Questions received and comments submitted from stakeholders during the Information Webinar on BPA on 15 September 2020

Due to problems with the audio quality of the recording of the information session, the questions and comments made by participants as well as the responses during the Q&A segment are summarised in this document.

Document History
5 October 2020 – Version 1.0
15 October 2020 – Version 1.1 – Question 1 & 2: The link to the RoI and CfE have been included in the responses. Question 4: The response has been amended to include guidance on potential alternative information to be submitted in absence of data on lifecycle testing.

A. Questions and comments on procedural aspects and next steps:

1) *For which date is the submission of the dossier planned?*

The submission of the restriction dossier is planned for 1 October 2021 at the latest. The publication of the restriction intention in ECHA's Registry of Intentions (RoI) is planned for 7 October 2020.

Update: The RoI entry on the ECHA website can be accessed here (link to ECHA website).

2) *Until when will the call for evidence be open?*

The call for evidence is an informal process, for which no legal requirements have to be followed. Currently, it is anticipated to open the Call for Evidence (CfE) on 15 October and keep it open for up to three months.

Update: The CfE has been launched by ECHA on 14 October and will be open until 15 January. It can be accessed here (link to ECHA website)

3) *Three months may be too short to generate substantial information on the use of BPA in an organisation wishing to contribute to the CfE.*

The CfE is meant to gather existing information which is already existing in an organisation's structure. It is an additional, informal step, which takes place before the submission of the dossier. Information generated during or after the CfE may also be submitted during the public consultation of the dossier. This Public consultation is open six months after submission and confirmation of conformity of the restriction dossier by ECHA.

4) *BPA is used as a monomer in materials in the aircraft industry. Article service life is up to 40 years and information on exposure to BPA over the whole life cycle is not possible even with accelerated testing.*

Updated response: While testing of direct release from articles throughout their lifecycle serves best to estimate the expected environmental emissions of BPA from these uses, further information can be submitted in the CfE or the consultation which may be used for the sake of the restriction in case release data is not available.

This may for example be general stability testing, information regarding life cycle length and conditions of use and stressors to be expected as well as information on legal or technical requirements for these articles which have to be complied with outside of REACH.

While this information does not inform on BPA release directly, it may however be used by the dossier submitter to assess the role of BPA for these uses and the likelihood of release during the life cycle.

5) *To which levels will BPA be restricted in Germany?*

A REACH restriction is a community-wide measure and would apply to the whole EU. The RoI entry and the final dossier will contain further details on the scope and envisaged measures.

6) *Will there be exclusion cases within the proposal?*

There is the possibility for the dossier submitter to propose derogations to the restriction. However, these will not be user- but use-specific and need to be justified via use-specific information submitted by the respective stakeholders. Derogations might be justified if socio-economic costs are disproportionately high compared to the expected environmental benefits, i.e. reduced emissions.

Requests for derogations should be submitted as early as possible and be accompanied by information that allows the dossier submitter to analyse economic costs and environmental benefits.

7) *When will further details on the restriction be made available?*

Preliminary information will be contained in the entry in the registry of intentions. The CfE will aim to also address further information on the scope. The CfE will take the form of a questionnaire which addresses different aspects of the planned restriction in the form of questions to the stakeholders. The finished dossier will contain all information on the scope of the restriction.

8) *Which time frame is set/planned to implement the restriction after the approval of the dossier?*

Following submission of the dossier to ECHA, there is a time period of ca. 3 months during which the dossier's conformity will be checked by the scientific committees of ECHA. With the start of the opinion making process by the scientific committees (Committee for Risk Assessment RAC and Socio-economic Analysis Committee SEAC) a 6 months lasting public consultation period starts. The Committees will then finalise their opinion making and after that the dossier will be processed by the EU commission. The final restriction will potentially include derogations and different transitional periods for different sectors of use based on all information obtained and the conclusion of the scientific committees and the EU commission. Therefore, currently it cannot be estimated when the different elements of the restriction will enter into force.

9) *The listing of BPA as an SVHC due to ED properties for the environment is currently being challenged before the European Court.* When can a decision be expected on the decision of the European Court on the SVHC listing of the European Court?

Currently, it is still open when the European Court will finally decide on the plea. If BPA should eventually no longer be identified as an SVHC based on a community-wide agreement, this would need to be reflected when preparing the restriction dossier. However, it should be noted that SVHC listing is not a prerequisite for a restriction per se. In the dossier it needs to be shown that BPA is an ED according to the WHO/IPCS definition and that these hazardous properties raise a concern that demands for community wide measures to protect the environment. Generally, there is the possibility to appeal the decision of the European Court.

B. Questions and comments on the scope of the restriction:

10) *For articles with a very short-term use, is the restriction focused on the release during use or the disposal of the article?*

RAC and SEAC will normally consider time periods of 20 years to evaluate the impacts of a restriction proposal unless there are reasons for adaption. Emissions from all stages of the life cycles are relevant. If the service life of an article is only very short and there is no controlled end of life where emissions are not expected, emissions for this end of the service life also have to be addressed.

11) *Will mainly be additive uses of BPA be targeted by the restriction?*

Additive uses are a main target of this restriction. However, also the release rate of BPA from articles during the service life, e.g. via residual BPA, are a direct or indirect source of BPA emissions to e.g. surface water and therefore will be addressed by the restriction.

12) *How will the risk to the environment be justified based on the emissions of BPA?*

A safe threshold for endocrine disrupting chemicals in the environment cannot be currently derived as it could not be regarded as sufficiently protective for all species and ecosystems. BPA is an identified endocrine disruptor, therefore a classical quantitative environmental risk assessment will not be performed in the dossier. Instead, risk management measures able to minimise the environmental emissions as far as possible will be taken into account for the dossier. Thus, the emissions of BPA will serve as a proxy to describe the risk.

