EUROPEAN
COMMISSION

Brussels, XXX
[…](2021) XXX draft

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)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

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 substance tetraethyllead meets the criteria for classification as toxic for reproduction (category 1A) in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[2] and therefore meets the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 set out in Article 57, point (c), of that Regulation.

(2) The substance 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol (with ≥ 0,1% of Michler's ketone (EC No 202-027-5) or Michler's base (EC No 202-959-2)) meets the criteria for classification as carcinogenic (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, point (a), of that Regulation.

(3) Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) (with ≥ 0,1% w/w 4-heptylphenol, branched and linear) are substances that have endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment. They give rise to an equivalent level of concern to those of other substances listed in Article 57, points (a) to (e), of Regulation (EC) No 1907/2006 and, therefore, meet the criteria for inclusion in Annex XIV to that Regulation set out in Article 57, point (f), of that Regulation.

(4) The substance 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE) meets the criteria for classification as toxic for reproduction (category 1B) in accordance with Regulation (EC) No 1272/2008 and

[1] OJ L 396, 30.12.2006, p. 1.

[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (OJ L 353, 31.12.2008, p. 1).

therefore meets the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 set out in Article 57, point (c), of that Regulation.

(5) Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE) is a substance that 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, point (c), of that Regulation.

(6) All the above-mentioned substances have been identified as meeting the criteria referred to in Article 57 of Regulation (EC) No 1907/2006 and included in the candidate list for eventual inclusion in Annex XIV to that Regulation. They have furthermore been prioritised for inclusion in that Annex by the European Chemicals Agency ("the Agency") in its recommendation of 1 October 2019[3].

(7) The Agency conducted a public consultation on its draft recommendation where interested parties were invited to submit comments. In addition, the Commission 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 recommendation.

(8) The above-mentioned substances should therefore be included in Annex XIV to Regulation (EC) 1907/2006.

(9) 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 is to be prohibited unless an authorisation is granted should be set as required by Article 58(1), point (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), point (c)(ii), of Regulation (EC) No 1907/2006 should be set earlier than 18 months before the date referred to in Article 58(1), point (c)(i), of that Regulation.

(10) Article 58(1), point (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 available, it is not appropriate to set exemptions based on those provisions.

(11) 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. On the basis of the information available, it is therefore not appropriate to set those exemptions.

(12) As the available information on the uses of the substances included in Annex XIV to Regulation (EC) No 1907/2006 by this Regulation is limited, it is not appropriate to set review periods referred to in Article 58(1), point (d), of that Regulation at this stage.

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[3] https://echa.europa.eu/documents/10162/13640/9th_axiv_recommendation_October2019_en.pdf/d4d55dea-cc36-8f57-0d9f-33b8e64c4f07

(13) The substances 2-methoxyethanol (EGME) and 2-ethoxyethanol (EGEE) 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, point (c), of that Regulation. The placing on the market and use of both substances on their own, as constituents of other substances or in mixtures for supply to the general public are restricted in accordance with Annex XVII to Regulation (EC) No 1907/2006. As regards the protection of workers, indicative occupational exposure limit values have been established for those substances at Union level by Commission Directive 2009/161/EU[4] as provided for in Council Directive 98/24/EC[5]. As those values are not binding, the implementation of that Directive by the Member States may vary. The Commission is assessing what could be the most appropriate regulatory approach regarding those substances. It is therefore appropriate to postpone their inclusion in Annex XIV to Regulation (EC) No 1907/2006.

