Helsinki, 11.11.2021

Note for the attention of Dr Tim Bowmer, Chairman of the Committee for Risk Assessment

Ref: Request to the Committee for Risk Assessment to examine the feasibility of finding a threshold in the context of applications for authorisation and review reports in the cases of bis(2-ethylhexyl) phthalate (DEHP) and dibutyl phthalate (DBP)

The Committee for Risk Assessment (RAC) is requested to examine the feasibility of finding a threshold in the context of applications for authorisation and review reports for DEHP and DBP.

1. Background

Since 2012, RAC recommended on a case-by-case basis 8 derived no-effect levels and 7 dose response relationships for in total 15 Annex XIV substances prior to receiving applications for authorisation (AfAs). Derived no-effect levels (DNELs), Predicted no-effect concentrations (PNECs) and dose response relationships so derived serve as non-binding 'reference values' and have thereby increased predictability and legal certainty for applicants on how RAC would evaluate the applications. Reference values in the form of DNELs/PNECs for threshold substances and/or dose response relationships for non-threshold substances are published in advance of applications for authorisation providing greater consistency and better use of the legally defined periods (e.g., the latest application date by applicants or to keep the 10 months deadline for RAC and SEAC to issue draft opinions).

The substances bis(2-ethylhexyl) phthalate (DEHP), benzyl butyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) are listed in entries 4 to 7 of Annex XIV to Regulation (EC) No 1907/2006 due to their toxicity to reproduction[1]. All the four substances have furthermore been identified as having endocrine disrupting (ED) properties to human health[2]. DEHP has been additionally identified as having ED properties to the environment.

[1] COMMISSION REGULATION (EU) No 125/2012 of 14 February 2012 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals ('REACH')
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32012R0125

Corrigendum to Commission Regulation (EU) No 143/2011 of 17 February 2011 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals ('REACH')
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32011R0143R%2801%29

[2] Commission Implementing Decision (EU) 2017/1210 of 4 July 2017 on the identification of bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP) as substances of very high concern according to Article 57(f) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (notified under document C(2017) 4462) (Text with EEA relevance.)
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017D1210&qid=1631631119846

The identification of DEHP and DBP as SVHC for ED properties has not been considered by the applicants in the applications for authorisation nor evaluated thus far by RAC.

The draft Commission decision concerning the review report of Plastic Planet srl for DEHP is expected to be adopted in the coming months. The draft proposal sets a very short review period in order for the authorisation holder to submit a review report by June 2022 taking into account the new ED properties.

In its request to ECHA's Executive Director, the European Commission asked RAC to deliver, in accordance with Art. 77(3)(c) of REACH, an opinion on reference DNEL/PNEC[3] values or dose-response curves considering the updated properties of DEHP, BBP, DIBP and DBP.

ECHA has not received any applications for BBP and DIBP and has neither received any information that an application would be forthcoming at this late stage. Thus, it is not meaningful for ECHA or RAC in the context of authorisations to deliver an opinion on these two phthalates.

For **human health**, it is noted that reference DNELs for DEHP and DBP were derived in 2013 (RAC 2013)[4] for reproductive toxicity and thus pre-date RAC's opinion of 2017 (RAC 2017)[5] on the restriction proposal from ECHA and Denmark on these phthalates. Given the short timeframe of this request and the narrow application of the outcome to a small number of Authorisation applications, the aforementioned reports should form the basis of RAC assessment.

As far as environment is concerned and limited to DEHP, ECHA suggest that RAC considers to take a similar approach to that taken in the cases of octylphenol and nonylphenol ethoxylates (OPnEO/NPnEO). It is noted that RAC evaluated in 2019-2021 PNEC proposals included in several applications and concluded that the data were not sufficiently representative to derive PNECs. For DEHP, there is no comprehensive environmental dossier to refer to which would contain also recent available data on ED properties; this appears to include the registration dossier. The latest dossier on the environmental ED properties of DEHP is the support document of the SVHC-identification (ECHA, 2014)[6]. RAC should evaluate whether the fish, amphibian and invertebrate studies available have a similar lack of representativeness as did those for OPnEO/NPnEO and thus whether by analogy, a non-threshold approach seems the way forward.

