26 June 2019 Final

OPINION OF THE MEMBER STATE COMMITTEE ON ECHA'S DRAFT RECOMMENDATION FOR THE FIRST AMENDMENT OF EXISTING ENTRIES IN ANNEX XIV OF THE REACH REGULATION

Adopted on 26 June 2019

OPINION

This opinion of the Member State Committee (MSC) is on the draft recommendation of European Chemicals Agency (ECHA) to amend the existing entries of four phthalates included in Annex XIV of the REACH Regulation (EC) No 1907/2006[1] (REACH). The amendment follows the identification of the substances as SVHC with additional intrinsic properties since the initial inclusion in Annex XIV. These substances are bis(2-ethylhexyl) phthalate (DEHP, EC No. 204-211-0), benzyl butyl phthalate (BBP, EC No. 201-622-7), dibutyl phthalate (DBP, EC No. 201-557-4) and diisobutyl phthalate (DIBP, EC No. 201-553-2). The opinion was adopted on 26 June 2019 in accordance with Article 58(3) of the REACH Regulation.

THE DRAFT RECOMMENDATION OF ECHA

DEHP, BBP and DBP have been included in Annex XIV to REACH in February 2011 (entries 4, 5 and 6, respectively)[2], and DIBP in February 2012 (entry 7)[3] following their listing on the Candidate List due to their toxic for reproduction properties (category 1B). Since then, DEHP has been identified as a SVHC in accordance with Article 57(f) of REACH due to its endocrine disrupting properties for the environment[4], and all four phthalates have been identified as SVHCs in accordance with Article 57(f) of REACH due to their endocrine disrupting properties for human health[5]. The Candidate List has been amended in order to reflect these additional intrinsic properties of the four phthalates[6]. Therefore, a draft recommendation for the amendment of the Annex XIV entries was prepared by ECHA in accordance with Articles 58(3) and (4) of REACH. The draft recommendation for amendment of the four entries in Annex XIV of REACH (hereafter referred to as the "draft amendment") specified the following information for the substances:

- The identity of the substance as specified in section 2 of Annex VI

[1] Regulation (EC) No 1907/2006 of the European Parliament and the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, 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

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

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

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

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

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

- The intrinsic property(-ies) of the substance referred to in Article 57
- Transitional arrangements
    - The latest application date
    - The sunset date
- Uses or categories of uses exempted from the authorisation requirement, if any, and conditions for such exemptions, if any.

The draft amendment addressed in the public consultation is attached to this opinion (Annex I). Given that the draft recommendation concerns the amendment of the existing entries of Annex XIV, all the changes under consideration were separately marked [in grey shade].

PROCESS FOR ADOPTION AND FOCUS OF THE OPINION OF MSC

MSC appointed a Rapporteur and a Co-Rapporteur for preparing its opinion on the first draft amendment of the four entries of Annex XIV of REACH at its 63rd meeting (5-7 February 2019).

For the preparation of its opinion MSC took into account the draft amendment of entries of Annex XIV (published 12 December 2018 on ECHA website), comments of interested parties provided during the public consultation period that started on 12 December 2018 and closed on 12 March 2019, comments to the previous public consultation hosted on behalf of the Commission (5 June 2018 to 6 August 2018), as well as the assessment by ECHA Secretariat of the information received.

The opinion of MSC focuses on the changes that this draft recommendation would be introducing to the currently existing Annex XIV entries, and the comments received during the public consultation on this draft recommendation. Emphasis is given to such matters which MSC considers there is a need for changes in ECHA's final recommendation compared to the draft recommendation or where MSC members and/or MSC and ECHA have expressed diverging views.

OPINION OF MSC ON THE DRAFT RECOMMENDATION FOR AMENDMENT OF ENTRIES OF FOUR PHTHALATES INCLUDED IN ANNEX XIV

SUBSTANCES

The draft amendment has a limited scope where priority of the substances is not part of the amendment recommendation since the substances have already been prioritised and listed in the Annex XIV of REACH.

