances would neither be covered by condition 1 (as the actual substances in scope are free bisphenols) nor by the exemption in condition 2 (as they are not covalently bound and do not serve as an intermediate in the manufacture of polymers). In the spirit of a broad REACH restriction, the restriction conditions should also apply to these substances. We kindly ask the dossier submitter and RAC to clarify this aspect and to include such uses and substances in the restriction proposal.

2. Hazard assessment

Not least thanks to the earlier hazard assessments of individual, but structurally and (eco)toxicologically related bisphenols, the present restriction dossier rests on solid prior science.

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[3] As an example, S. Kitamura *et al.* (2005), *Toxicological Sciences*, 84 (2), 249–259 is such a meta-study. Its publication date shows that endocrine effects were described and recognised long before Art. 57 of REACH became effective.

[4] Available here.

[5] We add the precision "in scope" here for clarity; henceforth "bisphenols" will refer mostly to those bisphenols in the scope of this restriction proposal.

Among others, the non-threshold ecotoxicological properties of bisphenols are mentioned in the dossier (on p. 11 and elsewhere) - a reminder of the approach applied by RAC to environmental EDs, for example when assessing authorisation applications for nonylphenol and octylphenols. We recommend that the proposal more clearly references the documents supporting the SVHC identification of bisphenols, including other scientific literature, which would further support the present assessment.

3. Exposure assessment

3.1. Mapping of emissions

Generally, when it comes to BPA, the restriction dossier very well describes the *current* emissions to the environment during each life cycle stage. However it hardly provides a clear picture on the reduced emissions that can be expected from the restriction once in place. This makes it difficult to understand the potential effectiveness of the restriction to reach its goal, i.e. avoiding bisphenols' emissions to the environment.

3.1.1. Manufacture of bisphenols and polymers

The dossier mentions in section 1.1.6.2 (p. 43) that manufacturing plants are generally subject to IED requirements. While this mention is correct, it deserves further refining.
It should be noted that the Industrial Emissions Directive does not set emission limits based on (eco)toxicological effects as a general rule, but based on:

- BAT-AELs (i.e. the ranges permit writers are allowed to use for emission limit values). It is important to note that relevant BREFs, such as the POL, CWW, WGC and LVOC BREFs[6] **do not set any BAT or BAT-AEL for the emissions of bisphenols to water or air. Therefore this legal mechanism is practically irrelevant.**
- the lists of the IED's Annex II, which are correctly recognised in Table 20 on p. 51 of the dossier (although the reference of the idea has the year 2012 instead of 2010). However, it should be noted that the Commission's text for a revision of the IED[7] proposes to replace the rather open Annex II with a reference to the exhaustive list of pollutants under the (also to be revised) Industrial Emissions Portal Regulation (formerly E-PRTR Regulation 166/2006). This change has the potential to lower environmental protection by disregarding relevant pollutants, as criticised by EEB.[8]
- on EQS (Environmnetal Quality Standards, according to IED Art. 18). While the latter are indeed ecotoxicologically derived, it should be noted that **no EQS for bisphenols exists at the European level, and that most member states or regions have not set ad-hoc EQS.**

For these reasons, the emissions of bisphenols during manufacture are not necessarily permitted nor monitored. **Absence of publicly available information on emissions does not mean absence of emissions.**

Further, studies on workplace exposure indicate high levels of ambient BPA in plants using or manufacturing BPA, PC, epoxy resins and other polymers. This should be considered as

[6] The reader is invited to consult these documents on the JRC's webpage on BREFs.
[7] Published in April 2022, and available here.
[8] The interested reader is referred to EEB's situational briefing on this topic.

an indication of potential environmental exposure from the thousands of sites using these polymers and resins on a daily basis. [9]

3.1.2. BPA leaching from microplastics

The dossier does not analyse the release of bisphenols via microplastics (e.g in Annex section 3.4.4 or 3.4.5), although microplastics have been recognised to be ubiquitous and environmentally relevant. General hazards of microplastics related to their particulate form, their potential to cause effects and persistence have been well documented and assessed by the RAC.[10] Several studies have moreover documented the release of bisphenols and related molecular species from microplastics.