13) *The handling of BPA-containing mixtures by consumers is planned to be regulated above a certain limit. What will this limit be?*

The current plan is to align the limit to the existing limit of BPA in thermal paper, i.e. 0.02% w/w. The rationale behind this limit value is that it is anticipated that unlike professional or trained users, consumers lack the knowledge and techniques to limit emissions to the environment during use.

14) *Will this limit also apply to the residual content of BPA in articles?*

The restriction will address these residual amounts of BPA based on their potential for release. This will both be addressed by a limit to the residual amount as well as a provision for limiting the release from articles. It is planned to align the residual amount with the limit in consumer mixtures (i.e. 0.02% w/w). Further data on the release limit and the analytical feasibility will be gathered during dossier preparation.

15) *How will the limit for BPA-containing articles be determined?*

Analytical feasibility has e.g. been proven for the migration limit of BPA in toys as per the toy directive. Similar limits will be derived based on the conditions for BPA in different use categories.

16) *Will recycled materials and imported articles be covered by the restriction?*

It is planned to also apply the restriction conditions to recycled materials. The restriction will apply to imported mixtures and articles, too.

17) *Will refurbished articles or second-hand articles be covered by the restriction?*

In general, yes. The dossier submitter will consider submitted information to determine whether derogations from a general restriction are justified, e.g. of the second-hand market.

18) *Which pathways of emission to the environment are considered relevant for BPA?*

Currently, all pathways – air, water, soil – are considered relevant. Therefore, all information on these emissions are requested during the CfE and the public consultation.

19) *Will the restriction only address intended use or also unintended residuals and/or contamination?*

The restriction will cover all of these scenarios for the occurrence of BPA.

20) *How will the grouping of substances with regard to regrettable substitution be handled in the dossier?*

It is currently still being evaluated how to include substances which also bear the bisphenols structure element in the restriction dossier and which give rise to a similar concern for the environment as BPA.

21) How would the safety of (non-bisphenolic) alternatives be demonstrated if there are less relevant data available compared to BPA?

The primary aim of the restriction dossier is not to assess in-depth or exonerate alternatives but primarily to establish the concern arising from BPA. However, as soon as assessing this information may become necessary, it will be drawn from registration and open-literature data on these substances.

22) *Will the results of the EU biomonitoring project (HBM4EU) be taken into account for the restriction dossier?*

The data from this project will be used indirectly to elaborate on the scenario “environment via man” exposure to BPA. However, no human health risk assessment will be performed using this biomonitoring data, as the scope of this restriction is solely the environment.

23) *Will small quantities of BPA be allowed or will the restriction be solely restriction-concentrated?*

The use of small quantities does not justify a derogation per se. Socio-economic considerations will be evaluated by the dossier submitter, SEAC and the European Commission for all known uses and a use-specific

derogation might be justified for uses where expected economic impacts of the restriction are disproportionate when compared to the expected emissions reduction.

24) *What are the requirements to obtain an exemption from the restriction? How high is the confidence with regard to the success of obtaining such an exemption?*

Derogations need to be justified, e.g. by lack of suitable alternatives or high substitution costs. This can either be already demonstrated to the dossier submitter based on in-depth information or needs to be demonstrated later in the process. The dossier submitter and the scientific committees work very closely during the process and assess information which may lead to a potential exemption. Eventually, the EU commission decides on the derogations.

25) *Can exemptions also be granted for use scenarios for which it can be demonstrated that there are no emissions under intended use conditions?*

If the lack of emissions can be conclusively demonstrated for such a case, an exemption can be granted.

26) On which bases are SMEs excluded from being able to perform controlled production?

Unlike larger industrial facilities and companies which operate according to the Sevilla process and fall under the provisions of the Industry Emissions Directive (IED), there may be small and Medium Enterprises (SMEs) which may be excluded from these legal provisions and therefore are not required to monitor or minimize emissions. Hence, there may be a need to address emission minimization of these SMEs via the intended restriction.

27) *Will there be a distinction on the restriction between "public" articles (toys etc.) and "professional" (defence, aerospace etc.)?*

The restriction proposal will not contain exemptions for specific sectors or article categories a priori. Specific derogations for articles will need to be justified.

28) *What will be the approach for assessing releases during service life for indoor applications (e.g. chargers of electrical devices which do not contribute to release into water during service life of the device)*

There will be three categories of uses which are assessed: outdoor uses, indoor uses and indoor uses with stressors (e.g. via cleaning, abrasion, temperature or UV radiation). These stressors may also lead to emissions during the life cycle in indoor applications. The potential for release will be highly use-dependent for indoor applications.

29) *Will the contribution of microplastics as carrier for BPA to the BPA emission be assessed?*

Currently, there is no specific approach to address this issue in the restriction dossier. Further information during the process is welcome.

30) Is the concern for the restriction based on polymers using BPA as a monomer?

Yes, this is the case in principle for the restriction, unless these polymers can be shown to not release BPA during their life cycle. Additionally, the use of BPA as an additive is a main driver for the proposed restriction.

31) How to know if an article can release monomeric BPA?

Currently, appropriate analytical measures are collected for the restriction dossier which may be used in the future to show that articles placed on the market fulfil the limit values contained in the restriction and thereby conform to the legal requirements. Additionally, already existing stability tests might also be appropriate to show that the articles fulfil the conditions of the restriction.