

BRIEFING

Comments on the ECHA's recommendation to amend REACH Authorisation List entries: Dibutyl phthalate (DBP)

16 May 2024

HEAL strongly supports the proposed amendments to the Annex XIV entries for Dibutyl phthalate (DBP), a substance listed as substance of very high concern (SVHC) under REACH due to its toxicity for reproduction properties (2008) and its endocrine disrupting properties for human health (2017) and the environment (2023).

These amendments appropriately reduce the existing exemptions and will thus contribute to reducing people and environment exposure to this substance of very high concern. Reducing exemptions is an important part of reducing substances of very high concern (SVHC) use in Europe thus reducing negative impacts on human and environmental health. In accordance with Article 60(4) of REACH, exemptions and derogations should be used only where there are truly no alternatives. We note that it is the authorisation process as described in Title VII of REACH — and not the use of exemptions in the Annex XIV entry—that is the proper mechanism for establishing the socioeconomic need for an SVHC and the presence or absence of suitable alternatives. HEAL calls on ECHA to maintain the fastest possible timeline in each case, as each day of delay prolongs the exposure of people and the environment to harmful substances. There are well-established safer alternatives to DBP already in use, and no additional development time can be justified.

The toxicity of DBP is not disputed. It was identified in 2008 as SVHC in accordance with Article 57(c) of REACH due to its toxic for reproduction properties (category 1B) and included in the Candidate List in 2008. It was then identified as SVHC in accordance with Article 57(f) of REACH due to its endocrine disrupting properties for human health in 2017, and due to its endocrine disrupting properties for the environment in 2023, followed by respective amendment of the Candidate List. A recent review of the literature [1] also “observed a significant association between urinary phthalates and phthalate metabolites (MEHHP, MECPP, DBP and MBzP) and cancer risk [reinforcing] the existing evidence that urinary phthalates and phthalate metabolites is strongly associated with cancer development”.

Recent studies have detected alarming level of DBP both in the environment and in human body fluids [2] warranting swift action at EU level to minimise environmental and human exposure to DBP. A study conducted by America's Children and the Environment (2017) found significant levels of DBP in urine samples, and DBP was detected in blood and breast milk [3]. Other studies have shown that exposure to DBP during pregnancy or childhood can impair the development of nerve cells, increasing the risk of behavioural and cognitive disorders [4][5]

We comment on the specific elements open for consultation below.

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1. Transitional arrangements

As a result of the identification of DBP as a SVHC in accordance with Article 57(f) of REACH due to its endocrine disrupting properties for the environment the proposed amendments remove exemptions for DBP in food contact material and in medical devices, which were previously in place respectively in Article 56(5)(b) and in Article 60(2). **This is a welcome and much-anticipated change, and should be held to the shortest timeline possible, namely 18 months for the latest application date and 18 months after the latest application date for the sunset date for both uses food contact materials and medical devices.**

There are many safer, phthalate-free materials appropriate for FCM, and DBP should be phased out of all FCM as quickly as possible. Moreover, although benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP) are not addressed specifically by this exemption, we call on ECHA to make special note of the possibility that they could be used as regrettable substitutes and to take appropriate measures as soon as possible.

2. Uses that should be exempted from authorisation including reasons for that.

No uses of DBP in food contact materials should be exempted from the authorisation requirement as Dibutyl phthalate (DBP) is mainly taken up by the general population from food intake [6]. DBP is also widely used as a plasticizer in medical device, with studies raising concern about the leaching of DBP from medical devices [7][8] and finding that most children recovering from intensive care in the neonatal intensive care unit will face long-term neurocognitive impairments, growth delays, and other developmental disorders [9]. Therefore, no uses of DBP in medical devices should be exempted from the authorisation requirement from the onset.

Should a manufacturer or user have a different point of view about the use of DBP in any of the uses covered, an application for authorisation is possible and is the appropriate venue for that discussion.

NOTES:

[Click here](#) to read HEAL's full comments on the ECHA's recommendation to amend REACH Authorisation List entries: Dibutyl phthalate (DBP)

[1] Meng et al. 2024. Association between urinary phthalates and phthalate metabolites and cancer risk: A systematic review and meta-analysis. *Heliyon* 10(8) <https://doi.org/10.1016/j.heliyon.2024.e29684>

[2] Sicińska 2019. Di-n-butyl phthalate, butylbenzyl phthalate, and their metabolites exhibit different apoptotic potential in human peripheral blood mononuclear cells. *Food and Chemical Toxicology* 133. <https://doi.org/10.1016/j.fct.2019.110750>

[3] Yang et al. 2024. Crosstalk between aryl hydrocarbon receptor and Wnt/ β -catenin signaling pathway: Possible culprit of di (2-ethylhexyl) phthalate-mediated cardiotoxicity in zebrafish larvae. *Science of The Total Environment* 907. <https://doi.org/10.1016/j.scitotenv.2023.167907>.

[4] Engel et al. 2018. Prenatal Phthalates, Maternal Thyroid Function, and Risk of Attention-Deficit Hyperactivity Disorder in the Norwegian Mother and Child Cohort. *Environmental Health Perspectives* 126(5) <https://doi.org/10.1289/EHP2358>

[5] Kassab et al. 2019. Neurochemical alterations following the exposure to di-n-butyl phthalate in rats. *Metab Brain Dis* 34 (235–244). <https://doi.org/10.1007/s11011-018-0341-0>

[6] Zeng et al. 2013. Approach to distribution and accumulation of dibutyl phthalate in rats by immunoassay. *Food and Chemical Toxicology* 56 (18–27). <http://dx.doi.org/10.1016/j.fct.2013.01.045>

[7] Šimunović et al. 2022. Medical Devices as a Source of Phthalate Exposure: A Review of Current Knowledge and Alternative Solutions *Arh Hig Rada Toksikol* 73(3) (179–190) <https://doi.org/10.2478/2Faiht-2022-73-3639>

[8] Wang et al. 2023. Leaching of Phthalates from Medical Supplies and Their Implications for Exposure. *Environ Sci Technol* 57(20) (7675–7683) <https://doi.org/10.1021%2Facs.est.2c09182>

[9] Vanhorebeek et al. 2022. Phasing out DEHP from plastic indwelling medical devices used for intensive care: does it reduce the long-term attention deficit of critically ill children? *Environ Int* 158 <https://doi.org/10.1016%2Fj.envint.2021.106962>

View HEAL's comments on draft recommendation for amendment of authorisation List entries: bis(2-ethylhexyl) phthalate (DEHP), benzyl butyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP): https://www.env-health.org/wp-content/uploads/2024/05/3455_HEAL_contribution_PC_AnnexVIV_Amend_4phthalates.pdf

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The Health and Environment Alliance (HEAL) is the leading not-for-profit organisation addressing how the environment affects human health in the European Union (EU) and beyond. HEAL works to shape laws and policies that promote planetary and human health and protect those most affected by pollution, and raise awareness on the benefits of environmental action for health.

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HEAL gratefully acknowledges the financial support of the European Union (EU) for the production of this publication. The responsibility for the content lies with the authors and the views expressed in this publication do not necessarily reflect the views of the EU institutions and funders. The European Climate, Infrastructure and Environment Executive Agency (CINEA) and the funders are not responsible for any use that may be made of the information contained in this publication.

HEAL's EU Transparency Register Number: 00723343929-96

