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Delegations will find attached document D057230/02.

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EUROPEAN
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Brussels, XXX
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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(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP)

(Text with EEA relevance)

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(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP)

(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) Bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP) ('the four phthalates') are listed in Annex XIV to Regulation (EC) No 1907/2006 as substances toxic for reproduction, category 1B, with a sunset date of 21 February 2015, specified in accordance with Article 58(1)(c)(i) of that Regulation.

(2) After the sunset date referred to in Article 58(1)(c)(i) for a substance listed in Annex XIV, Article 69(2) of Regulation (EC) No 1907/2006 requires the European Chemicals Agency ('the Agency') to consider whether the use in articles of substances listed in Annex XIV to that Regulation poses a risk to human health or the environment that is not adequately controlled and, if the Agency considers that it does, to prepare a dossier for a restriction proposal which conforms to the requirements of Annex XV to Regulation (EC) No 1907/2006 ('the Annex XV dossier').

(3) On 1 April 2016, the Agency, in cooperation with Denmark, submitted an Annex XV dossier for the four phthalates[2]. The dossier built on a previous restriction proposal submitted by Denmark in 2011 in relation to which the Agency's Risk Assessment Committee (RAC) and Socio-Economic Analysis Committee (SEAC) adopted opinions[3] based on which the Commission decided not to amend Annex XVII to Regulation (EC) No 1907/2006[4] on the grounds that the data available at the time did not indicate that combined exposure to the four phthalates presented a risk. The 2016

1 OJ L 396, 30.12.2006, p. 1.

2 https://echa.europa.eu/previous-consultations-on-restriction-proposals/-/substance-rev/13919/term

3 2012 RAC and SEAC Opinion on an Annex XV dossier proposing restrictions on the four phthalates: https://echa.europa.eu/documents/10162/58050be8-f7be-4b55-b106-76dda4989dd6

4 Commission Communication 2014/C 260/01.

Annex XV dossier took into account new information on exposure from different sources including human biomonitoring data from the Union-wide DEMOCOPHES project[5] which measures the presence of the four phthalates in urine samples.

(4) The four phthalates are found in a wide variety of articles as they are commonly present in plasticised materials. Exposure may occur through the ingestion of food and dust, the placing of articles in the mouth, the inhalation of air and dust in indoor environments, and contact of dust and articles with human mucous membranes and skin.

(5) The Annex XV dossier proposed to restrict the placing on the market of articles containing the four phthalates in a concentration equal to or greater than 0,1 % by weight individually or in any combination in such plasticised materials. This concentration limit would effectively discourage the use of the four phthalates in articles within the scope of the restriction. The dossier suggested exemptions for articles exclusively for open air use without prolonged contact with skin or contact with mucous membranes, certain articles exclusively for industrial and agricultural use, measuring devices, articles covered by existing Union legislation and articles already placed on the market in the Union.

(6) On 10 March 2017, RAC adopted its opinion concluding that the proposed restriction is the most appropriate Union-wide measure to address the identified risks arising from these substances in terms of effectiveness in reducing those risks.

(7) RAC considered that a combined concentration of the four phthalates of 0,1 % or less in plasticised materials in articles is required to address the risk to human health..

(8) On 15 June 2017, SEAC adopted its opinion, indicating that the proposed restriction, as modified by RAC and SEAC, is the most appropriate Union-wide measure to address the identified risks in terms of its socio-economic benefits and socio-economic costs.

(9) SEAC concurred with the conclusions in the Annex XV dossier that a deferral of 36 months of the application of the restriction seems reasonable and sufficient in order to enable actors involved in the supply chains to comply with it. SEAC also concurred with the exemptions suggested in the Annex XV dossier. In addition, due to socio-economic considerations based on additional information provided by the automotive and aircraft sectors during the public consultation, SEAC suggested certain derogations for these sectors.

