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Proposal for a

COUNCIL DECISION

on the submission, on behalf of the European Union, of a proposal for the listing of additional chemicals in Annex A, B and/or C to the Stockholm Convention on Persistent Organic Pollutants

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

The Stockholm Convention on Persistent Organic Pollutants (the Convention), which was approved by Council Decision 2006/507/EC, entered into force on 17 May 2004. The aim of the Convention is to protect human health and the environment from persistent organic pollutants (POPs). The Convention provides a framework, based on the precautionary principle, for elimination of production, use, import and export of currently twenty-three priority POPs, their safe handling and disposal and elimination or reduction of releases of certain unintentional POPs.

Regulation (EC) No 850/2004 on persistent organic pollutants implements in Union law the commitments set out in the Convention and in the Protocol on Persistent Organic Pollutants to the 1979 Convention on Long-Range Transboundary Air Pollution (the Protocol), approved by Council Decision 259/2004/EC.

Article 8(1) of the Convention stipulates that any Party may submit a proposal to the Secretariat for listing a chemical in Annexes A, B or C to the Convention which will then be reviewed by the Persistent Organic Pollutants Review Committee (POP RC) following Articles 8(3) and (4). The proposal shall contain the information specified in Annex D. The procedure for the adoption of amendments to Annexes is governed by Article 22 of the Convention.

This proposal for a Council decision is addressing the intention of the European Union to submit a proposal for the listing of octamethylcyclotetrasiloxane (D4), which entails the submission of an Annex D dossier containing *screening* criteria information on that chemical and initiates the review to be done by the POP RC.

If D4 meets the screening criteria, further information necessary to establish the risk profile of that chemical will be submitted. This includes inter alia information on production, uses, hazard assessments and risk evaluations in the Union. In the event that a risk management evaluation will be prepared, additional information on socio-economic considerations reflecting the situation in the Union pursuant to Annex F will be submitted.

According to available scientific information and review reports, as well as taking due account of the screening criteria laid down in Annex D to the Convention, D4 exhibits characteristics of POPs.

D4 is manufactured in the EU, and also imported as a substance (on its own or in mixtures) and in articles. D4 is released from the formulation and processing stage ("production"), the service life of products and articles and from the waste stage (recycling, landfilling and incineration). The major use of D4 is as a feedstock for the production of silicone polymers.

According to the ECHA dissemination website, the registered tonnage band for D4 is 100,000 – 1,000,000 tonnes/year.

The United Kingdom Competent Authorities have prepared a dossier under Annex XV to REACH with the intention of proposing two siloxane compounds for inclusion in the restriction process under REACH. This Restriction dossier proposes a restriction on the placing on the market or use of D4 and decamethylcyclopentasiloxane (D5) in concentrations equal to or greater than 0,1% by weight in personal care products that are washed off in normal use conditions.

The major use of these substances is as a feedstock for the production of silicone polymers. Those silicone fluids, elastomers, gels and resins in turn have a very wide range of uses, including as rubber; elastomers for coatings and sealants; antifoams; flow and/or gloss improvers in alkyd paints and varnishes; softening, waterproofing and wetting agents in textile manufacturing; components of polishes and other surface treatment formulations; lubricants, greases, anti-adhesion coatings and mould release agents; paper coatings; hydraulic, dielectric and heat transfer fluids; and consumer products such as personal, household, and automotive care products. The polymers may also be modified with additional functional groups, with a myriad of other applications. D4 and D5 are used in various consumer products as well as in industrial applications, and these uses lead to the wide-dispersive release into the environment.

The Member State Committee at the European Chemicals Agency (ECHA) at its 41st Meeting in 2015 adopted an opinion¹ on the persistence (P/vP) and bioaccumulation (B/vB) of D4 and D5 at the request of the Executive Director of ECHA under Article 77(3)c of REACH. This Committee was of the opinion that both D4 and D5 fulfil the REACH Annex XIII criteria for vP and vB. Therefore, they fulfil the Annex D criteria of the Convention for persistency and bioaccumulation.

D4 has a harmonised classification in Annex VI of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) as toxic for reproduction category 2 and as toxic to aquatic life category 4. However, the new criteria on chronic aquatic toxicity introduced by Commission Regulation (EU) No 286/2011 in the CLP Regulation is expected to result in a more stringent environmental classification since the lowest reliable aquatic chronic no observed effect concentration (NOEC) is around 4.4 µg/L. This chronic NOEC is expected to result in a harmonised classification of chronic aquatic toxicity category 1. Therefore D4 would meet the POP criteria for toxicity based on both aquatic and mammalian end points.

In addition to the proven PBT/vPvB properties, as evidenced in the REACH assessment noted above, the Annex XV Restriction dossier also investigates the long-range environmental transport (LRT) potential of D4 and D5 and concluded that due to their propensity to reside in the air compartment and their long atmospheric half-lives, D4 and D5 also have the potential to undergo long-range transport to remote regions via the atmosphere.

Health Canada concluded in their 2008 screening assessment² that, based on modelling data that estimated the characteristic travel distance of D4, the long-range atmospheric transport potential of D4 is high, supporting that D4 is subject to atmospheric transport to remote regions such as the Arctic.

