Official Journal
of the European Union

EN
L series

2024/1328

17.5.2024

COMMISSION REGULATION (EU) 2024/1328

of 16 May 2024

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), decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6)

(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 10 January 2018, the Commission adopted Commission Regulation (EU) 2018/35 ([2]) restricting the placing on the market of octamethylcyclotetrasiloxane ('D4') and decamethylcyclopentasiloxane ('D5') in wash-off cosmetic products. This restriction was inserted as entry 70 of Annex XVII to Regulation (EC) No 1907/2006.

(2) On 13 June 2018, D4, D5 and dodecamethylcyclohexasiloxane ('D6') were identified by the Member State Committee ('MSC') of the European Chemicals Agency ('the Agency') as substances of very high concern ('SVHC') with very persistent and very bioaccumulative ('vPvB') properties. D4 was identified as having persistent, bioaccumulative and toxic ('PBT') properties. D5 and D6 were also identified as having PBT properties when they contain 0,1 % or more by weight of D4.

(3) When the Agency's Risk Assessment Committee ('RAC') assessed the proposal of a restriction to the placing on the market and use of D4 and D5 that was ultimately adopted in Regulation (EU) 2018/35, it did not exclude a potential risk from their use in leave-on cosmetic products. For this reason, on 15 December 2016, the Commission requested ([3]) the Agency to prepare a dossier pursuant to Article 69(1) of Regulation (EC) No 1907/2006 (the 'Annex XV dossier'), with a view to a potential restriction of D4 and D5 in leave-on cosmetic products and other consumer and professional products. On 5 February 2018, the Commission requested ([4]) the Agency to include D6 in the Annex XV dossier.

(4) On 20 March 2019, the Agency submitted the Annex XV dossier ([5]), which demonstrated that action on a Union-wide basis is necessary to address the risks to the environment posed by the use of D4, D5 and D6 when discharged into environmental compartments.

(5) On 28 November 2019, RAC adopted its opinion ([6]), confirming that the hazard properties of D4, D5 and D6 give rise to specific concerns for the environment when present in consumer and professional products that end up released into both the aquatic and the atmospheric compartments.

([1]) OJ L 396, 30.12.2006, p. 1.
([2]) 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') (OJ L 6, 11.1.2018, p. 45).
([3]) https://echa.europa.eu/documents/10162/13641/echa_commission_request_en.pdf/a0bdbb25-9641-9df1-9511-4208cac224ce.
([4]) https://echa.europa.eu/documents/10162/13641/note_to_echa_annex_xv_d6_en.pdf/722217b2-95c1-a5a0-90c5-82f2afed48f9.
([5]) https://echa.europa.eu/documents/10162/039f5415-d7a2-b279-d270-0d07e18f6392.
([6]) https://echa.europa.eu/documents/10162/44c5f15a-a022-5084-762e-03bbb00599d5.

(6) RAC concluded that total releases of D4, D5 and D6 into the environment should be used as a proxy for risk. RAC also concluded that consumer and professional uses of leave-on cosmetic products and other consumer and professional products containing D4, D5 and D6 result in releases to the environment, with the wide-dispersive uses in cosmetic products constituting the main source of releases. RAC agreed with the Agency's assessment in the Annex XV dossier that the risk is not adequately controlled and that emissions of these vPvB and PBT substances are not minimised through their life cycle, as required in paragraph 6.5 of Annex I to Regulation (EC) No 1907/2006.

(7) RAC also concluded that the proposed restriction is targeted and the most appropriate Union-wide measure to minimise the emissions caused by leave-on cosmetic products and other consumer and professional products and to address the identified risk in terms of its effectiveness in reducing that risk, its practicality, and the manner in which it can be monitored.

(8) On 12 March 2020, the Agency's Socio-Economic Assessment Committee ('SEAC') adopted its opinion ([7]), indicating that the proposed restriction, as modified by RAC and SEAC, is the most appropriate Union-wide measure to reduce the emissions of D4, D5 and D6 to the environment in terms of its socioeconomic benefits and costs.

(9) SEAC concurred with the conclusions in the Annex XV dossier for a general deferral of two years of the application of the restriction.

(10) SEAC also concurred with longer deferrals for a number of specific uses. Based on the time required for substitution, SEAC agreed with a deferral of five years for leave-on cosmetic products and medical devices. As likely alternative substances or technologies would not result in an overall reduction of the risk, SEAC also agreed with a deferral of the restriction of the use of D5 as a solvent in the dry cleaning of textiles, leather and fur of 10 years. As regards medicinal and veterinary products, SEAC supported a seven-year deferral of the restriction. This seven-year deferral takes into account the time necessary to substitute the use of D4, D5 and D6 in medicinal and veterinary products with alternative substances or technologies, as well as the time needed for qualification and registration of such products.

