



EUROPEAN
COMMISSION

Brussels, **XXX**
[...](2016) **XXX** draft

COMMISSION IMPLEMENTING DECISION (EU) .../...

of **XXX**

on the identification of bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP) as substances of very high concern according to Article 57(f) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council

(Text with EEA relevance)

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 (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/EC¹, and in particular Article 59(9) thereof,

Whereas:

- (1) Bis(2-ethylhexyl) phthalate (DEHP), (EC No. 204-211-0, CAS No. 117-81-7), dibutyl phthalate (DBP) (EC No. 201-557-4, CAS No. 84-74-2), benzyl butyl phthalate (BBP) (EC No. 201-622-7, CAS No. 85-68-7) and diisobutyl phthalate (DIBP) (EC No. 201-553-2, CAS No. 84-69-5) are included in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006 as substances toxic for reproduction (category 1B) according to Article 57(c) of that Regulation. Those substances are also listed in Annex XIV to that Regulation.
- (2) In accordance with Article 59(3) of Regulation (EC) No 1907/2006, on 26 August 2014 Denmark submitted to the European Chemicals Agency (hereinafter referred to as "the Agency") four dossiers in accordance with Annex XV to that Regulation (hereinafter referred to as "Annex XV dossiers") for the identification of DEHP, DBP, BBP and DIBP as substances of very high concern under Article 57(f) of that Regulation due to their endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in paragraphs (a) to (e) of Article 57.
- (3) When the four Annex XV dossiers were considered by the Member State Committee of the Agency ("MSC"), they were considered in two parts each, one covering the human health aspects and the other covering the environmental aspects of the dossier, respectively.
- (4) As for the Annex XV dossiers for DBP, BBP and DIBP, the dossier submitter subsequently withdrew the part of its proposal concerning identification of these

¹ OJ L 396, 30.12.2006, p. 1.

substances as having endocrine disrupting properties whose effects in relation to the environment give rise to an equivalent level of concern according to Article 57(f) of Regulation (EC) No 1907/2006, in order to further elaborate on the justifications provided in the documentation.

- (5) On 11 December 2014 the MSC adopted its opinions² on the remaining part of the Annex XV dossiers. The MSC reached a unanimous agreement on the identification of DEHP as having endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment which give rise to an equivalent level of concern according to Article 57(f) of Regulation (EC) No 1907/2006. Accordingly the Agency amended the DEHP entry in the candidate list on 17 December 2014.
- (6) The MSC unanimously acknowledged that for DEHP, BBP, DBP and DIBP there is scientific evidence on the endocrine activity and on the link between this activity and the adverse effects to human health and further, that the substances can be considered endocrine disruptors for human health as they fulfil the WHO/IPCS definition for an endocrine disruptor and the recommendations from the European Commission's Expert Advisory Group for a substance to be identified as an endocrine disruptor.
- (7) However, the MSC did not reach unanimous agreement on the identification of the four substances under Article 57(f) of Regulation (EC) No 1907/2006 as giving rise to an equivalent level of concern to those of other substances listed in points (a) to (c) of that Article due to endocrine disrupting properties in relation to human health. According to four members of the MSC the effects for human health pointed out in the Annex XV dossiers were the same effects, caused by the same mode of action, as those already taken into account when the substances were included in the candidate list due to their toxicity for reproduction according to Article 57(c) of that Regulation.
- (8) On 20 February 2015, pursuant to Article 59(9) of Regulation (EC) No 1907/2006, the MSC referred its opinion to the Commission for a decision on the identification of the four substances as having endocrine disrupting properties for human health giving rise to an equivalent level of concern according to Article 57(f).
- (9) The Commission notes the unanimous agreement in MSC that the four substances have endocrine disrupting properties and that the adverse effects caused by this mode of action are the same effects that led to their classification as toxic for reproduction and their identification as substances of very high concern according to Article 57(c) of Regulation (EC) No 1907/2006. The Commission also notes that the majority of members of the MSC considered that the level of concern of those effects is equivalent to those of substances referred to in Article 57 (a) to (e).
- (10) The Commission notes that Article 57 does not preclude identifying a substance as being of very high concern several times based on more than one intrinsic property causing the same effect on human health.
- (11) Therefore DEHP, BBP, DBP and DIBP should be identified under Article 57 (f) as substances of very high concern due to their endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health which give rise to an equivalent level of concern to those of other substances listed in paragraph(s) (a) to (e) of that Article.

² <http://echa.europa.eu/role-of-the-member-state-committee-in-the-authorisation-process/svhc-opinions-of-the-member-state-committee>

- (12) This Decision is without prejudice to the outcome of the on-going activities related to the definition of criteria for the identification of endocrine disruptors in accordance with the provisions of Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market and repealing Directives 79/117/EEC and 91/441/EEC³, and Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.⁴
- (13) The measures provided for in this Decision are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS DECISION:

Article 1

1. The following substances are identified as substances having endocrine disrupting properties whose effects to human health give rise to an equivalent level of concern according to Article 57(f) of Regulation (EC) No 1907/2006:

- Bis(2-ethylhexyl) phthalate (DEHP), (EC No. 204-211-0, CAS No. 117-81-7)
- Dibutyl phthalate (DBP) (EC No. 201-557-4, CAS No. 84-74-2)
- Benzyl butyl phthalate (BBP) (EC No. 201-622-7, CAS No. 85-68-7)
- Diisobutyl phthalate (DIBP) (EC No. 201-553-2, CAS No. 84-69-5)

2. The entry of the substances specified in paragraph 1 in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006 shall be amended by adding, under “Reason for inclusion”, “Equivalent level of concern having probable serious effects to human health”.

This Decision is addressed to the European Chemicals Agency.

Done at Brussels,

For the Commission
Elżbieta BIENKOWSKA
Member of the Commission

³ OJ L 309, 24.11.2009, p. 1.

⁴ OJ L 167, 27.6.2012, p. 1.