According to the Member State Committee opinion D4 can be found in a wide range of organisms (particularly fish and aquatic invertebrates but also birds and mammals) and is present in biota in remote regions, including fish and birds in the European Arctic.

¹ http://echa.europa.eu/documents/10162/13641/art77-3c_msc_opinion_on_d4_and_d5_20150422_en.pdf.

² Environment Canada and Health Canada. Screening Assessment for the Challenge Octamethylcyclotetrasiloxane (D4) Chemical Abstracts Service Registry Number 556-67-2. November 2008. See: <http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=2481B508-1#a1>.

Given the information currently available regarding the PBT and LRT properties of D4 and considering the studies and reports outlined above, it is proposed that D4 meets the criteria of Annex D to the Convention and therefore could be considered as a POP.

D4 is a high production volume chemical that is widely used in household goods and personal care products. Due to the potential for long-range environmental transport of this chemical, the measures taken nationally or at the Union level are not sufficient to safeguard the high level of protection of the environment and human health and wider international action is necessary.

With a view to the next POP RC meeting in September 2016, it is appropriate that the Commission submits on behalf of the Union a proposal for the listing of octamethylcyclotetrasiloxane for inclusion in Annex A, B and/or C to the Secretariat of the Stockholm Convention. This constitutes a position to be adopted on the Union's behalf for the purpose of Article 218(9) TFEU.

2. STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

In the event that D4 meets the screening criteria pursuant to Annex D to the Convention, all Parties and observers will be invited to provide information allowing to establish the risk profile of that chemical. This includes *inter alia* information on production, uses, hazard assessments and risk evaluations. If, on the basis of the risk profile, it is decided to proceed with the next step and to prepare a risk management evaluation, all Parties and observers will be invited to submit information on socio-economic considerations pursuant to Annex F to the Convention. The broad invitation for submission of information addressed to all Parties and observers has the objective to prepare a comprehensive evaluation of the impact of that chemical on human health and the environment and to reflect due regard for the differing capabilities and conditions among the Parties with respect to risk management and elimination.

If the POP RC comes to the conclusion that D4 meets the screening criteria according to Annex D of the Stockholm Convention, the Commission will launch a study in order to gather information on the socio-economic impacts of a possible listing of D4.

3. LEGAL ELEMENTS OF THE PROPOSAL

This proposal will result in the compilation of an information dossier pursuant to the provisions of Article 8(1) and criteria of Annex D to the Convention upon which a proposal will be submitted to the Convention's Secretariat to add D4 to Annex A, B and/or C of the Convention.

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THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 191(1), in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Union ratified the Stockholm Convention on Persistent Organic Pollutants (the Convention) on 16 November 2004 by Council Decision 2006/507/EC of 14 October 2004 concerning the conclusion, on behalf of the European Community, of the Stockholm Convention on Persistent Organic Pollutants³.
- (2) As a Party to the Convention, the Union may make proposals for amendment of the Annexes to the Convention. Annex A to the Convention lists persistent organic pollutants (POPs) to be eliminated, whereas Annex B lists POPs to be restricted, and Annex C lists POPs of which the unintentional production needs to be addressed.
- (3) With regard to available scientific information and review reports as well as taking due account of the screening criteria laid down in Annex D to the Convention, octamethylcyclotetrasiloxane (CAS No 556-67-2) exhibits characteristics of POPs.
- (4) Based on the available information, octamethylcyclotetrasiloxane meets the criteria of Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁴ for both a 'persistent, bioaccumulative and toxic' (PBT) and a 'very persistent and very bioaccumulative' (vPvB) substance in the environment.
- (5) Under Article 69(4) of Regulation (EC) No 1907/2006, the United Kingdom prepared an Annex XV restriction dossier⁵ on octamethylcyclotetrasiloxane to address the risk to environment from the placing on the market or use of octamethylcyclotetrasiloxane in concentration equal to or greater than 0,1% by weight in personal care products that are washed off in normal use conditions.

³ OJ L 209, 31.7.2006, p. 1.

⁴ 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 (OJ L 396, 30.12.2006, p. 1).

⁵ Available at: <http://www.echa.europa.eu/web/guest/restrictions-under-consideration>
Decamethylcyclopentasiloxane is also included in the scope of the restriction proposal.

- (6) Octamethylcyclotetrasiloxane is a substance with worldwide dispersive uses and is detected in the environment. Due to the potential for long-range environmental transport of octamethylcyclotetrasiloxane, the measures taken nationally or at Union level are not sufficient to safeguard the high level of protection of the environment and human health and wider international action is necessary.
- (7) The Union should therefore submit a proposal to the Secretariat of the Convention for the listing of octamethylcyclotetrasiloxane in Annex A, B and/or C to the Convention,

HAS ADOPTED THIS DECISION:

Article 1

1. The Union shall submit a proposal for the listing of octamethylcyclotetrasiloxane in Annex A, B and/or C to the Stockholm Convention on Persistent Organic Pollutants (the Convention).

2. The Commission shall communicate the proposal on behalf of the Union to the Secretariat of the Convention with all the information required under Annex D to the Convention.

Article 2

This Decision shall enter into force on the date of its adoption.

Done at Brussels,

*For the Council
The President*