

COMMISSION IMPLEMENTING DECISION (EU) 2018/636**of 17 April 2018****on the identification of dicyclohexyl phthalate (DCHP) as a substance of very high concern according to Article 57(c) and (f) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council***(notified under document C(2018) 2167)***(Only the English text is authentic)****(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/EC ⁽¹⁾, and in particular Article 59(9) thereof,

Whereas:

- (1) In accordance with Article 59(3) of Regulation (EC) No 1907/2006, on 17 February 2016 Sweden submitted to the European Chemicals Agency ('the Agency') a dossier prepared in accordance with Annex XV to that Regulation ('Annex XV dossier') for the identification of dicyclohexyl phthalate (DCHP) (EC No 201-545-9, CAS No 84-61-7) as a substance of very high concern in accordance with Article 57(c) and (f) of that Regulation, due respectively to its classification as toxic for reproduction category 1B under Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽²⁾, and to its 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.
- (2) On 9 June 2016 the Member State Committee of the Agency (MSC) adopted its opinion ⁽³⁾ on the Annex XV dossier. Before the MSC adopted its opinion, Sweden withdrew its proposal to identify DCHP under Article 57(f) of Regulation (EC) No 1907/2006 due to its endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment, in order to further elaborate on the justifications provided in the dossier.
- (3) The MSC reached a unanimous agreement on the identification of DCHP as a substance of very high concern because it meets the criteria of Article 57(c) of Regulation (EC) No 1907/2006.
- (4) The MSC unanimously acknowledged that for DCHP 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 substance can be considered an endocrine disruptor for human health as it fulfils the WHO/IPCS definition for an endocrine disruptor.
- (5) However, the MSC did not reach unanimous agreement on the identification of DCHP 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 five members of the MSC, the effects for human health pointed out in the Annex XV dossier were the same effects, caused by the same mode of action, as those already taken into account in the dossier for identification of the substance as a substance of very high concern in accordance with Article 57(c) due to the adverse effects on development.

⁽¹⁾ OJ L 396, 30.12.2006, p. 1.

⁽²⁾ 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 (OJ L 353, 31.12.2008, p. 1).

⁽³⁾ <https://echa.europa.eu/documents/10162/a0ed7099-d284-45e4-87ae-9984c71024c8>

- (6) On 22 June 2016, pursuant to Article 59(9) of Regulation (EC) No 1907/2006, the Agency referred the MSC opinion to the Commission for a decision on the identification of DCHP on the basis of Article 57(f).
- (7) The Commission notes the unanimous agreement in the MSC that DCHP has endocrine disrupting properties and that the adverse effects caused by this mode of action are the same effects that led to its classification as toxic for reproduction and to the proposal for its identification as a substance 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).
- (8) 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 and relying on the same scientific evidence. This approach was also followed for the identification of bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP) in accordance with Article 57(f) of REACH ⁽¹⁾.
- (9) Therefore DCHP should be identified under Article 57 (c) as a substance of very high concern meeting the criteria for classification as toxic for reproduction category 1B under Regulation (EC) No 1272/2008 and under Article 57(f) due to its endocrine disrupting properties with probable serious effects to human health.
- (10) 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 of the European Parliament and of the Council ⁽²⁾.
- (11) 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:

Sole Article

1. Dicyclohexyl phthalate (DCHP) (EC No 201-545-9, CAS No 84-61-7) is identified in accordance with Article 57(c) of Regulation (EC) No 1907/2006 due to its classification as toxic for reproduction category 1B under Regulation (EC) No 1272/2008, and in accordance with Article 57(f) of Regulation (EC) No 1907/2006, due to its endocrine disrupting properties with probable serious effects to human health.
2. The substance shall be included in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006 with the following indication under 'Reason for inclusion': 'Toxic for reproduction (Article 57(c)); endocrine disrupting properties (Article 57(f) - human health)'.

This Decision is addressed to the European Chemicals Agency.

Done at Brussels, 17 April 2018.

For the Commission
Elżbieta BIENKOWSKA
Member of the Commission

⁽¹⁾ Commission Implementing Decision (EU) 2017/1210 of 4 July 2017 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 (OJ L 173, 6.7.2017, p. 35).

⁽²⁾ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).