(11) SEAC also concurred with a number of derogations proposed in the Annex XV dossier. SEAC agreed with the derogation for the placing on the market of D5 and D6 for use in devices for the treatment and care of scars and wounds, the prevention of wounds, and the care of stoma. SEAC also agreed with the derogation for the placing on the market of D5 for professional use in the cleaning or restoration of art and antiques, and with the inclusion of a clearer description of the activities on industrial sites to which the restriction to the placing on the market of D4, D5 and D6 is not to apply. SEAC concurred with the derogation for the placing on the market and the use of D5 as a solvent in dry cleaning systems of textile, leather and fur, under certain conditions.

(12) Based on information on uses in mixtures and on enforcement considerations, SEAC concurred with the suggested clarifications and further derogations proposed in the Annex XV dossier for certain mixtures that contain D4, D5 and D6 as residues from silicone polymers.

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

(14) On 25 May 2020, the Agency submitted the opinions of RAC and SEAC to the Commission.

(15) The Commission concludes that there is an unacceptable risk arising from the emissions of D4, D5 and D6 from consumer and professional products and that the restriction proposed by the Agency, with the changes suggested by RAC and SEAC, is the most appropriate Union-wide measure to address that risk.

([7]) https://echa.europa.eu/documents/10162/a3e8195a-23d3-5859-6fdc-7805a3148b46.

(16) The Commission concurs with the conclusion, in RAC's and SEAC's opinions, that the proposed restriction is complementary and provides a logical extension to the existing restriction on the placing on the market of D4 and D5 in wash-off cosmetic products, contained in entry 70 of Annex XVII to Regulation (EC) No 1907/2006. In the interest of legal certainty and for ease of reading, that entry should be replaced in its entirety.

(17) Stakeholders should be allowed sufficient time to take appropriate measures to comply with the proposed restriction. The Commission therefore proposes a general deferral period of two years, and longer deferral periods for specific uses. The Commission also concurs with the need for derogations for a number of specific uses.

(18) As regards the deferral period for cosmetic products other than wash-off cosmetic products, the Commission notes the high emissions from that product group and the conclusion by RAC that for vPvB and PBT substances, the length of the transitional period is the most critical element from a risk point of view, as more emissions occur the longer the transitional period is. Consequently, emissions of vPvB and PBT substances into the environment should be minimised with a short transitional period. The Commission also notes the significant costs to industry to reformulate a high number of cosmetic products other than wash-off cosmetic products per year. In view of the cost-effectiveness of the proposed restriction for cosmetic products other than wash-off cosmetic products and the need to balance a high protection of human health and the environment with the minimisation of socioeconomic impacts, the Commission concludes that a three-year deferral period for those products is appropriate.

(19) As regards the deferral period for medical devices as defined in Article 1(4) of Regulation (EU) 2017/745 of the European Parliament and of the Council ([8]), taking into account concerns from the sector and some Member States on the estimated time for redesign steps, namely to find an alternative, to perform a qualification process and to seek registration of a newly designed mixture according to Regulation (EU) 2017/745, the Commission considers appropriate to grant a 7-year deferral period to these devices. Moreover, D4 and D5 may be found at concentrations above 0,1 % in some *in vitro* diagnostic devices (IVD) as defined in Article 1(2) of Regulation (EU) 2017/746 of the European Parliament and of the Council ([9]). As substitution in IVD presents similar concerns, it is appropriate to give these devices the same deferral period.

(20) The use as a laboratory reagent in research and development activities should only be exempted if taking place under controlled conditions as referred to in Article 3(23) of Regulation (EC) No 1907/2006, without being limited to 1 tonne per year.

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

(22) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 133(1) of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

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*.

([8]) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

([9]) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

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

Done at Brussels, 16 May 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Entry 70 of Annex XVII to Regulation (EC) No 1907/2006 is replaced by the following:

