Commission Regulation (EU) 2017/999 of 13 June 2017 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) 2017/999

of 13 June 2017

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 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 Council[(2)] 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) The substance 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) The substance 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) The substance 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.

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(5) The substance 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) The substance 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) The substance 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) The substance 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) When containing a certain percentage of benzo[a]pyrene, the substance anthracene oil 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 (e) of that Regulation.

(10) The substance 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, bioccumulative 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 (e) of that Regulation.

(11) The substance group 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) are substances which through their degradation have endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment. As such, they 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) The substance group 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), are substances which through their degradation have endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment. As such, they 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 ('the Agency') in its recommendations of 6 February 2014[(3)] and 1 July 2015[(4)], in accordance with Article 58 of that Regulation. In addition, the Commission has received information on socioeconomic impacts provided in the numerous stakeholder submissions after receipt of the Agency's fifth recommendation or provided through a public consultation conducted in parallel with the Agency's public consultation on its draft sixth recommendation. Notwithstanding the information received, it is appropriate to include those substances in that Annex.

(14) It is appropriate to indicate the dates referred to in Article 58(1)(c)(ii) of Regulation (EC) No 1907/2006 in line with the Agency's recommendations of 6 February 2014 and of 1 July 2015. 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. To that purpose, the Agency's capacity to handle applications in the time provided for in Regulation (EC) No 1907/2006 should also been taken into account, as provided in Article 58(3) of that Regulation.

(15) For each of those substances listed in the Annex to this Regulation there are no reasons why the date referred to in Article 58(1)(c)(i) of Regulation (EC) No 1907/2006 should be set later than 18 months after the date referred to in Article 58(1)(c)(ii) of that Regulation.

(16) 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.

(17) On the basis of the information currently available it is not appropriate to set exemptions for product and process orientated research and development.

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(18) On the basis of the information currently available it is not appropriate to set review periods for certain uses. In accordance with Article 60(8) of Regulation (EC) No 1907/2006 review periods are to be determined on a case-by-case basis taking into account, inter alia, the risks posed by the uses of the substance, the socioeconomic benefits arising from its use and the analysis of alternatives or any substitution plan submitted for uses for which authorisation is requested. In instances where there is no suitable alternative, the risks posed by the use are limited by appropriate and effective risk management measures, and when the benefits arising from the use are expected to be high, as could be the case for uses in the production of medicinal products or medical devices, review periods could be long.

(19) 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 the repair of such articles. To that end, applications for authorisation for the use of an Annex XIV 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.

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

(21) 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.

(22) 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

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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 highly complex 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.

(23) 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.

(24) 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 highly complex 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.

(25) 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: