7 February 2024

Consultation on draft recommendation to amend DBP Annex XIV entry following its identification as SVHC due to additional intrinsic property

Explanatory note[1]

Regulation (EC) No 1907/2006 (REACH)[2] sets out an authorisation requirement for substances of very high concern (SVHCs), with the objective of ensuring the good functioning of the internal market, while assuring that the risks from those substances are properly controlled and that these substances are progressively replaced by suitable alternatives. Annex XIV to REACH lists the SVHCs that are subject to the authorisation requirement. Those substances may not be placed on the market for a use or be used unless an authorisation has been granted for that use. The list of substances subject to authorisation specifies *inter alia*, for each substance, the intrinsic properties for which the substance is identified as an SVHC.

The substance dibutyl phthalate (DBP, EC 201-557-4) was identified in 2008 as substance of very high concern (SVHC) in accordance with Article 57(c) of REACH due to its toxic for reproduction properties (category 1B) and included in the Candidate List of SVHCs[3] in 2008. DBP was included in Annex XIV to REACH in February 2011 (entry 6)[4]. In July 2017, DBP was identified as SVHC in accordance with Article 57(f) of REACH due to its endocrine disrupting properties for human health and the property added in the Candidate List. Annex XIV of REACH was amended in November 2021 adding this intrinsic property.

In December 2023, DBP was identified as a SVHC in accordance with Article 57(f) of REACH due to its endocrine disrupting properties for the environment. The Candidate List has been amended in order to reflect this additional intrinsic property of DBP.

ECHA has prepared a draft recommendation for the amendment of the Annex XIV entry in accordance with Articles 58(3) and (4) of REACH. The purpose of this consultation is to receive relevant information in particular from those actors affected by the change in authorisation requirements due to the inclusion of the additional intrinsic property of DBP, already prioritised and included in the Authorisation List (Annex XIV of the REACH Regulation).

---

[1] This note is based on the explanatory note the European Commission provided in connection with the public consultation on the same issue that ECHA ran on their behalf (5 June to 6 August 2018). See also https://echa.europa.eu/-/consultation-on-four-phthalates-for-updating-their-authorisation-list-entries-with-endocrine-disrupting-properties

[2] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 396, 30.12.2006, p. 1)

[3] https://echa.europa.eu/candidate-list-table

[4] Commission Regulation (EU) No 143/2011 of 17.02.2011 amending Annex XIV to REACH (OJ L 44, 18.02.2011, p. 2).

Interested parties are invited to send comments on the following elements[5]:

I. Transitional arrangements: comments on the proposed dates

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

III. Uses for which review periods should be included in Annex XIV, including reasons for that

The consultation on the elements listed above does not concern uses which are already subject to authorisation, including inter alia, those uses for which an authorisation decision has been adopted, is pending or under review. The question whether the inclusion of the additional intrinsic property in Annex XIV for existing or pending authorisations will trigger a review in accordance with Article 61(2) of REACH is not part of this consultation.

The inclusion of the above-mentioned Article 57(f) property into the entry of DBP in Annex XIV to REACH has implications regarding some uses of the substance which are at present not subject to the authorisation requirement:

- The inclusion of environmental hazards among the intrinsic properties of DBP in Annex XIV will imply that the authorisation requirement becomes applicable to uses currently exempted from authorisation, namely uses referred to in Article 56(5)(b) (uses in food contact materials within the scope of Regulation (EC) No 1935/2004[6]) and in Article 60(2), second subparagraph (uses in a medical device regulated by Council Directive 90/385/EEC relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices[7] or Directive 98/79/EC on *in vitro* diagnostic medical devices[8])[9].

Since the above-mentioned changes to Annex XIV under consideration as regards DBP would affect operators who place those substances on the market for the above-mentioned uses as well as operators who perform these uses, transitional arrangements (latest application date and sunset date) should be provided in order to enable those operators to

[5] Some more explanation on the elements of the substance entries in Annex XIV can be found in ECHA's General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV (https://echa.europa.eu/draft-recommendation-for-inclusion-in-the-authorisation-list-consulation).
[6] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food (OJ L 338, 13.11.2004, p. 4)
[7] Council Directive 90/385/EEC, of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17). Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1). Council Directives 90/385/EEC and 93/42/EEC have been repealed and are gradually replaced by the Medical Devices Regulation 2017/745 from 26 May 2021.
[8] Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, p. 1). Council Directive 98/79/EC has been repealed and replaced by the In Vitro Diagnostic Medical Devices Regulation 2017/746 from 26 May 2022.
[9] Article 56(5)(a) exempts the use of a substance in cosmetic products within the scope of Regulation (EC) No 1223/2009 of the European Parliament and of the Council where the substance is identified as SVHC only because of human health hazards. However, that Regulation bans the use of DBP in cosmetic products. Consequently, the use of that substance in cosmetic products cannot be authorised under REACH.

phase out the use of the substance or to prepare applications for authorisation, as appropriate. On a preliminary basis, the starting point for such transitional arrangements would be the standard time which is generally considered necessary to prepare an application for authorisation, i.e. 18 months (from the date of entry into force of the amendment) as the latest application date. The starting point for the sunset date would be the minimum required by Article 58(1)(c)(ii) of REACH, i.e. 18 months after the latest application date.

Furthermore, parties concerned should be given the opportunity to submit comments on uses which should be exempt from the authorisation requirement. Conditions for providing for such exemptions are laid down in Article 56(3) and Article 58(2) of REACH.

Finally, Article 58(1)(d) of REACH provides for the possibility that Annex XIV sets out review periods for certain uses, if appropriate.

The document *ECHA's general responses on issues commonly raised in public consultations on draft recommendations*[10] provides for guidance on the comments sought on the above-mentioned elements as regards ECHA's draft recommendations. Since the above-mentioned substances are already included in Annex XIV, the object of the present consultation is not the prioritisation of these substances. Consequently, for the purpose of this consultation only sections B and C of that document are relevant.

[10] https://echa.europa.eu/documents/10162/17232/recom_general_responses_doc_en.pdf