12 December 2018

Consultation on draft recommendation to amend DEHP, BBP, DBP and DIBP Annex XIV entries following their identification as SVHC due to additional intrinsic properties

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 substances bis(2-ethylhexyl) phthalate (DEHP, EC 204-211-0), benzyl butyl phthalate (BBP, EC 201-622-7), dibutyl phthalate (DBP, EC 201-557-4) and diisobutyl phthalate (DIBP, EC 201-553-2) were identified in 2008 and 2009 as substances of very high concern (SVHC) in accordance with Article 57(c) of REACH due to their toxic for reproduction properties (category 1B) and included in the Candidate List of SVHCs[3] in 2008 and 2010. DEHP, BBP and DBP were included in Annex XIV to REACH in February 2011 (entries 4, 5 and 6, respectively)[4], and DIBP in February 2012 (entry 7)[5].

In December 2014, DEHP was identified as a SVHC in accordance with Article 57(f) of REACH due to its endocrine disrupting properties for the environment[6]. In July 2017, the four phthalates were identified as SVHCs in accordance with Article 57(f) of REACH due to their endocrine disrupting properties for human health[7]. The Candidate List has been amended in order to reflect these additional intrinsic properties of the four phthalates[8].

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[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/documents/10162/c2ecc989-445d-40b9-a054-28671849b092
https://echa.europa.eu/documents/10162/8f861ec5-40ca-43d6-be8a-7bc22b96f84f

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

[5] Commission Regulation (EU) No 125/2012 of 14.02.2012 amending Annex XIV to REACH (OJ L 41, 15.02.2012, p. 1).

[6] https://echa.europa.eu/documents/10162/30b654ce-1de3-487a-8696-e05617c3173b

[7] Commission Implementing Decision (EU) 2017/1210 of 4.07.2017 (OJ L 173, p. 35)

[8] https://echa.europa.eu/documents/10162/3b0d2893-b8db-86b9-6db0-6e06dc9aa10e

The Commission is currently considering the inclusion of the above-mentioned Article 57(f) properties into the respective entries of these four substances in Annex XIV to REACH. In turn, ECHA has prepared a draft recommendation for the amendment of the Annex XIV entries 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 additional intrinsic properties of the four substances DEHP, BBP, DBP and DIBP, already prioritised and included in the Authorisation List (Annex XIV of the REACH Regulation). Interested parties are invited to send comments on the following elements[9]:

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 public 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 properties 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 public consultation.

The inclusion of the above-mentioned Article 57(f) properties into the respective entries of these four substances in Annex XIV to REACH has implications regarding some uses of those substances which are at present not subject to the authorisation requirement:

1) Regarding DEHP, the inclusion of environmental hazards among its intrinsic properties 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[10]) 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[11], Council

[9] 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/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf/2b80fc7f-fc40-4c1a-971f-023691baf702).

[10] 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)

[11] 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). This Directive will be repealed as of 26 May 2020 and replaced by Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (OJ L 117, 5.5.2017, p. 1).

Directive 93/42/EEC concerning medical devices[12] or Directive 98/79/EC on *in vitro* diagnostic medical devices[13])[14].

2) Regarding all four phthalates, their identification as SVHCs in accordance with Article 57(f) of REACH will imply that the concentration limit for the substance in a mixture below which the use is exempted from the authorisation requirement will be reduced from the present 0.3% weight by weight[15] (generic concentration limit set out in Annex I to Regulation (EC) No 1272/2008 for reprotoxic substances) to 0.1% weight by weight, in accordance with Article 56(6)(a) of REACH.

3) The use of DEHP, BBP and DBP in the immediate packaging of medicinal products covered by Regulation (EC) No 726/2004, Directive 2001/82/EC or Directive 2001/83/EC is exempted from the authorisation requirement as indicated in Annex XIV in column *'exempted (categories of) uses*'. This Union legislation relates to the protection of human health. Regarding DEHP, the inclusion of environmental hazards among its intrinsic properties in Annex XIV will require assessing whether this exemption would still be justified considering the environmental risks.

Since the above-mentioned changes to Annex XIV under consideration as regards DEHP, BBP, DBP and DIBP 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 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.

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[12] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1). This Directive will be repealed as of 26 May 2020 and replaced by Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (OJ L 117, 5.5.2017, p. 1).

[13] 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). This Directive will be repealed as of 26 May 2022 and replaced by Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices (OJ L 117, 5.5.2017, p. 176).

[14] 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 DEHP in cosmetic products. Consequently, the use of that substance in cosmetic products cannot be authorised under REACH.

[15] Generic concentration limit applicable to reprotoxic substances in accordance with Annex I to Regulation (EC) No 1272/2008 which results in the classification of the mixture as hazardous.

The document *ECHA's general responses on issues commonly raised in public consultations on draft recommendations*[16] 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 public consultation only sections B and C of that document are relevant.

Please note that ECHA had already hosted a public consultation on behalf of the Commission on this issue, which ran from 5 June 2018 to 6 August 2018. Comments submitted during that previous consultation will be published on the Commission's website and will be considered for ECHA's recommendation on the amendment of Annex XIV.

16 https://echa.europa.eu/documents/10162/13640/recom_general_responses_doc_en.pdf/44e192e5-ac72-4458-b4f5-c016754a1d4c