Commission Regulation (EU) 2020/171 of 6 February 2020 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) 2020/171

of 6 February 2020

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 1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear, and dihexyl phthalate and the substance group 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0,3 % of dihexyl phthalate meet the criteria for classification as toxic for reproduction (category 1B) in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[(2)] and therefore meet the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 set out in Article 57(c) of that Regulation.

(2) The substance trixylyl phosphate meets the criteria for classification as toxic for reproduction (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore meets the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 set out in Article 57(c) of that Regulation.

(3) The substances sodium perborate; perboric acid, sodium salt and sodium peroxometaborate meet the criteria for classification as toxic for reproduction (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore meet the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 set out in Article 57(c) of that Regulation.

(4) The substances 5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2]

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(covering any of the individual stereoisomers of [1] and [2] or any combination thereof) are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII to Regulation (EC) No 1907/2006 and therefore meet the criteria for inclusion in Annex XIV to that Regulation set out in Article 57(e) of that Regulation.

(5) The substances 2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328); 2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327); 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) and 2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320) are persistent, bioaccumulative and toxic and/or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII to Regulation (EC) No 1907/2006 and therefore meet the criteria for inclusion in Annex XIV to that Regulation set out in Article 57(d) and/or (e) of that Regulation.

(6) All the above-mentioned substances have been identified and included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006. They have furthermore been prioritised for inclusion in Annex XIV to Regulation (EC) No 1907/2006 by the European Chemicals Agency ('the Agency') in its recommendations of 10 November 2016[(3)] and 5 February 2018[(4)], in accordance with Article 58(3) and (4) of that Regulation. In addition, the Commission has received submissions from interested parties to calls for information on the possible economic, social, health and environmental impacts (costs and benefits) of the inclusion in Annex XIV to Regulation (EC) No 1907/2006 of the substances proposed by the Agency in its draft recommendations.

(7) For each of the substances included in Annex XIV to Regulation (EC) No 1907/2006 by this Regulation a date from which the placing on the market and the use of the substance shall be prohibited unless an authorisation is granted should be set as required by Article 58(1)(c)(i) of Regulation (EC) No 1907/2006, taking into account the Agency's capacity to handle applications for authorisation. For each of those substances there are no reasons why the date referred to in Article 58(1)(c)(ii) of Regulation (EC) No 1907/2006 should be set earlier than 18 months before the date referred to in Article 58(1)(c)(i) of that Regulation.

(8) 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.

(9) As there is no information justifying the need for an exemption for product and process orientated research and development, it is not appropriate to consider any such exemption.

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

(11) The substances tetralead trioxide sulphate; pentalead tetraoxide sulphate; orange lead (lead tetroxide) and lead monoxide (lead oxide) meet the criteria for classification as toxic for reproduction (category 1A) in accordance with Regulation (EC) No 1272/2008 and therefore meet the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 set out in Article 57(c) of that Regulation. They have also been identified and included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006 and prioritised for inclusion in Annex XIV to that Regulation by the Agency's recommendation of 10 November 2016 in accordance with Article 58(3) and (4) of that Regulation. The use of lead and its compounds is covered by Council Directive 98/24/EC[(5)] and to some extent by Directive 2010/75/EU of the European Parliament and of the Council[(6)] and its implementing measures establishing Best Available Techniques (BAT) conclusions. Furthermore the current Union binding occupational limit value and binding biological limit value for lead compounds under Directive 98/24/EC will be reviewed. Therefore, and in view of possible adoption of more stringent measures at the workplace, it is appropriate to postpone a decision on the inclusion of those substances in Annex XIV to Regulation (EC) No 1907/2006. In addition, through implementation of Directive 2010/75/EU and its predecessors, emissions of lead and its compounds to the environment have decreased and continue to decrease as shown by the European Pollutant Release and Transfer Register (E-PRTR) reporting and further reductions are expected as new BAT conclusions are adopted and as permits are updated to reflect them.

(12) All uses of 1-methyl-2-pyrrolidone (NMP) are restricted in accordance with Annex XVII to Regulation (EC) No 1907/2006. NMP has similar intrinsic properties to those of N,N-dimethylacetamide (DMAC) and N,N-Dimethylformamide (DMF), and the three substances have similar industrial uses and may be considered as interchangeable, at least for some uses, even if in general they cannot be considered 'drop-in' alternatives. In view of the similarities of the three substances in order to ensure a consistent regulatory approach[(7)], the decision on the inclusion of NMP in Annex XIV to Regulation (EC) No 1907/2006 should be postponed, as has been done for DMAC and DMF when the Commission considered the Agency's recommendations of 17 January 2013[(8)] and of 6 February 2014[(9)], respectively.

(13) In order to avoid the premature obsolescence of articles or complex products that are no longer produced after the sunset dates referred to in Annex XIV to Regulation (EC) No 1907/2006, some substances (by themselves or in mixtures) included in that Annex need to be available for the production of spare parts as articles or as complex products for the repair of those articles or complex products, where those articles or complex products cannot function as intended without those spare parts, as well as where some Annex XIV substances (by themselves or in mixtures) are necessary for the repair of such articles or complex products. In order to facilitate application for authorisation for those uses, the existing transitional arrangements should be extended, allowing the adoption of implementing measures for simplified application for authorisations in such cases. In addition, the wording of the notes to the table of Annex XIV to Regulation (EC) No 1907/2006 should be revised in order to ensure consistency of the terminology

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as regards articles and complex products in the light of the judgement of the Court of Justice in Case C-106/14[(10)].

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

(15) 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 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*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 6 February 2020.

For the Commission

The President

Ursula VON DER LEYEN

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ANNEX

The table in Annex XIV to Regulation (EC) No 1907/2006 is amended as follows:

(1) The following entries are added:

			Transitional arrangements			
EntryNo	**Substance**	**Intrinsic property(ies) referred to in Article 57**	**Latest application date**[a]	**Sunset date**[b]	**Exempted (categories of) uses**	**Review periods**
‘44.	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear EC No: 271-093-5 CAS No: 68515-50-4	Toxic for reproduction (category 1B)	27 August 2021 (*)	27 February 2023 (**)		
45.	Dihexyl phthalate EC No: 201-559-5 CAS No: 84-75-3	Toxic for reproduction (category 1B)	27 August 2021 (*)	27 February 2023 (**)		
46.	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0,3 % of dihexyl phthalate	Toxic for reproduction (category 1B)	27 August 2021 (*)	27 February 2023 (**)		

a Date referred to in Article 58(1)(c)(ii).

b Date referred to in Article 58(1)(c)(i).