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Contents

II *Non-legislative acts*

REGULATIONS

- ★ **Council Regulation (EU) 2017/997 of 8 June 2017 amending Annex III to Directive 2008/98/EC of the European Parliament and of the Council as regards the hazardous property HP 14 ‘Ecotoxic’⁽¹⁾** 1
- ★ **Commission Implementing Regulation (EU) 2017/998 of 12 June 2017 amending for the 268th time Council Regulation (EC) No 881/2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the ISIL (Da’esh) and Al-Qaida organisations** 5
- ★ **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)⁽¹⁾** 7
- ★ **Commission Regulation (EU) 2017/1000 of 13 June 2017 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards perfluorooctanoic acid (PFOA), its salts and PFOA-related substances⁽¹⁾** 14

Corrigenda

- ★ **Corrigendum to Commission Implementing Regulation (EU) 2016/1821 of 6 October 2016 amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 294, 28.10.2016)** 19

⁽¹⁾ Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

II

(Non-legislative acts)

REGULATIONS

COUNCIL REGULATION (EU) 2017/997

of 8 June 2017

amending Annex III to Directive 2008/98/EC of the European Parliament and of the Council as regards the hazardous property HP 14 'Ecotoxic'

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives ⁽¹⁾, and in particular Article 38(2) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) Annex III to Directive 2008/98/EC lists properties of waste which render it hazardous.
- (2) Directive 2008/98/EC states that the classification of waste as hazardous should be based, inter alia, on the Union legislation on chemicals, in particular concerning the classification of mixtures as hazardous, including concentration limit values used for that purpose. Commission Decision 2000/532/EC ⁽²⁾ established a list of the types of waste in order to encourage a harmonised classification of waste and to ensure the harmonised determination of hazardous properties of waste within the Union.
- (3) Annex III to Directive 2008/98/EC provides that the attribution of the hazardous property HP 14 'Ecotoxic' is to be made on the basis of the criteria laid down in Annex VI to Council Directive 67/548/EEC ⁽³⁾.
- (4) Directive 67/548/EEC was repealed with effect from 1 June 2015 and replaced by Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽⁴⁾. That Directive may, however, continue to apply to some mixtures until 1 June 2017, in case they were classified, labelled and packaged in accordance with Directive 1999/45/EC of the European Parliament and of the Council ⁽⁵⁾ and already placed on the market before 1 June 2015.

⁽¹⁾ OJ L 312, 22.11.2008, p. 3.

⁽²⁾ Commission Decision 2000/532/EC of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste (OJ L 226, 6.9.2000, p. 3).

⁽³⁾ Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196, 16.8.1967, p. 1).

⁽⁴⁾ 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, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

⁽⁵⁾ Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (OJ L 200, 30.7.1999, p. 1).

- (5) Annex III to Directive 2008/98/EC was replaced by Commission Regulation (EU) No 1357/2014 ⁽¹⁾ in order to align, where appropriate, the definitions of hazardous properties with Regulation (EC) No 1272/2008, and replace references to Directive 67/548/EEC by references to Regulation (EC) No 1272/2008.
- (6) The definition of the hazardous property HP 14 'Ecotoxic' was not amended by Regulation (EU) No 1357/2014 as an additional study was needed in order to ensure completeness and representativeness as regards information on the possible impact of an alignment of the assessment of the hazardous property HP 14 'Ecotoxic' with the criteria laid down in Regulation (EC) No 1272/2008. That study being completed, it is appropriate to reflect its recommendations in the assessment of hazardous property HP 14 'Ecotoxic' for waste set out in Annex III to Directive 2008/98/EC, and to align that assessment, to the extent possible, with the criteria laid down in Regulation (EC) No 1272/2008 for the assessment of ecotoxicity of chemicals. When determining the hazard classification of waste for hazardous property HP 14 'Ecotoxic' by applying calculation formulae, generic cut-off values, as defined in Regulation (EC) No 1272/2008, should be applied.
- (7) Annex VI to Regulation (EC) No 1272/2008 contains harmonised multiplying factors assigned to a limited number of substances classified as 'hazardous to the aquatic environment, acute category 1' or 'hazardous to the aquatic environment, chronic category 1', which are used to derive the classification of a mixture in which such substances are present. In light of progress made in establishing such multiplying factors, the Commission may, in accordance with Article 38(2) of Directive 2008/98/EC, review the calculation method for the assessment of substances with regard to the hazardous property HP 14 'Ecotoxic' in view of the possible inclusion of multiplying factors in that method.
- (8) When a test is performed to assess waste for the hazardous property HP 14 'Ecotoxic', it is appropriate to apply the relevant methods established in Commission Regulation (EC) No 440/2008 ⁽²⁾ or other internationally recognised test methods and guidelines. Decision 2000/532/EC provides that, where a hazardous property of waste has been assessed by a test and by using the concentrations of hazardous substances as indicated in Annex III to Directive 2008/98/EC, the results of the test are to prevail. Furthermore, Article 12 of Regulation (EC) No 1272/2008, in particular Article 12(b) and the methodologies for its application, should be taken into account. It is appropriate for the Commission to promote the exchange of best practices with regard to test methods for the assessment of substances as concerns the hazardous property HP 14 'Ecotoxic' with a view to their possible harmonisation.
- (9) It is appropriate to allow companies and competent authorities sufficient time to adapt to the new requirements.
- (10) The Committee referred to in Article 39 of Directive 2008/98/EC did not deliver an opinion on the measures provided for in this Regulation. The measures should therefore be adopted by the Council in accordance with Article 5a(4) of Council Decision 1999/468/EC ⁽³⁾,

