Recommendation of the European Chemicals Agency of 10 July 2019 to amend the Annex XIV entries to REACH of DEHP, BBP, DBP and DIBP

(List of Substances subject to Authorisation)

The European Chemicals Agency,

Having regard to 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 (the REACH Regulation), establishing a European Chemicals Agency (ECHA), amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[1], and in particular Article 58 thereof,

Having regard to the Candidate List of Substances of Very High Concern for authorisation, as amended by Decision ED/30/2017[2],

Having regard to the opinion of ECHA's Member State Committee of 26 June 2019[3],

Whereas:

(1) This Recommendation aims to assist the Commission in taking its decision pursuant to Article 58(1) of the REACH Regulation to include additional intrinsic properties for 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) into their respective entries in Annex XIV.

(2) These substances were included in the Candidate List of SVHCs[4] in 2008 and 2010 because they meet the criteria for identification as substances of very high concern (SVHC) in accordance with Article 57 (c) of the REACH Regulation due to their toxic for reproduction properties (category 1B).

(3) DEHP, BBP and DBP were included in Annex XIV to the REACH Regulation in February 2011 (entries 4, 5 and 6, respectively)[5], and DIBP in February 2012 (entry

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1 OJ L 396, 30.12.2006, p 1

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

3 https://www.echa.europa.eu/documents/10162/13576/msc_opinion_draft_amendment_dehp_bbp_dbp_dibp_26062019_en.pdf

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

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

7)[6]. For each of these entries the following intrinsic property was specified in accordance with Article 58(1)(b) - toxic for reproduction (category 1B).

(4) 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[7]. In July 2017, DEHP, BBP, DIBP and DBP were identified as SVHCs in accordance with Article 57(f) of the REACH Regulation due to their endocrine disrupting properties for human health. The Candidate List has been amended in order to reflect these additional intrinsic properties of these four substances.

(5) Between 5 June and 6 August 2018, ECHA conducted, on behalf of the European Commission, a public consultation on the inclusion of these additional intrinsic properties in Annex XIV to the REACH Regulation. Comments submitted during this consultation were published on the European Commission's website.

(6) On 12 December 2018, in accordance with Article 58(4) of the REACH Regulation, ECHA published on its website the draft recommendation for amending the existing entries of the above mentioned substances in Annex XIV and invited all interested parties to submit comments by 12 March 2019.

(7) ECHA has analysed and prepared responses to comments received from both the 5 June 2018 and 12 December 2018 consultations. These are provided to the Commission as part of the recommendation documents. Public versions are made available on ECHA's website[8].

(8) Since the four substances are already included in Annex XIV of the REACH Regulation they already meet the prioritisation criteria under Article 58 (3) of the REACH Regulation.

(9) ECHA is required by Articles 58(1) and (3) of the REACH Regulation to recommend for each priority substance an Annex XIV entry specifying: its identity; its intrinsic properties referred to in Article 57; the date(s) referred to in Article 58(1)(c)(ii) of the REACH Regulation by which an application should be received if the applicant wishes to continue to use the substance or place the substance on the market ("latest application date"); the date referred to in Article 58(1)(c)(i) of the REACH Regulation from which the placing on the market and use of a substance is prohibited unless an authorisation is granted ("sunset date"); the review periods for certain uses, if appropriate; and uses or categories of uses to be exempted from the authorisation requirement, if any, and conditions for such exemptions, if any.

(10) The addition of the above-mentioned intrinsic properties into Annex XIV means that some uses of the four substances will no longer be exempted from the authorisation requirement.

(11) In order to enable the operators concerned to phase out those uses of the above mentioned substances or to prepare applications for authorisation, ECHA has determined the transitional arrangements referred to in Article 58(1)(c) of the REACH Regulation (latest application date and sunset date).

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

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

[8] Comments and responses given under "Details" of all substances at the link: https://www.echa.europa.eu/previous-recommendations

(12) These transitional arrangements do not concern the uses which were already subject to the authorisation requirement under the current Annex XIV entries. ECHA has applied for each use of the four substances a standard time period of 18 months between the suggested latest application date and the sunset date because neither the available information for the recommended substances nor the comments received during public consultations provide information that would support the recommendation of longer periods.