(14) The substances cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3] (HHPA) and hexahydromethylphthalic anhydride [1], hexahydro-4-methylphthalic anhydride [2], hexahydro-1-methylphthalic anhydride [3], hexahydro-3-methylphthalic anhydride [4] (MHHPA) meet the criteria for classification as respiratory sensitiser (category 1) in accordance with Regulation (EC) No 1272/2008. The Agency concluded that there is scientific evidence of probable serious effects to human health which give rise to an equivalent level of concern to those of other substances listed in Article 57, points (a) to (e), of Regulation (EC) No 1907/2006 and that those substances therefore meet the criteria for inclusion in Annex XIV to that Regulation set out in Article 57, point (f), of that Regulation. According to available information, those substances are used at industrial sites, where the main concern is related to exposure of workers and there are no professional or consumer uses. As regards the protection of workers, there are no indicative occupational exposure limit values established for those substances at Union level in accordance with Directive 98/24/EC, and it may be difficult to establish a safe level of exposure for a respiratory sensitiser. The Commission is assessing what could be the most appropriate regulatory approach regarding those substances. It is therefore appropriate to postpone the inclusion of those substances in Annex XIV to Regulation (EC) No 1907/2006.

(15) The substance 1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.16,9.02,13.05,10]octadeca-7,15-diene (“Dechlorane Plus”™) (covering any of its individual anti- and syn-isomers or any combination thereof) is a very persistent and very bioaccumulative substance, in accordance with the criteria set out in Annex XIII to Regulation (EC) No 1907/2006, and therefore meets the criteria for inclusion in Annex XIV to that Regulation set out in its Article 57, point (e). An Annex XV dossier is under preparation to restrict uses of that substance. In addition, steps have been taken towards the inclusion of that substance in the Stockholm Convention on Persistent Organic Pollutants[6]. Once a substance is subject to the Convention, its manufacturing, placing on the market and use are to be

[4] Commission Directive 2009/161/EU of 17 December 2009 establishing a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC (OJ L 338, 19.12.2009, p. 87).

[5] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

[6] OJ L 209, 31.7.2006, p. 3.

prohibited, phased out as soon as possible or restricted at Union level by Regulation (EU) 2019/1021 of the European Parliament and of the Council[7]. Substances for which all uses have been prohibited by other Union legislation cannot be listed in Annex XIV to Regulation (EC) No 1907/2006. In order to ensure a consistent regulatory approach, the outcome of those initiatives should be taken into consideration prior to taking a decision on the inclusion of "Dechlorane Plus"™ in Annex XIV to Regulation (EC) No 1907/2006. It is therefore appropriate to postpone the inclusion of that substance in Annex XIV to Regulation (EC) 1907/2006.

(16) The seven lead compounds dioxobis(stearato)trilead; fatty acids, C16-18, lead salts; trilead dioxide phosphonate; sulfurous acid, lead salt, dibasic; [Phthalato(2-)]dioxotrilead; trilead bis(carbonate) dihydroxide and lead oxide sulfate 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, point (c), of that Regulation. Those substances are mainly present in recycled polyvinyl chloride (PVC) and cannot be removed with the current technology. The Commission is working on a Regulation to prohibit the use of lead and its compounds in PVC articles and restrict the placing on the market of PVC articles containing more than 0,1% lead, with some derogations. Furthermore, the current Union binding occupational exposure limit value and binding biological limit value for lead compounds established under Directive 98/24/EC are under review. Therefore, in view of the ongoing discussions on restriction of use of lead and its compounds as well as 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) 1907/2006.

(17) The substance 4,4'-isopropylidenediphenol (Bisphenol A; BPA) meets the criteria for classification as toxic for reproduction (category 1B) in accordance with Regulation (EC) No 1272/2008. It also has endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and the environment. It gives rise to an equivalent level of concern to those of other substances listed in Article 57, points (a) to (e), of Regulation (EC) No 1907/2006. It therefore meets the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 set out in Article 57, points (c) and (f), of that Regulation. An Annex XV dossier is under preparation to restrict the use of Bisphenol A and structurally related bisphenols of similar concerns for the environment. That restriction is to cover the uses of Bisphenol A that would fall under the authorisation regime. It is therefore appropriate to postpone the inclusion of that substance in Annex XIV to Regulation (EC) 1907/2006.Regulation (EC) No 1907/2006 should therefore be amended accordingly.

(18) 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.

[7] Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45).

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,

For the Commission
The President
Ursula VON DER LEYEN