Combining the degradation mechanisms already described with so far unassigned material transfers between different environmental compartments should yield good estimates on an likely major contributor to environmental exposure. Where bulk material of a PC-based object disintegrates to microplastics (by abrasion, embrittlement via UV irradiation followed by mechanical action etc.), these microplastics will act as a source of bisphenol to the environment. This can be either residual bisphenol leaching out of the microplastics, or via any of the polymer degradation mechanisms described in section 3.4.4.1 of Annex H, thereby releasing bisphenols or related degradation products.

It has been described in the literature that BPA leached from PVC microplastics negatively affects methanogenesis from waste activated sludge.[11] More recently, researchers have demonstrated that a similar effect can be seen when waste activated sludge is exposed to PC microplastics; a mechanistic experiment has linked the effect to BPA itself.[12]
Likewise, additive uses of BPA and BPS as a plasticiser in PVC[13] have also been described to yield microplastics releasing BPA and BPS.[14]

We recommend that the dossier submitter and RAC take into account this emission pathway and conduct a solid assessment of associated risks.

4. Proposed derogations

4.1. Polycarbonate

4.1.1. Residual monomer content

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[9] Assessment of Occupational Exposure to Bisphenol A in Five Different Production Companies in Finland, Milla Heinälä. DOI: https://doi.org/10.1093/annweh/wxw006
[10] RAC opinion on the microplastics restriction, section B.1.2.2, p. 46, available here.
[11] W. Wei *et al.* (2019), Polyvinyl chloride microplastics affect methane production from the anaerobic digestion of waste activated sludge through leaching toxic bisphenol-A, *Environ. Sci. Technol. 53*, 5, 2509–2517, https://doi.org/10.1021/acs.est.8b07069/
[12] H. Chen *et al.* (2023), Polycarbonate microplastics induce oxidative stress in anaerobic digestion of waste activated sludge by leaching bisphenol A, *J. Hazard. Mat. 443*, 130158, https://doi.org/10.1016/j.jhazmat.2022.130158
[13] only of relevance in the EU from imported articles according to the dossier submitter. It is interesting to note that the dossier submitter describes the use of the bisphenols as stabilisers for the plasticiser, while the paper describes them as plasticisers themselves. Given that both BPA and BPS are solids with high melting points and therefore poor plasticisers, the use as a stabiliser appears more plausible.
[14] A.M. Gulizia *et al.* (2023), Understanding plasticiser leaching from polystyrene microplastics, *Sci. Total Environ. 566*, 159099.

The proposed limit value for residual bisphenol in PC is not justified, and therefore not credible. We would like to comment on some, to our understanding, incomplete and unsupported assumptions and assertions in the Annex XV dossier.

The proposed[15] concentration limit for free bisphenol in polycarbonates (PC) is 150 ppm. The explanatory text states that 10 ppm "can only be met by less than 30% of the currently manufactured PC", but that "European manufacturers can meet 150 ppm concentration limit".

First, this approach equates to not imposing any effective restriction on European manufacturers, and likely not on non-European ones either as almost all PC grades would meet the cut-off value and would therefore be derogated.

Secondly, the value of 150 ppm is at odds with many values reported in the institutional and academic literature - this is an overview of some of our findings prior to publication of the dossier:

- A Danish study from 2015[16] shows residual levels of 5-13 µg/g (i.e. ppm) of BPA in PC from EU manufacturers, and values between 5 and and 80 µg/g from non-EU countries. The levels of residual BPA given by the European manufacturers were all below 10 ppm.
- A SCENIHR report from 2015[17] on BPA in medical devices links high residual amounts of free BPA to suboptimal processing conditions (section 3.6.2) such as the presence of water, temperatures and some additives. The same SCENIHR report handles a concentration of 10 ppm as a worst-case scenario for medical devices (p. 9 and section 3.7.3.vi).
- Biles et al.[18] analysed baby bottles in the US in 1997 and found residual amounts of BPA (table 1) below 35 ppm for all US-made bottles and below 50 ppm for bottles manufactured in Asia. This was 25 years ago.

In their comprehensive literature review in annex H, the DS mentions (p. 89):

- Fischer *et al.* (2014) stating that "residual content [in PC] is typically < 10 mg/kg (i.e. < 10 ppm) - this is consistent with our analysis. Merely two data points at ca. 400 and 500 ppm attributed to Hoekstra *et al.* (2013) that would be excluded by the proposed value, although they were already illegal in Japan twenty-five years ago.[19]
- The next data points seemingly used to justify the 150 ppm limit are from 2005 (Onn Wong *et al.*), Mountford *et al.* (1997!) and Groshart *et al.* (2001), as well as one sample each from the more recent Ramboll (2017)[20] and Pedersen *et al.* (2015) studies.
- A JRC 2010 study is cited with "a maximum of 100 ppm residual BPA".