(13) The latest application date for each substance has been set having regard to ECHA's capacity to handle applications in the time provided for, in accordance with Article 58(3) of the REACH Regulation, over a period of 18 months from the entry into force of the amendment to the Annex XIV entries.

(14) The information available for the recommended amendment to the Annex XIV entries of the four substances including the comments received during the public consultations does not provide information that would justify for the upfront definition of review periods for any uses of the substances in accordance with Article 58(1)(d) of the REACH Regulation.

(15) Article 58(1)(e) in conjunction with Article 58(2) of the REACH Regulation provides for the possibility of exemptions of uses or categories of uses in cases where there is specific EU legislation imposing minimum requirements relating to the protection of human health or the environment that ensures proper control of the risks.

(16) ECHA has received during the public consultations comments requesting exemptions of uses for DEHP, BBP, DBP and DIBP. Based on its assessment of these exemption requests[8], ECHA does not recommend any additional exemptions from the authorisation requirement on the basis of Article 58(1)(e) and Article 58(2) of the REACH Regulation.

(17) For the substance DEHP, ECHA recommends the removal of the exemption granted under Article 58(2) for uses in immediate packaging of medicinal products covered under Regulation (EC) No 726/2004[9], Directive 2001/82/EC[10], and/or Directive 2001/83/EC[11]. This is because this legislation does not constitute specific legislation imposing minimum requirements relating to the protection of the environment.

(18) Article 56(3) of the REACH Regulation requires Annex XIV to specify if it applies to product and process orientated research and development (PPORD). The information available for the recommended substances, including the comments received during public consultations, does not provide grounds to recommend exemptions from the authorisation requirement for PPORD on the basis of Article 56(3) of the REACH Regulation.

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9 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1)

10 Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1)

11 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67)

HEREBY RECOMMENDS that the following entries in Annex XIV to the REACH Regulation (List of Substances subject to Authorisation) are amended with changes marked in grey shade

Draft Annex XIV entries									
Entry Nr.	**Substance**	**EC number**	**CAS Number**	**SVHC-relevant intrinsic properties***	**Latest application date pursuant to REACH Art. 58 (1) (c) (ii) ****	**Sunset date**	**Review periods**	**Exempted uses or categories of uses**	**Exemptions for PPORD**
4.	Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	117-81-7	Toxic for reproduction (category 1B) Endocrine disrupting properties (Article 57(f) - human health) Endocrine disrupting properties (Article 57(f) - environment)	(a) 21 August 2013 (b) [18 months after entry into force] for uses in: – food contact materials within the scope of Regulation (EC) No 1935/2004[12]; – medical devices regulated by Directive 90/385/EEC[13], Directive 93/42/EEC[14] or Directive 98/79/EC[15]; – immediate packaging of	(a) 21 February 2015 (b) [36 months after entry into force] for uses in: – food contact materials within the scope of Regulation (EC) No 1935/2004; – medical devices regulated by Directive 90/385/EEC, Directive 93/42/EEC or Directive 98/79/EC; – immediate packaging of	None	~~Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC~~ None	None

[12] 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 and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4)
[13] 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)
[14] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1)
[15] 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)

Draft Annex XIV entries									
Entry Nr.	**Substance**	**EC number**	**CAS Number**	**SVHC-relevant intrinsic properties***	**Latest application date pursuant to REACH Art. 58 (1) (c) (ii) ****	**Sunset date**	**Review periods**	**Exempted uses or categories of uses**	**Exemptions for PPORD**
					– medicinal products covered under Regulation (EC) No 726/2004[16], Directive 2001/82/EC[17], and/or Directive 2001/83/EC[18]; – mixtures containing DEHP between 0,1% and 0,3% weight by weight	– medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC; – mixtures containing DEHP between 0,1% and 0,3% weight by weight			
5.	Benzyl butyl phthalate (BBP)	201-622-7	85-68-7	Toxic for reproduction (category 1B) Endocrine disrupting properties (Article 57(f) - human health)	(a) 21 August 2013 (b) [18 months after entry into force] for uses in mixtures containing BBP between 0,1% and 0,3% weight by weight	(a) 21 February 2015 (b) [36 months after entry into force] for uses in mixtures containing BBP between 0,1% and 0,3% weight by weight	None	Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC	None