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

(11) On 29 August 2017, the Agency submitted the opinions of RAC and SEAC[6] to the Commission. Based on those opinions concluding on the combined exposure via various routes to these four phthalates that adversely affect human health, the Commission concluded that the four phthalates pose an unacceptable risk to human health when present in any plasticised material in articles at a concentration, individually or in any combination, equal to or greater than 0,1 % by weight of any of such material. For the purposes of this restriction, plasticised materials are materials that may contain phthalates for which there is great potential for combined exposure,

5 http://www.eu-hbm.info/democophes/project-partners

6 https://echa.europa.eu/documents/10162/a265bf86-5fbd-496b-87b4-63ff238de2f7

via various routes, of both consumers and workers. Those materials include polyvinyl chloride (PVC), polyvinylidene chloride (PVDC), polyvinyl acetate (PVA), polyurethanes, any other polymer (including inter alia polymer foams and rubber material) except silicone rubber and natural latex coatings, surface coatings, non-slip coatings, finishes, decals, printed designs, adhesive, sealants, inks and paints. The Commission considers that the risk needs to be addressed on a Union-wide basis.

(12) Annex XVII to Regulation (EC) No 1907/2006 already bans the placing on the market of toys and childcare articles containing DEHP, DBP and BBP under certain conditions which fall within the scope of the proposed restriction. In addition, in view of both the opinion of RAC that DIBP has a hazard profile similar to that of DEHP, DBP and BBP, that toys and childcare articles can contribute considerably to risks for infants from phthalates and that DIBP can replace DBP in toys and childcare articles, and the recommendation of the Forum, the Commission takes the view that the placing on the market of toys and childcare articles containing DIBP should also be restricted. In addition, the placing on the market of the four phthalates in toys and childcare articles should be subject to updated conditions.

(13) In the case of articles exclusively for industrial and agricultural use, or for open air use, the proposed restriction should only apply to those articles containing plasticised material that comes into contact with human mucous membranes or into prolonged contact with the skin, because such contacts lead to exposure which poses risk to human health.

(14) The proposed restriction should not apply to articles regulated by other Union legislation, such as materials and articles intended to come into contact with food within the scope of Regulation (EC) No 1935/2004 of the European Parliament and of the Council[7] and Commission Regulation (EU) No 10/2011[8], medical devices within the scope of Council Directives 90/385/EEC[9] or 93/42/EEC[10], or Directive 98/79/EC of the European Parliament and of the Council[11], or components for such devices, articles within the scope of Directive 2011/65/EU of the European Parliament and of the Council[12] or the immediate packaging of medicinal products within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council[13] or of Directives 2001/82/EC[14] or 2001/83/EC[15] of the European Parliament and of the Council.

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7 Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

8 Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1).

9 Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).

10 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

11 Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

12 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)

13 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

14 Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

(15) The proposed restriction should also not apply to measuring devices for laboratory use or articles that form part of such devices and to articles placed on the market prior to the date of entry into application of the restriction, for practicality and enforceability reasons. Moreover, certain derogations should apply for motor vehicles and aircraft. First, a longer deferral of application of the restriction for motor vehicles and an indefinite exemption for articles used in the maintenance or repair of those vehicles, where the vehicles cannot function as intended without those articles, are justified in consideration of the specific economic implications of this sector. A longer deferral of application of the restriction for certain aircraft and an indefinite exemption for articles used in the maintenance or repair of those aircraft where these are essential for safety and airworthiness, are justified on the basis that aircrafts have a very long useful life, their airworthiness may be jeopardised if parts meeting the design specifications are not available and the timelines needed for requalification are very long.

(16) Taking into account the Annex XV dossier as well as the opinions of RAC and SEAC, the Commission considers that the proposed restriction would address the identified risks without imposing significant burden on industry, supply chain or consumers and concludes that the restriction proposed, is an appropriate Union-wide measure to address the identified risk.

(17) Stakeholders should be allowed sufficient time to take appropriate measures to comply with the proposed restriction and 18 months is sufficient to this end. Therefore there should be a general deferral of its application by 18 months. A longer specific deferral of 60 months should apply to address the particular cases of certain motor vehicles and aircraft.

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

(19) 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,

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[15] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

Done at Brussels,

For the Commission
The President
Jean-Claude Juncker