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COMMISSION REGULATION (EU) No .../..

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)

DISCLAIMER: subject to potential further changes

COMMISSION REGULATION (EU) No .../..

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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/EC¹, and in particular Articles 58 and 131 thereof,

Whereas:

- (1) 1-Bromopropane (n-propyl bromide) meets the criteria for classification as toxic for reproduction (category 1B) in accordance with Regulation (EC) No 1272/2008 of the European Parliament and the Council² 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.
- (2) Diisopentylphthalate 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) 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich, 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.
- (4) 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters, 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.

¹ OJ L 396, 30.12.2006, p. 1.

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

- (5) 1,2-Benzenedicarboxylic acid, dipentylester, branched and linear, 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.
- (6) Bis(2-methoxyethyl) phthalate 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.
- (7) Dipentylphthalate 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.
- (8) N-Pentyl-isopentylphthalate 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.
- (9) Anthracene oil meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 (when containing ≥ 0.005 % (w/w) of benzo[a]pyrene (EINECS No 200-028-5)) and therefore meets the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 set out in Article 57(a) of that Regulation. The substance is also persistent, bioaccumulative and toxic, as well as very persistent and very bioaccumulative 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 Article 57(d) and 57(e) of that Regulation.
- (10) Pitch, coal tar, high temp. 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(a) of that Regulation. The substance is also persistent, bioaccumulative and toxic, as well as very persistent and very bioaccumulative 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 Article 57(d) and 57(e) of that Regulation.
- (11) 4-(1,1,3,3-Tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and substances of unknown or variable composition, complex reaction products or biological materials (“UVCB substances”), polymers and homologues] through their degradation are substances with endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of Regulation (EC) No 1907/2006 and, therefore, meet the criteria for inclusion in Annex XIV to that Regulation set out in Article 57 (f) of that Regulation.
- (12) 4-Nonylphenol, branched and linear, ethoxylated [including substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof] through their degradation are substances with endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment which

give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of Regulation (EC) No 1907/2006 and, therefore, meet the criteria for inclusion in Annex XIV to that Regulation set out in Article 57 (f) of that Regulation.

- (13) Those 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 (hereinafter "the Agency") in its recommendations of 6 February 2014³ or 1 July 2015⁴, in accordance with Article 58 of that Regulation. It is therefore appropriate to include those substances in that Annex.
- (14) It is appropriate to specify the latest application dates and the sunset dates referred to in points (i) and (ii) of Article 58(1)(c) of Regulation (EC) No 1907/2006 in Annex XIV to that Regulation.
- (15) The Agency's recommendations of 6 February 2014 and of 1 July 2015 have identified the dates referred to in Article 58(1)(c)(ii) of Regulation (EC) No 1907/2006, by which applications must be received if the applicant wishes to continue to use a substance or place it on the market for certain uses, for each of the substances listed in the Annex to this Regulation. Those dates have been identified on the basis of the estimated time that would be required to prepare an application for the authorisation, taking into account the information available on the different substances and the information received during the public consultation carried out in accordance with Article 58(4) of Regulation (EC) No 1907/2006. The Agency's capacity to handle applications in the time provided for in Regulation (EC) No 1907/2006 has also been taken into account, as provided in Article 58(3) of that Regulation.
- (16) For each of the substances listed in the Annex to this Regulation the date referred to in Article 58(1)(c)(i) of Regulation (EC) No 1907/2006 should be set at 18 months after the date referred to in Article 58(1)(c)(ii) of that Regulation.
- (17) 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.
- (18) On the basis of the information currently available it is not appropriate to set exemptions for product and process orientated research and development.
- (19) On the basis of the information currently available it is not appropriate to set review periods for certain uses.
- (20) In order to avoid the premature obsolescence of articles that are no longer produced after the sunset dates referred to 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 for the repair of those articles, where those articles cannot function as intended without those spare parts as well as where some Annex XIV substances (by themselves or in mixtures) are necessary for repair of such articles. To that end, applications for authorisation for the use of an Annex XIV

³ http://echa.europa.eu/documents/10162/13640/5th_a_xiv_recommendation_06feb2014_en.pdf

⁴ http://echa.europa.eu/documents/10162/13640/6th_a_xiv_recommendation_01july2015_en.pdf

substance for the production of such spare parts and for the repair of such articles should be simplified. The transitional arrangements applicable to the substances concerned by those uses should be extended in order to allow for the adoption of implementing measures for such simplified applications for authorisation.

