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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Subject:	COMMISSION REGULATION (EU) …/… of XXX amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Delegations will find attached document […](2021) XXX draft - D 071308/02.

Encl.: […](2021) XXX draft - D 071308/02

EUROPEAN
COMMISSION

Brussels, XXX
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COMMISSION REGULATION (EU) …/…

of XXX

amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

(Text with EEA relevance)

Commission Regulation (EU) …/… of XXX amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

(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 Articles 58 and 131 thereof,

Whereas:

(1) The substances bis(2-ethylhexyl) phthalate (DEHP), benzyl butyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) are listed in entries 4 to 7 of Annex XIV to Regulation (EC) No 1907/2006 because they meet the criteria set out in point (c) of Article 57 of that Regulation. In accordance with Article 59 of Regulation (EC) No 1907/2006, DEHP has subsequently been additionally identified as meeting the criteria set out in point (f) Article 57 of that Regulation, namely as having endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment[2]. All the four substances have further been identified in accordance with Article 59 of Regulation (EC) No 1907/2006 as meeting the criteria set out in point (f) Article 57 of that Regulation, namely as having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health[3]. In accordance with Article 58(3) of Regulation (EC) No 1907/2006, on 10 July 2019 the European Chemicals Agency ('the Agency') recommended[4] the elements referred to in Article 58(1) of that Regulation to be specified for each of those substances.

(2) The inclusion of intrinsic properties relating to hazards for the environment in the entry for DEHP in Annex XIV to Regulation (EC) No 1907/2006, means that the uses of that substance in medical devices falling within the scope of Council Directive

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1 OJ L 396, 30.12.2006, p. 1.

2 Decision by the Executive Director of ECHA of 12 December 2014, Inclusion of Substances of Very High Concern in the Candidate List for eventual inclusion in Annex XIV, (ED/108/2014) https://echa.europa.eu/documents/10162/30b654ce-1de3-487a-8696-e05617c3173b

3 Commission Implementing Decision (EU) 2017/1210 of 4 July 2017 on the identification of bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP) as substances of very high concern according to Article 57(f) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (OJ L 173, 6.7.2017, p. 35).

4 Recommendation of the European Chemicals Agency of 10 July 2019 to amend the Annex XIV entries to REACH of DEHP, BBP, DBP and DIBP (List of Substances subject to Authorisation),

https://echa.europa.eu/documents/10162/13640/axiv_amend_recommendation_phthalates_july2019_en.pdf/1889866a-bec3-fe16-6322-67c16a13b09d

90/385/EEC[5], Council Directive 93/42/EEC[6] or Directive 98/79/EC of the European Parliament and of the Council[7] are subject to authorisation requirement as the second subparagraph of Article 60(2) of Regulation (EC) No 1907/2006 provides that the Commission shall not consider risks to human health only arising from those uses. As regards the uses of that substance in food contact materials within the scope of Regulation (EC) No 1935/2004 of the European Parliament and of the Council[8], the inclusion of intrinsic properties relating to hazards for the environment means that those uses are subject to authorisation requirement as Article 56(5) of Regulation (EC) No 1907/2006 no longer applies to them.

(3) By including in the entries of DEHP, BBP, DBP and DIBP intrinsic properties referred to in point (f) of Article 57 of Regulation (EC) No 1907/2006, the concentration limit applicable to the presence of those substances in mixtures for the purposes of the exemption set out in Article 56(6) of that Regulation becomes 0,1% weight by weight.

(4) Article 58(1)(e) in conjunction with Article 58(2) of Regulation (EC) No 1907/2006 provides for the possibility of exemptions of uses or categories of uses in cases where specific Union legislation imposes minimum requirements relating to the protection of human health or the environment ensuring proper control of the risks. In accordance with the information currently available, it is not appropriate to set exemptions based on those provisions.

(5) Commission Regulation (EU) No 143/2011[9] exempted from the authorisation requirement the use of DEHP, BBP and DBP in the immediate packaging of medicinal products covered by Regulation (EC) No 726/2004 of the European Parliament and of the Council[10], Directive 2001/82/EC of the European Parliament and of the Council[11] and/or Directive 2001/83/EC of the European Parliament and of the Council[12]. The judgment of the Court of Justice of 13 July 2017 in Case C-651/15 P, *VECCO and Others v. Commission*[13], provided clarifications on certain aspects of Article 58(2) of Regulation (EC) No 1907/2006 for granting an exemption from the authorisation requirement. The Commission has re-assessed the exemption set out in Annex XIV to that Regulation and has concluded that it does not meet the conditions in Article 58(2). In particular, in the light of that judgement, Regulation (EC) No 726/2004, and Directives 2001/82/EC and 2001/83/EC do not constitute existing specific Union

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5 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).

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

7 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).

8 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).

9 Commission Regulation (EU) No 143/2011 of 17 February 2011 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals ('REACH') (OJ L 44, 18.2.2011, p. 2).

10 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).

11 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).

12 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).

13 Judgment of the Court of Justice of 13 July 2017, *Verein zur Wahrung von Einsatz und Nutzung von Chromtrioxid und anderen Chrom-VI-Verbindungen in der Oberflächentechnik eV (VECCO) and Others v European Commission*, C-651/15 P, ECLI:EU:C:2017:543.

legislation imposing minimum requirements relating to the protection of human health or the environment for the use of DEHP, BBP and DBP in immediate packaging of medicinal products within the meaning of Article 58(2) of Regulation No 1907/2006 since they do not contain provisions specific to those substances imposing such requirements. Furthermore, Regulation (EC) No 726/2004 and Directives 2001/82/EC and 2001/83/EC lay down requirements related to the protection of human health only, while, as regards DEHP, intrinsic properties relating to hazards for the environment have been included in the entry for that substance in Annex XIV to Regulation (EC) No 1907/2006. Those exemptions are therefore not justified and should be deleted.

(6) For the uses of DEHP, BBP, DBP and DIBP that will no longer be exempted from the authorisation requirement, it is appropriate to indicate the dates referred to in point (i) of Article 58(1)(c) of Regulation (EC) No 1907/2006, taking into account the Agency's recommendation of 10 July 2019 and its capacity to handle applications for authorisations. As regards uses of DEHP in medical devices, the dates should also take into account the transitional provisions for the application of Regulations (EU) 2017/745[14] and (EU) 2017/746[15] of the European Parliament and of the Council.

(7) For each of the uses of DEHP, BBP, DBP and DIBP that will no longer be exempted from the authorisation requirement, there are no reasons for which the date referred to in point (ii) of Article 58(1)(c) of Regulation (EC) No 1907/2006 should be set earlier than 18 months than the date referred to in Article point (i) 58(1)(c) of that Regulation.

(8) During the public consultation conducted by the Agency on its draft recommendation, no specific comments were submitted with regard to possible exemptions for product and process orientated research and development. As there is no information justifying the need for such an exemption, the exemption was not considered.

(9) As the available information on the uses of the substances concerned by this Regulation is limited, it is not appropriate to set review periods at this stage, pursuant to point (d) of Article 58(1) of Regulation (EC) No 1907/2006.

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

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

HAS ADOPTED THIS REGULATION:

Article 1

Annex XIV 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*.

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[14] 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).

[15] 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,

For the Commission
The President
Ursula VON DER LEYEN