The substances in the draft amendment are

#	Substance	EC number	CAS number
1	Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	117-81-7
2	Benzyl butyl phthalate (BBP)	201-622-7	85-68-7
3	Dibutyl phthalate (DBP)	201-557-4	84-74-2
4	Diisobutyl phthalate (DIBP)	201-553-2	84-69-5

TRANSITIONAL ARRANGEMENTS

Transitional arrangements for DEHP, BBP, DBP and DIBP were originally set to 21 August 2013 (latest application date) and 21 February 2015 (sunset date) when

included in the Annex XIV due to toxicity for reproduction Repr. 1B (Art. 57c). In 2014, DEHP was also identified as a SVHC due to its endocrine disrupting properties in the environment (Art. 57f) and in 2017, all four were identified as SVHC due to their endocrine disrupting properties for human health (Art. 57f).

MSC notes that the draft recommendation of ECHA proposed to allocate the substances to a latest application date (LAD) of 18 months after the date of inclusion of these additional properties in Annex XIV of REACH.
Taking into account all available information, the MSC is of the opinion that the following LAD allocation is appropriate:

Substance	EC number	CAS number	Proposed LAD
Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	117-81-7	18 months
Benzyl butyl phthalate (BBP)	201-622-7	85-68-7	18 months
Dibutyl phthalate (DBP)	201-557-4	84-74-2	18 months
Diisobutyl phthalate (DIBP)	201-553-2	84-69-5	18 months

Some of the comments received in the public consultation argued for longer transitional periods for DEHP due to 1) the faster regulatory action of amending Annex XIV in contrast to the normal prioritisation process, 2) issues with overlap in regulation (e.g. RoHS) as well as 3) ongoing authorisation applications.

1) As DEHP already is on Annex XIV, the process of amendment is indeed shorter as no prioritisation step is performed. DEHP was identified as an SVHC in 2008 and once again in 2014 due to its endocrine disrupting properties in the environment. MSC is of the opinion that the LAD should not be extended merely due to the process of amendment in itself.
2) As described below, the RoHS legislation does not have the same scope as REACH and MSC is of the opinion that this should not form the basis for changing the LAD proposed by ECHA.
3) Ongoing applications for authorisation are not considered relevant for the opinion of the MSC on the amendment of Annex XIV.

Furthermore, based on the comments it seems that it is only the specific use of DEHP in medical devices that would potentially trigger the need for extending the LAD, and it is the opinion of the MSC that this use should be feasible to apply for in 18 months. MSC therefore sees no reasons (e.g. in terms of complexity of supply chains) to deviate from the LAD proposed by ECHA.

Taking into account all available information, MSC is of the opinion that the sunset date for all substances should be assigned as the LAD plus 18 months.

REVIEW PERIODS FOR CERTAIN USES

The current entries do not include review periods for certain uses and in its draft recommendation/amendment, ECHA did not suggest any changes to this.

MSC is of the opinion that upfront specified review periods are not warranted in the recommendation for inclusion of substances in Annex XIV of REACH.

USES OR CATEGORIES OF USES EXEMPTED FROM THE AUTHORISATION REQUIREMENT

In its draft recommendation for BBP, DBP and DIBP, ECHA did not suggest any modifications to the existing exemptions from authorisation pursuant to Article 58(2). As regards DEHP, ECHA in its draft recommendation removed the exemption for uses in the immediate packaging of medicinal products.

In the public consultation, some comments questioned the continuation of the exemption for DBP and BBP in immediate packaging in medicinal products. ECHA responded by inviting the Commission to assess this exemption in the light of the new human health hazards and in accordance with the considerations of the General Court and the European Court of Justice in their judgements in Cases T-360/13 and C-651/15 P Vecco and others v. Commission.

MSC would like ECHA to request the Commission to assess whether this exemption should continue to apply for DBP and BBP. The reasons for this request are similarly the new human health hazards identified for DBP and BBP, and a concern whether the exemption is in line with the current interpretation of Article 58(2) of the REACH Regulation.