‘70. Octamethylcyclotetrasiloxane (D4) CAS No 556-67-2 EC No 209-136-7 Decamethylcyclopentasiloxane (D5) CAS No 541-02-6 EC No 208-764-9 Dodecamethylcyclohexasiloxane (D6) CAS No 540-97-6 EC No 208-762-8	1. Shall not be placed on the market (a) as a substance on its own; (b) as a constituent of other substances; or (c) in mixtures; in a concentration equal to or greater than 0,1 % by weight of the respective substance after 6 June 2026. 2. Shall not be used as a solvent for the dry cleaning of textiles, leather and fur after 6 June 2026. 3. By way of derogation: (a) for D4 and D5 in wash-off cosmetic products, paragraph 1, point (c), shall apply after 31 January 2020. For the purposes of this point, “wash-off cosmetic products” means cosmetic products as defined in Article 2(1), point (a), of Regulation (EC) No 1223/2009 of the European Parliament and of the Council (*) that, under normal conditions of use, are washed off with water after application; (b) for all cosmetic products other than the ones mentioned in paragraph 3(a), paragraph 1 shall apply after 6 June 2027; (c) for devices as defined in Article 1(4) of Regulation (EU) 2017/745 of the European Parliament and of the Council (**) and in Article 1(2) of Regulation (EU) 2017/746 of the European Parliament and the Council (***), paragraph 1 shall apply after 6 June 2031; (d) for medicinal products, as defined in Article 1, point 2, of Directive 2001/83/EC, and for veterinary medicinal products, as defined in Article 4(1) of Regulation (EU) 2019/6 (****), paragraph 1 shall apply after 6 June 2031; (e) for D5 as a solvent in the dry cleaning of textiles, leather and fur, paragraphs 1 and 2 shall apply after 6 June 2034. 4. By way of derogation, paragraph 1 shall not apply to the: (a) placing on the market of D4, D5 and D6 for the following industrial uses: — as a monomer in the production of silicone polymer, — as an intermediate in the production of other silicon substances, — as a monomer in polymerisation, — in the formulation or (re)packing of mixtures, — in the production of articles, — in non-metal surface treatment; (b) placing on the market of D5 and D6 for use as devices, as defined in Article 1(4) of Regulation (EU) 2017/745, for the treatment and care of scars and wounds, the prevention of wounds and the care of stoma; (c) placing on the market of D5 for professional use in the cleaning or restoration of art and antiques; (d) placing on the market of D4, D5 and D6 for use as laboratory reagent in research and development activities carried out under controlled conditions. 5. By way of derogation, paragraph 1, point (b), shall not apply to the placing on the market of D4, D5 and D6: — as a constituent of a silicone polymer on its own,

	— as a constituent of a silicone polymer in a mixture derogated under paragraph 6. 6. By way of derogation, paragraph 1, point (c), shall not apply to the placing on the market of mixtures that contain D4, D5 or D6 as residues from silicone polymers, under the following conditions: (a) D4, D5 or D6 in a concentration equal to or less than 1 % by weight of the respective substance in the mixture, for use in adhesion, sealing, gluing and casting; (b) D4 in a concentration equal to or less than 0,5 % by weight, or D5 or D6 in a concentration equal to or less than 0,3 % by weight of either substance in the mixture for use as protective coatings (including marine coatings); (c) D4, D5 or D6 in a concentration equal to or less than 0,2 % by weight of the respective substance in the mixture, for use as devices as defined in Article 1(4) of Regulation (EU) 2017/745 and in Article 1(2) of Regulation (EU) 2017/746, other than the devices referred to in paragraph 6(d); (d) D5 in a concentration equal to or less than 0,3 % by weight in the mixture or D6 in a concentration equal to or less than 1 % by weight in the mixture, for use as devices as defined in Article 1(4) of Regulation (EU) 2017/745, for dental impression; (e) D4 in a concentration equal to or less than 0,2 % by weight in the mixture, or D5 or D6 in a concentration equal to or less than 1 % by weight of either substance in the mixture for use as silicone insoles for horses, or as horseshoes; (f) D4, D5 or D6 in a concentration equal to or less than 0,5 % by weight of the respective substance in the mixture, for use as adhesion promoters; (g) D4, D5 or D6 in a concentration equal to or less than 1 % by weight of the respective substance in the mixture, for use in 3D-printing; (h) D5 in a concentration equal to or less than 1 % by weight in the mixture or D6 in a concentration equal to or less than 3 % by weight in the mixture, for rapid prototyping and mould making, or high performance uses stabilised by quartz filler; (i) D5 or D6 in a concentration equal to or less than 1 % by weight of either substance in the mixture, for use in pad printing, or manufacturing of printing pads; (j) D6 in a concentration equal to or less than 1 % by weight of the mixture, for professional use in the cleaning or restoration of art and antiques. 7. By way of derogation, paragraphs 1 and 2 shall not apply to the placing on the market for use, or to the use, of D5 as a solvent in strictly controlled closed dry cleaning systems for textile, leather and fur, where the cleaning solvent is recycled or incinerated.

(*) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) (OJ L 342, 22.12.2009, p. 59).

(**) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

(***) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

(****) Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).'