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[15] Annex XV dossier, Annex Y, p. 6.

[16] Danish Ministry of the Environment, 2015, *Migration of bisphenol A from polycarbonate plastic of different qualities*, No. 1710, available here, table 5, p. 32.

[17] SCENIHR, 2015, *The safety of the use of bisphenol A in medical devices,* available here.

[18] J. E. Biles *et al.*, (1997) *J. Agric. Food Chem. 45*, 3541-3544, doi: https://doi.org/10.1021/jf980629+.

[19] Closer analysis of Hoekstra *et al.* (2013) reveals that these were "contravened" (illegal) samples by Japanese samples in twenty-five years ago (Kawamura *et al.* (1998)).

[20] It is unclear of us if the Ramboll 2017 study is publicly available.

The DS's states in annex E.4.8.3, penultimate bullet point on p. 376, that it "is very unlikely that PC contains above 150 ppm [...]" BPA. Setting the limit at 10 ppm would have forced some producers to reduce their content, while rewarding the better ones by leaving their production methods untouched - all of this while reducing (albeit only moderately) the source of possible migration into the environment of human exposure.

However, it is unclear to us what the DS's intention was by proposing a value of 150 ppm.
It appears that **a more realistic value is of the order of 10 or 20 ppm.** Setting a limit as high as 150 ppm would not only have no effect of banning any high-BPA materials, but it may even encourage manufacturers and customers to accept higher BPA levels, arguing e.g. that "120 ppm must be fine, otherwise they would not have set 150 ppm as the limit in the restriction".

The dossier does not only omit the above sources, but it does not appear to base the 150 ppm on any transparently available data sources, using any reasoning that can be followed clearly (annex E.4.8).

We urge the DS and RAC to conduct a transparent and evidence-based analysis of residual bisphenol levels in PC and derive from this analysis a limit concentration aligned with the aim of this restriction, while under no circumstances increasing risk to human health on grounds that it is out of scope.

4.1.2. Link between quality and residual monomer content

One statement on p. 378 of the Annex raises questions regarding the DS's interpretation of relevant polymer physics.

The text states that "the increasing use of PC that meets the [10 ppm] limit value might occur, thereby shortening the durability and service-life of an article. No further information is available but the dossier submitter agrees in theory that this could happen [...]". Regrettably, the DS does not reveal what theory they used to consider this a realistic consequence. Worse, the text appears to hint that the dossier submitter considers that free BPA plays a role of improving durability and service-life of the PC article. We were unable to find any rationale in the dossier and its annexes to explain such an assumption, nor could we conceive any such mechanism.

In case protection against UV radiation is meant: although bisphenols arguably have antioxidant properties, this is not how protection of polycarbonate works. Polycarbonate itself is rather opaque to UV radiation (meaning it only requires surface protection) but is usually protected using UV absorbers[21] or coatings[22].
In case resistance to mechanical stress is meant: a small molecule like a bisphenol cannot act as a reinforcing filler (like carbon black in rubber, or, actually, glass fibres in PC, which provide multiple anchoring points to different molecular strands) or as a plasticiser (like DEHT in PVC, which is effective in concentrations of the range of 10 or 30%).

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[21] We refer the reader to the study of the Danish Ministry of the Environment, 2015, *op. cit.*, available here, section 2.2.
[22] Such as the HL5500 headlight repair kit by Cromax.

PC has on its own excellent impact strength, which can be modulated with fillers - this is one of its main attractions. A (physically speaking) very low content of free BPA will not have any noteworthy effect on mechanical properties, and certainly not a positive one. Any statement to the opposite should be provided with underlying physical arguments or trustworthy evidence.

4.2. Epoxies

The threshold of 65 ppm of residual bisphenol in epoxies proposed for this restriction, like the one in polycarbonates, appears to be set in such a way that it does not affect any suppliers and that it does not drive a general reduction of free bisphenol.

The threshold value for epoxies is more strongly based on information in the call for evidence, and less so on experimental data from independent and peer-reviewed sources. It is therefore not possible for the reader to judge if the value is in any way restrictive or conducive to a reduction in emissions (after all 13% percent of all emissions according to table 17 in annex H), and how it has been derived.