Commission Regulation (EU) 2019/957 of 11 June 2019 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 (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and TDFAs (Text with EEA relevance)

COMMISSION REGULATION (EU) 2019/957

of 11 June 2019

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 (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and TDFAs

(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 20 April 2016, the Kingdom of Denmark submitted to the European Chemicals Agency (‘the Agency’) a dossier pursuant to Article 69(4) of Regulation (EC) No 1907/2006, in order to initiate the restrictions process as set out in Articles 69 to 73 of that Regulation (the ‘Annex XV dossier’). The Annex XV dossier indicated that exposure to (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives (those derivatives are referred to as TDFAs) combined with organic solvents in spray products causes serious acute lung injury and therefore poses a risk to human health. Accordingly, it was proposed to prohibit the placing on the market of those mixtures in spray products for supply to the general public. Denmark concluded that the Annex XV dossier demonstrated that action on a Union-wide basis is necessary.

(2) Denmark proposed a concentration limit of 2 ppb by weight for the presence of (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and any of the TDFAs in mixtures containing organic solvents as such concentration limit corresponds to a limit of detection.

(3) On 10 March 2017, the Agency's Committee for Risk Assessment (RAC) adopted an opinion, concluding that the risks to the general public arising from the use of proofing

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2019/957. (See end of Document for details)*

or impregnating spray products containing (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol or TDFAs and organic solvents are not adequately controlled and that the proposed restriction is the appropriate measure to reduce the risks. Moreover, RAC considered that the mixture of TDFA and/or (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol with organic solvents should be labelled in a way that ensures that professional users of those products are aware of the specific hazard associated with the use of those mixtures.

(4) On 15 June 2017, the Agency's Committee for Socioeconomic Analysis (SEAC) adopted its opinion, indicating that the proposed restriction, subject to modifications proposed by RAC and SEAC, is the most appropriate Union-wide measure to address the risks associated with the exposure to spray products containing mixtures of (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and TDFAs with organic solvents, in terms of its socioeconomic benefits and socioeconomic costs. Taking into account the uncertainties with regard to the presence of the spray products concerned on the market for supply to the general public, the effectiveness of the proposed measure, as well as the probable low costs of the proposal, SEAC concluded that the proposed restriction is not disproportionate.

(5) SEAC concurred with Denmark that a deferral of 18 months of the application of the restriction seems sufficient in order to allow stakeholders sufficient time to take appropriate measures to comply with the proposed restriction.

(6) The Forum for Exchange of Information on Enforcement was consulted during the restriction process in accordance with Article 77(4)(h) of Regulation (EC) No 1907/2006 and its recommendations were taken into account.

(7) On 29 August 2017, the Agency submitted to the Commission the opinions of RAC and SEAC[(2)] based on which the Commission concluded that placing on the market for supply to the general public of spray products containing (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and/or TDFAs combined with organic solvents poses an unacceptable risk to human health, that needs to be addressed on a Union-wide basis.

(8) Taking into account the Annex XV dossier and the opinions of RAC and SEAC, including on the availability of alternatives, the Commission considers that the proposed restriction, as amended, would address the identified concern without imposing a significant burden on industry, supply chain or consumers. Thus, the Commission concludes that the restriction proposed by Denmark, amended as proposed by RAC and SEAC, is an appropriate Union-wide measure to address the risk to the general public from spray products containing a mixture of (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and TDFAs with organic solvents.

(9) Placing on the market for supply to the general public of spray products containing (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and/or TDFAs combined with organic solvents includes making them available to the general public.

(10) Stakeholders should be allowed sufficient time to take appropriate measures to comply with the proposed restriction. The application of the new restriction should therefore be deferred.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2019/957. (See end of Document for details)*

(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:

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, 11 June 2019.

For the Commission

The President

Jean-Claude JUNCKER