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[...] (2016) **XXX** draft

COMMISSION REGULATION (EU) .../...

of **XXX**

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 bis(pentabromophenyl)ether

(Text with EEA relevance)

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(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/EC¹, and in particular Article 68(1) thereof,

Whereas:

- (1) Bis(pentabromophenyl)ether ('decaBDE') is widely used as an additive flame retardant with applications in many different sectors, in particular in plastic and textile articles but also in adhesives, sealants, coatings and inks.
- (2) On 29 November 2012, the Member State Committee, referred to in Article 76(1)(e) of Regulation (EC) No 1907/2006, identified decaBDE as a persistent, bioaccumulative and toxic substance ('PBT') and a very persistent and very bioaccumulative ('vPvB') substance in accordance with points (d) and (e) respectively of Article 57 of Regulation (EC) No 1907/2006. On 19 December 2012 the substance was included in the Candidate List of Substances of Very High Concern ('SVHC') for possible inclusion in Annex XIV to REACH.
- (3) On 2 May 2013, Norway proposed that decaBDE should be listed in Annex A (Elimination) to the Stockholm Convention on Persistent Organic Pollutants (POPs).
- (4) Following Norway's proposal, the Commission considered that making decaBDE subject to the authorisation requirement under Regulation (EC) No 1907/2006 was no longer the most appropriate regulatory measure. On 21 June 2013, the Commission requested the European Chemicals Agency ('the Agency') to prepare a dossier conforming to the requirements of Annex XV to Regulation (EC) No 1907/2006 (an 'Annex XV dossier'), with a view to initiating a restriction process under Articles 69 to 73 of that Regulation.
- (5) On 4 August 2014, the Agency, in collaboration with Norway, submitted an Annex XV dossier² to its Committee for Risk Assessment ('RAC') and its Committee for

¹ OJ L 396, 30.12.2006, p 1.

² <http://echa.europa.eu/documents/10162/a3f810b8-511d-4fd0-8d78-8a8a7ea363bc>

Socio-Economic Analysis ('SEAC'). The dossier demonstrated that action on a Union-wide basis is necessary to address the risks to human health and the environment posed by the manufacture, placing on the market or use of decaBDE, on its own, as a constituent of other substances, in mixtures or in articles.

- (6) On 2 June 2015, RAC adopted its opinion, which confirmed that the persistent and bioaccumulative properties of decaBDE give rise to specific concerns about its widespread distribution and potential to cause irreversible long-term harm to the environment, even after emissions have ceased. In addition, exposure to decaBDE in its lower brominated transformation products may result in neurotoxicity in mammals, including humans.
- (7) RAC agreed with the conclusion of the Annex XV dossier that a general restriction on all uses of decaBDE, with some specific exceptions, would reduce emissions of decaBDE as much as possible in the medium- to long-term.
- (8) On 10 September 2015, SEAC adopted its opinion, indicating that the proposed restriction, as modified by SEAC, is the most appropriate Union-wide measure to reduce emission of decaBDE in terms of its socio-economic benefits and its socio-economic costs. SEAC based its opinion on the cost-effectiveness of the proposed restriction, as modified, and on a number of additional qualitative arguments.
- (9) SEAC agreed with the eighteen-month deferral of application of the restriction proposed in the Annex XV dossier to allow stakeholders to take the necessary compliance measures.
- (10) RAC and SEAC agreed with the exemption from the restriction proposed in the Annex XV dossier for the civil aviation sector. Following comments received during the public consultation, SEAC also suggested that it should cover military aircraft.
- (11) The proposed restriction should not apply to electrical and electronic equipment within the scope of Directive 2011/65/EU of the European Parliament and of the Council³, as the placing on the market of such equipment containing polybrominated diphenyl ethers ('PBDE') in a concentration above 0,1 % by weight is already regulated by that Directive.
- (12) RAC and SEAC also agreed to exempt from the proposed restriction articles already placed on the market before the date of application of that restriction.
- (13) Based on information from the public consultation, SEAC suggested exemptions for spare parts for motor vehicles covered by Directive 2007/46/EC of the European Parliament and of the Council⁴, for agricultural and forestry vehicles covered by Regulation (EU) No 167/2013 of the European Parliament and of the Council⁵ and for machinery covered by Directive 2006/42/EC⁶ of the European Parliament and of the Council, provided such vehicles and machines are produced before 1 July 2018. SEAC justified those exemptions on the basis of the disproportionate burden that the

³ Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174 1.7.2011, p. 88).