- (21) Regulation (EC) No 1907/2006 should therefore be amended accordingly.
- (22) N,N-Dimethylformamide (DMF) 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. It has 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 6 February 2014 in accordance with Article 58 of that Regulation. DMF has similar intrinsic properties to those of N,N-Dimethylacetamide (DMAC) and N-Methyl-2-pyrrolidone (NMP) and the three substances may be considered as potential alternatives for some of their major uses. NMP is the subject of an on-going restriction procedure in accordance with Article 69 of Regulation (EC) No 1907/2006. In view of the similarities of the three substances, both regarding their intrinsic properties and their industrial applications, and in order to ensure a consistent regulatory approach, the Commission considers it appropriate to postpone the decision on the inclusion of DMF in Annex XIV as has already been done for DMAC when the Commission considered the Agency's recommendation of 17 January 2013.
- (23) Diazene-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA) meets the criteria for classification as a respiratory sensitiser (Resp. Sens.1). Taking into account all available information about the intrinsic properties of ADCA and about its adverse effects, the Agency concluded that it can be regarded as a substance for which 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 points (a) to (e) of Article 57 of Regulation (EC) No 1907/2006 and therefore meets the criteria for inclusion in Annex XIV to that Regulation set out in Article 57(f) of that Regulation. It has 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 6 February 2014 in accordance with Article 58 of that Regulation. Uses of ADCA are very diverse and concern a broad range of different manufacturing industries, expected to lead to a very high workload for the Agency and the Commission as regards the number and complexity of applications for authorisation. As currently the experience for handling authorisation applications covering broad ranges of uses is still limited, it is appropriate to postpone the decision on the inclusion of ADCA in Annex XIV, for the time being. Moreover, new information has been submitted on the classification of ADCA which could be relevant for its respiratory sensitizer properties as well as for the identification of this substance under Article 57(f) of Regulation (EC) No 1907/2006, and is currently being examined by a Member State.
- (24) Certain Aluminosilicate Refractory Ceramic Fibres (Al-RCF) and Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF) meet the criteria for classification as carcinogenic (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(a) 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 6 February 2014 in accordance with Article 58 of that Regulation. The actual fibres are manufactured at a very limited number of industrial sites and are in general directly transformed within the same manufacturing process into articles that are subsequently used in a broad range of industrial equipment for high-temperature insulation, which can potentially lead to significant worker exposure. However, the use of articles made of the fibres is not subject to authorisation under Regulation (EC) No 1907/2006. In order to decide on the most relevant regulatory approach, the Commission considers it appropriate to postpone the decision on the inclusion of Al-RCF and Zr-RCF in Annex XIV to Regulation (EC) No 1907/2006 for the time being.

- (25) Boric acid, disodium tetraborate (anhydrous), diboron trioxide, and tetraboron disodium heptaoxide (hydrate) 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. 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 1 July 2015 in accordance with Article 58 of that Regulation. Furthermore, the uses of these substances are very diverse and concern a broad range of different manufacturing industries, expected to lead to a very high workload for the Agency and the Commission as regards the number and complexity of applications for authorisation. As currently the experience for handling authorisation applications covering broad ranges of uses is still limited, it is appropriate to postpone the decision on the inclusion of these substances in Annex XIV for the time being.
- (26) 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 third 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
Jean-Claude JUNCKER