Brussels, 10 March 2021
(OR. en)

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COVER NOTE
From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt: 9 March 2021
To: Mr Jeppe TRANHOLM-MIKKESEN, Secretary-General of the Council of the European Union
No. Cion doc.: […](2021) XXX draft - D 071308/02

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

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

of XXX


(Text with EEA relevance)
THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,


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. 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. In accordance with Article 58(3) of Regulation (EC) No 1907/2006, on 10 July 2019 the European Chemicals Agency (‘the Agency’) recommended 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 [numerical references to specific articles and decisions are provided].
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.

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.


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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\(^\text{14}\) and (EU) 2017/746\(^\text{15}\) 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:

\textbf{Article 1}

Annex XIV to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

\textbf{Article 2}

This Regulation shall enter into force on the twentieth day following that of its publication in the \textit{Official Journal of the European Union}.


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