⁴ Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (OJ L 263, 9.10.2007, p. 1).

⁵ Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OL L 60, 2.3.2013, p. 1).

⁶ Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24).

proposed restriction would impose in relation to such spare parts, given the low volumes involved, the progressive reduction in the quantity of decaBDE required (as vehicles and machinery reached the end-of-life stage) and the cost of testing alternative materials for the production of such spare parts. SEAC saw no basis for treating the spare parts of those vehicles and machines differently, although their life cycles vary.

- (14) 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.
- (15) On 28 September 2015, the Agency submitted to the Commission the opinions of RAC and SEAC⁷.
- (16) Based on those opinions, the Commission is of the opinion that an unacceptable risk to human health and the environment arises from the manufacture, use or placing on the market of decaBDE, on its own, as a constituent of other substances, in mixtures and in articles. The Commission considers that those risks need to be addressed on a Union wide basis.
- (17) The possibility to ensure the continued availability of decaBDE for the production of aircraft, whether civil or military, should be limited to ten years from the entry into force of this Regulation, since this should give the industry sufficient time to adapt. Exemptions should also be granted in relation to the production and the placing on the market of spare parts for all aircraft, civil or military, produced before the expiry of that period.
- (18) There should be an exemption for the production and placing on the market of spare parts for vehicles and machinery, referred to in recital (13), that are produced before [*date - 18 months after the date of entry into force*].
- (19) Regulation (EC) No 1907/2006 should therefore be amended accordingly.
- (20) 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.

⁷ <http://echa.europa.eu/documents/10162/b5ac0c91-e110-4afb-a68d-08a923b53275>

Done at Brussels,

*For the Commission
The President
Jean-Claude Juncker*

ANNEX

In Annex XVII to Regulation (EC) No 1907/2006, the following entry is added:

<p>“ 66. Bis(pentabromophenyl)ether (decabromodiphenyl ether; decaBDE)</p> <p>CAS No 1163-19-5 EC No 214-604-9</p>	<ol style="list-style-type: none">1. Shall not be manufactured or placed on the market as a substance on its own after [<i>date - eighteen months after the entry into force of this Regulation</i>].2. Shall not be used in the production of, or placed on the market in:<ol style="list-style-type: none">(a) another substance, as a constituent;(b) a mixture;(c) an article, or any part thereof, in a concentration equal to or greater than 0,1 % by weight, after [<i>date - eighteen months after the entry into force of this Regulation</i>].3. Paragraphs 1 and 2 shall not apply to a substance, constituent of another substance or mixture that is to be used, or is used:<ol style="list-style-type: none">(a) in the production of an aircraft before [<i>date – 10 years after entry into force of this Regulation</i>],(b) in the production of spare parts for either of the following:<ol style="list-style-type: none">(i) an aircraft produced before [<i>date – 10 years after entry into force of this Regulation</i>],(ii) motor vehicles within the scope of Directive 2007/46/EC, agricultural and forestry vehicles within the scope of Regulation (EU) No 167/2013 of the European Parliament and of the Council(*) or machinery within the scope of Directive 2006/42/EC of the European Parliament and of the Council(**), produced before (<i>date - 18 months after the entry into force of this Regulation</i>).4. Sub-paragraph 2(c) shall not apply to any of the following:<ol style="list-style-type: none">(a) articles placed on the market before [<i>date - eighteen months after the entry into force of this Regulation</i>];(b) aircraft produced in accordance with sub-paragraph 3(a);(c) spare parts of aircraft, vehicles or
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	<p>machines produced in accordance with sub-paragraph 3(b);</p> <p>(d) electrical and electronic equipment within the scope of Directive 2011/65/EU of the European Parliament and of the Council .</p> <p>5. For the purposes of this entry ‘aircraft’ means one of the following:</p> <p>(a) a civil aircraft produced in accordance with a type certificate issued under Regulation (EU) No 216/2008 of the European Parliament and of the Council (***) or with a design approval issued under the national regulations of a contracting State of the International Civil Aviation Organisation (ICAO), or for which a certificate of airworthiness has been issued by an ICAO contracting State under Annex 8 to the Convention on International Civil Aviation,</p> <p>(b) a military aircraft.”</p> <hr/> <p>(*) Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OL L 60, 2.3.2013, p. 1).</p> <p>(**) Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24).</p> <p>(***) Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (OJ L 079 19.3.2008, p. 1).</p>
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