[16] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1)

[17] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1)

[18] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67)

Draft Annex XIV entries									
Entry Nr.	**Substance**	**EC number**	**CAS Number**	**SVHC-relevant intrinsic properties***	**Latest application date pursuant to REACH Art. 58 (1) (c) (ii) ****	**Sunset date**	**Review periods**	**Exempted uses or categories of uses**	**Exemptions for PPORD**
6.	Dibutyl phthalate (DBP)	201-557-4	84-74-2	Toxic for reproduction (category 1B) Endocrine disrupting properties (Article 57(f) - human health)	(a) 21 August 2013 (b) [18 months after entry into force] for uses in mixtures containing DBP between 0,1% and 0,3% weight by weight	(a) 21 February 2015 (b) [36 months after entry into force] for uses in mixtures containing DBP between 0,1% and 0,3% weight by weight	None	Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC	None
7.	Diisobutyl phthalate (DIBP)	201-553-2	84-69-5	Toxic for reproduction (category 1B) Endocrine disrupting properties (Article 57(f) - human health)	(a) 21 August 2013 (b) [18 months after entry into force] for uses in mixtures containing DIBP between 0,1% and 0,3% weight by weight	(a) 21 February 2015 (b) [36 months after entry into force] for uses in mixtures containing DIBP between 0,1% and 0,3% weight by weight	None	None	None

* Reference is made to the identified SVHC properties in accordance with Article 57 of the REACH Regulation and to the corresponding classification in accordance with Annex VI, Table 3.1 (*List of harmonised classification and labelling of hazardous substances)* of REGULATION (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

** The latest application date was determined on the basis of the General approach for the preparation of draft Annex XIV entries for substances to be included in Annex XIV.

Done at Helsinki, 10 July 2019
For the European Chemicals Agency,
(e-signed)[19]

Jack de Bruijn

Director of Prioritisation and Integration

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

Annex I: Documents relevant for this amendment recommendation

This Annex provides links to all documents relevant for this recommendation.

Table 1 below lists all substances for which an amendment is recommended. It provides for each substance the links to

- **Comments and references to responses document (ComRef)**
  The ComRef document consists of the compilation of the comments submitted during the two public consultations for each substance. For each comment the reference(s) to ECHA's response(s) in the response document is given.

- **Response document**
  The response document is the compilation of ECHA's responses to the comments submitted during the two public consultations. There is one response document for the group of the four phthalates.

The additional documents relevant for the recommendation are listed below and can be found on ECHA's website under "Details" of all substances at the link: https://www.echa.europa.eu/previous-recommendations

- General approach for the preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV (18 November 2015);

- Draft amendment of Annex XIV entries (12 December 2018);

- Explanatory note provided at start of public consultation by ECHA on its website (12 December 2018)[20];

- Opinion of the Member State Committee on ECHA's draft recommendation for amendment of existing entries in Annex XIV (Adopted on 26 June 2019).

[20] https://www.echa.europa.eu/documents/10162/26059769/axiv_amend_recom_1_phthalates_expl_note_en.pdf

Table 1: List of substances, for which an amendment is recommended, and links to the relevant documents.

Entry Nr.	Substance name (EC number)	Comments and references to responses document (ComRef)	Response document
4.	Bis(2-ethylhexyl) phthalate (DEHP) (204-211-0)	https://echa.europa.eu/documents/10162/13640/axiv_amend_recom_comref_dehp_en.rtf	https://echa.europa.eu/documents/10162/13640/axiv_amend_recom_phthalates_respdoc_en.pdf
5.	Benzyl butyl phthalate (BBP) (201-622-7)	https://echa.europa.eu/documents/10162/13640/axiv_amend_recom_comref_bbp_en.rtf	
6.	Dibutyl phthalate (DBP) (201-557-4)	https://echa.europa.eu/documents/10162/13640/axiv_amend_recom_comref_dbp_en.rtf	
7.	Diisobutyl phthalate (DIBP) (201-553-2)	https://echa.europa.eu/documents/10162/13640/axiv_amend_recom_comref_dibp_en.rtf	