AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Brussels, Monday, 15 February 2021

RE: Application of the "one substance one assessment" principle in the case of BPA and TBBP-A

To whom it may concern,

AmCham EU strongly supports the European Commission's efforts to streamline its processes. This is especially important in the field of EU chemical policy where there is a need to reduce the burden on all stakeholders and to make decision-making more consistent and predictable. The EU's new Chemical Strategy for Sustainability (CSS) can be a unique opportunity for regulators to improve consistency between the actions of different authorities.

We believe the stated aims of the CSS mean that the outcomes of comprehensive assessments carried out under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and Classification, Labelling and Packaging (CLP) Regulations must be taken into account when considering further sectoral assessments under product legislation, such as medical devices, cosmetics or Reduction of Hazardous Substances (RoHS). Before new regulatory processes are initiated, formal mechanisms should be in place to ensure authorities are aware of and can adequately reference previous assessments that have been performed for the same substances, including those associated with sectoral risk assessments. Strong formal cooperation between EU agencies, Commission services and stakeholders is essential in this respect.

The case of BPA and TBBP-A

Under the RoHS Directive, the Commission appointed private consultants Oeko-Institut and Fraunhofer IZM to technically assist in a *'Study to support the review of the list of restricted substances […] under RoHS 2 (Pack 15)'.* As part of this work, the consultants developed a first list of substances in view of a possible inclusion in the list of substances restricted under RoHS. In April 2020, Oeko Institut published its interim recommendation advising **2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (Tetrabromobisphenol A, TBBP-A)** (CAS-79-94-7)[1] be restricted under the RoHS Directive (reactive applications not be affected by the recommended restriction). At the time of writing, the Commission has yet to make an official decision.

In parallel, on 1 October 2020, Germany submitted to the European Chemicals Agency (ECHA) its intention to restrict the placing on the market and use of a different substance, **4,4'-isopropylidenediphenol (bisphenol A, BPA)** (CAS- 80-05-7) and 'structurally related bisphenols of similar concern for the environment'. Among the examples of such 'structurally related bisphenols' provided by the German authorities in the documents annexed to the Call for Evidence, **TBBP-A is listed as possibly included in the scope of the restriction**.

The EU's CSS' 'one substance one assessment' principle precisely aims to prevent the multiplication of assessments and to limit occasions where the same chemical substance, or family of substances, is assessed in

[1] https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/Final_Results/TBBPA_RoHS_Dossier_V3-final.pdf

parallel by different regulatory bodies for the same applications. While the 'one substance one assessment' principle should not be misused to pre-empt sectoral risk assessment, AmCham EU believes the CSS is a tool, like the EU's Regulatory Management Option Analysis (RMOA)[2], which can prevent the risk associated with certain substances from being managed ineffectively and incoherently under REACH and different sectorial regulations and directives.

We believe the proposed BPA restriction under REACH (whose scope could include TBBP-A) is an example of the overlap that 'one substance one assessment' aims to prevent. TBBP-A therefore creates an early opportunity for the Commission to put the 'one substance one assessment' principle into practice. This is strengthened by the fact that TBBP-A and BPA have little in common and are used for different applications and purposes.

Overlaps between REACH and RoHS are not new and led the Commission to draft a Common understanding paper[3]' in 2015. The document helped address problems in the past, such as Sweden's proposed lead restriction, which included lead in electric and electronic equipment (EEE), even though lead in EEE was already restricted in RoHS. Such an overlap would have raised multiple problems in the RoHS exemption process and after receiving significant stakeholder feedback, the lead restriction's scope was amended to exclude uses in EEE covered by RoHS. A similarly coordinated approach should be ensured in the case of TBBP-A. This example, and new incarnation in the BPA restriction, exemplify the inconsistencies the Commission wants to address through the 'one substance one assessment' principle.

AmCham EU is a staunch supporter of the greater and more structured use of the RMOA. We believe it is the best tool to ensure upfront coordination on the most appropriate measures to address concerns and perceived risks for specific substances. We call on the European Commission and ECHA to make guidance publicly available on the benefits of RMOAs, when they should be used and how they should be structured.

Similarly, we encourage the Commission to promote upfront coordination between officials and stakeholders managing ongoing regulatory processes for TBBP-A under RoHS and REACH, in order to avoid an outcome where parallel and potentially inconsistent rules are developed for the same substance under the two pieces of legislation.

We remain at ECHA's disposal for further dialogue on this issue.

Kind regards,

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Chair, Environment Committee
AmCham EU

[2] AmCham EU's paper on Improving REACH in 2018 and beyond - Risk Management Option Analysis (RMOA): https://www.amchameu.eu/system/files/position_papers/improving_reach_in_2018_and_beyond_-_risk_management_option_analysis_rmoa.pdf

[3] REACH AND DIRECTIVE 2011/65/EU (RoHS) A COMMON UNDERSTANDING: file:///C:/Users/FS116972/Downloads/REACH%20and%20RoHS%20CU%20paper%20-%20endorsed%20(1).pdf