Comments were received in the public consultation asking to exempt the use of DEHP in blood bags as well as the use of DEHP in EEE (electrical or electronic equipment) under RoHS. MSC is of the opinion that no information was submitted during the public consultation that would form the basis for inclusion of a further specific exemption under Article 58(2) for a use or a category of use in Annex XIV for any of the substances. For EEE, the RoHS Directive does indeed include some requirements, which limits the impact of DEHP from the waste phase. As some stages in the life cycle are not covered by the RoHS Directive, MSC is of the opinion that it does not appear to constitute the basis for an exemption under Article 58(2).

EXEMPTIONS FOR THE USE IN PRODUCT AND PROCESS ORIENTED RESEARCH AND DEVELOPMENT

The current entries do not include any exemptions from the authorisation requirements for uses in product and process oriented research and development (PPORD) and ECHA in its draft amendment did not recommend any exemptions from the authorisation requirements for PPORD, as provided for in Article 56(3) of REACH. During the public consultation, no specific comments were received with regard to possible PPORD exemptions. Thus MSC is of the opinion that PPORD exemptions in Annex XIV are not required.

OTHER ISSUES

Comments were received during the public consultation on the socio-economic aspects of removing the exemption for DEHP in medical products. A number of comments addressed alternatives; many noting the lack of alternatives for their specific use and the fact that possible substitutes were similarly hazardous.

MSC took note of these comments and is of the view that they are relevant for the authorisation applications but are not in the scope of MSC's opinion on the amendment the entries in Annex XIV.

Annex I: ECHA's draft recommendation to amend entries for DEHP, BBP, DBP and DIBP Annex XIV, published on 12 December 2018

ECHA
EUROPEAN CHEMICALS AGENCY

12 December 2018

Draft Amendment of Annex XIV entries

(changes under consideration are marked in grey shade)

			Transitional arrangements			
Entry Nr.	**Substance**	**Intrinsic property(ies) referred to in Article 57**	**Latest application date[1]**	**Sunset date[2]**	**Exempted (categories of) uses**	**Review periods**
4.	Bis(2-ethylhexyl) phthalate (**DEHP**) EC No: 204-211-0 CAS No: 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) By derogation of point (a): [18 months after entry into force] for uses in: – food contact materials within the scope of Regulation (EC) No 1935/2004[1]; – medical devices regulated by Directive 90/385/EEC[2], Directive 93/42/EEC[3] or Directive 98/79/EC[4]; – immediate packaging of medicinal products covered under Regulation (EC) No 726/2004[5], Directive 2001/82/EC[6], and/or Directive 2001/83/EC[7]; – mixtures containing DEHP between 0,1% and 0,3% weight by weight	(a) 21 February 2015 (b) By derogation of point (a): [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 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	~~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~~ -	-

[1] 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)
[2] 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)
[3] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1)
[4] 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)
[5] 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)
[6] 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)
[7] 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)

5.	Benzyl butyl phthalate (**BBP**) EC No: 201-622-7 CAS No: 85-68-7	Toxic for reproduction (category 1B) Endocrine disrupting properties (Article 57(f) - human health)	(a) 21 August 2013 (b) By derogation of point (a): [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) By derogation of point (a): [36 months after entry into force] for uses in mixtures containing BBP between 0,1% and 0,3% weight by weight	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	-
6.	Dibutyl phthalate (**DBP**) EC No: 201-557-4 CAS No: 84-74-2	Toxic for reproduction (category 1B) Endocrine disrupting properties (Article 57(f) - human health)	(a) 21 August 2013 (b) By derogation of point (a): [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) By derogation of point (a): [36 months after entry into force] for uses in mixtures containing DBP between 0,1% and 0,3% weight by weight	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	-
7.	Diisobutyl phthalate **(DIBP)** EC No: 201-553-2 CAS No: 84-69-5	Toxic for reproduction (category 1B) Endocrine disrupting properties (Article 57(f) - human health)	(a) 21 August 2013 (b) By derogation of point (a): [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) By derogation of point (a): [36 months after entry into force] for uses in mixtures containing DIBP between 0,1% and 0,3% weight by weight	-	-

(1) Date referred to in Article 58(1)(c)(ii) of Regulation (EC) No 1907/2006
(2) Date referred to in Article 58(1)(c)(i) of Regulation (EC) No 1907/2006