Commission Regulation (EU) 2018/35 of 10 January 2018 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards octamethylcyclotetrasiloxane ('D4') and decamethylcyclopentasiloxane ('D5') (Text with EEA relevance)

COMMISSION REGULATION (EU) 2018/35

of 10 January 2018

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards octamethylcyclotetrasiloxane ('D4') and decamethylcyclopentasiloxane ('D5')

(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 68(1) thereof,

Whereas:

(1) On 17 April 2015, the United Kingdom submitted to the European Chemicals Agency ('Agency') a dossier pursuant to Article 69(4) of Regulation (EC) No 1907/2006 ('the Annex XV dossier[(2)]'), proposing to restrict octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5) in cosmetic products that are washed off in normal conditions of use. The dossier demonstrated that action on a Union-wide basis is necessary to address the risks to the environment posed by the use of D4 and D5 when discharged into waste water.

(2) On 22 April 2015, the Member State Committee, referred to in Article 76(1)(e) of Regulation (EC) No 1907/2006, at the request of the Executive Director of the Agency under Article 77(3)(c) of that Regulation, adopted an opinion that both D4 and D5 fulfil the criteria in Annex XIII to that Regulation for the identification of very persistent (vP) and very bioaccumulative (vB) substances.

(3) On 10 March 2016, the Agency's Risk Assessment Committee ('RAC') adopted its opinion, concluding that D4 meets the criteria in Annex XIII to Regulation (EC) No 1907/2006 for the identification of a persistent, bioaccumulative and toxic ('PBT') substance and a vPvB substance and that D5 fulfils the criteria for the identification of a vPvB substance. RAC confirmed that the hazard properties of D4 and D5 give rise to

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2018/35. (See end of Document for details)*

specific concerns for the environment when present in cosmetic products that are used or disposed with water. It also concluded that the proposed restriction is a targeted and appropriate Union-wide measure to minimise emissions caused by washed-off products.

(4) On 9 June 2016, the Agency's Socio-Economic Assessment Committee ('SEAC') adopted its opinion, indicating that the proposed restriction is the most appropriate Union-wide measure to reduce the discharge of D4 and D5 to waste water in terms of its socioeconomic benefits and its socioeconomic costs.

(5) SEAC recommended a 24-month deferral of application of the restriction, in line with the minimum period of deferral proposed in the Annex XV dossier, to allow stakeholders to take the necessary compliance measures.

(6) The Agency's Forum for Exchange of Information on Enforcement, referred to in Article 76(1)(f) of Regulation (EC) No 1907/2006, was consulted during the restriction process and its recommendations have been taken into account.

(7) On 10 August 2016, the Agency submitted to the Commission the opinions of RAC and SEAC[(3)].

(8) A risk to the environment arises from the presence of D4 and D5 in certain cosmetic products that are washed off with water after application, because of their hazard properties as a PBT and a vPvB substance in the case of D4 and a vPvB substance in the case of D5. The Commission considers that those risks should be addressed on a Union-wide basis. The concentration limit of 0,1 % set by this restriction effectively ensures that all intentional use of D4 and D5 will cease since those substances must be present in wash-off cosmetic products in a much higher concentration to perform their intended function.

(9) The proposed restriction concerns cosmetic products as defined in Article 2(1)(a) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council[(4)]. In cosmetic products that are intended to stay in prolonged contact with the skin, the hair or the mucous membranes, D4 and D5 evaporate over time after application and any residue is washed off in the course of normal ablutions. The Annex XV dossier did not cover those products, considering that they did not represent the major source of risk to the environment from D4 and D5, and consequently the risk which they may present to the environment has not yet been assessed by RAC. Therefore, the restriction should apply only to wash-off cosmetic products that, under normal condition of use, are removed with water shortly after application because in these circumstances D4 and D5 are emitted to the aquatic environment before evaporation.

(10) Stakeholders should be allowed sufficient time to take appropriate measures to comply with the proposed restriction. The new restriction should therefore only apply from a later date.

(11) Regulation (EC) No 1907/2006 should therefore be amended accordingly.

(12) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2018/35. (See end of Document for details)*

Article 1

Annex XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10 January 2018.

For the Commission

The President

Jean-Claude JUNCKER