ECHA is not aware of any methodologies to derive reference concentration-ecosystem effect curves for the environment that could be used to assess the level of risk in case no PNECs can be derived.

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[3] request to derive reference PNEC or reference concentration-ecosystem effect curve applies only to DEHP

[4] https://echa.europa.eu/documents/10162/1564405/rac_24_dnel_dehp_comments_en.pdf/e0506f6b-35f7-433e-99da-35464a26e2df?t=1441812802854
https://echa.europa.eu/documents/10162/1564405/rac_24_dnel_dbp_comments_en.pdf/44ab77fd-d6fa-4d73-b0ed-9317fd6c0422?t=1441812804827

[5] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1806e7a36

[6] ECHA (2014): Member State Committee support document for identification of bis(2-ethylhexyl) phthalate (DEHP) as a substance of very high concern because of its endocrine disrupting properties which cause probable serious effects to the environment which give rise to an equivalent level of concern to those of CMR and PBT/vPvB substances
https://echa.europa.eu/documents/10162/fa429d23-21e7-4764-b223-6c8c98f8a01c

Therefore, the scope of the request to RAC has been narrowed down as presented in the Terms of Reference.

2. Terms of Reference

In accordance with Article 77(3)(c) of the REACH Regulation, the Committee for Risk Assessment (RAC) is requested to examine the feasibility of finding a threshold in the context of applications for authorisation and review reports in the cases of bis(2-ethylhexyl) phthalate (DEHP) and dibutyl phthalate (DBP). RAC is requested to answer the following questions:

Endocrine effects on human health (DEHP and DBP):

- Are the RAC (2013)[7] reference DNELs, sufficiently protective as they are, i.e. have the effects related to endocrine mode(s) of action already been sufficiently addressed?
- If not, could these RAC (2013) reference DNELs be used to derive safer levels by the use of, e.g., appropriate assessment factors to cover remaining uncertainty?
- If the current DNELs are seen as insufficiently protective and cannot be readily adjusted, then what data would be needed to derive appropriate DNELs to cover the ED properties of the two substances?
- With the current state of knowledge, is a non-threshold approach the best option for RAC to evaluate the applications and review reports?

Endocrine effects on environment (DEHP only):

- Are the data provided in ECHA (2014)[8] sufficient to derive PNECs for water, sediment and soil?
- If not, are the data indicative of a possibility to find a threshold? What kind of data would be needed for that?
- With the current state of knowledge, is a non-threshold approach the best option for RAC to evaluate the applications and review reports?

RAC should draft its conclusion in the form of a "Line-to-take" document, which RAC applies when forming opinions on the respective applications. This document will be made public on ECHA's website for transparency and efficiency of the process.

3. Timescale for the RAC opinion

RAC should adopt its "Line-to-take" document by the end of December 2021.

4. Remuneration

[7] https://echa.europa.eu/documents/10162/1564405/rac_24_dnel_dehp_comments_en.pdf/e0506f6b-35f7-433e-99da-35464a26e2df?t=1441812802854
https://echa.europa.eu/documents/10162/1564405/rac_24_dnel_dbp_comments_en.pdf/44ab77fd-d6fa-4d73-b0ed-9317fd6c0422?t=1441812804827

[8] ECHA (2014): Member State Committee support document for identification of bis(2-ethylhexyl) phthalate (DEHP) as a substance of very high concern because of its endocrine disrupting properties which cause probable serious effects to the environment which give rise to an equivalent level of concern to those of CMR and PBT/vPvB substances
https://echa.europa.eu/documents/10162/fa429d23-21e7-4764-b223-6c8c98f8a01c

The task for RAC following from this request is not considered to fulfil any of the requirements of a transfer of funds to the competent authorities of the Member States pursuant to Article 14(1) of Regulation (EC) 340/2008 and therefore no remuneration of the rapporteurs will be paid by the Agency.

[e-signed][9]

Bjorn Hansen
Executive Director

Cc:
Peter van der Zandt
Director of Risk Management

[9] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision approval process.