HAS ADOPTED THIS REGULATION:

Article 1

Annex III to Directive 2008/98/EC 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*.

It shall apply from 5 July 2018.

⁽¹⁾ Commission Regulation (EU) No 1357/2014 of 18 December 2014 replacing Annex III to Directive 2008/98/EC of the European Parliament and of the Council on waste and repealing certain Directives (OJ L 365, 19.12.2014, p. 89).

⁽²⁾ Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 142, 31.5.2008, p. 1).

⁽³⁾ Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).

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

Done at Luxembourg, 8 June 2017.

For the Council

The President

K. SIMSON

ANNEX

Annex III to Directive 2008/98/EC is amended as follows:

(1) the entry for HP 14 'Ecotoxic' is replaced by the following:

'HP 14 'Ecotoxic': waste which presents or may present immediate or delayed risks for one or more sectors of the environment.

Waste which fulfils any of the following conditions shall be classified as hazardous by HP 14:

— Waste which contains a substance classified as ozone depleting assigned the hazard statement code H420 in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council (*) and the concentration of such a substance equals or exceeds the concentration limit of 0,1 %.

$$[c(\text{H420}) \geq 0,1 \text{ \%}]$$

— Waste which contains one or more substances classified as aquatic acute assigned the hazard statement code H400 in accordance with Regulation (EC) No 1272/2008 and the sum of the concentrations of those substances equals or exceeds the concentration limit of 25 %. A cut-off value of 0,1 % shall apply to such substances.

$$[\Sigma c (\text{H400}) \geq 25 \text{ \%}]$$

— Waste which contains one or more substances classified as aquatic chronic 1, 2 or 3 assigned to the hazard statement code(s) H410, H411 or H412 in accordance with Regulation (EC) No 1272/2008, and the sum of the concentrations of all substances classified as aquatic chronic 1 (H410) multiplied by 100 added to the sum of the concentrations of all substances classified as aquatic chronic 2 (H411) multiplied by 10 added to the sum of the concentrations of all substances classified as aquatic chronic 3 (H412) equals or exceeds the concentration limit of 25 %. A cut-off value of 0,1 % applies to substances classified as H410 and a cut-off value of 1 % applies to substances classified as H411 or H412.

$$[100 \times \Sigma c (\text{H410}) + 10 \times \Sigma c (\text{H411}) + \Sigma c (\text{H412}) \geq 25 \text{ \%}]$$

— Waste which contains one or more substances classified as aquatic chronic 1, 2, 3 or 4 assigned the hazard statement code(s) H410, H411, H412 or H413 in accordance with Regulation (EC) No 1272/2008, and the sum of the concentrations of all substances classified as aquatic chronic equals or exceeds the concentration limit of 25 %. A cut-off value of 0,1 % applies to substances classified as H410 and a cut-off value of 1 % applies to substances classified as H411, H412 or H413.

$$[\Sigma c \text{ H410} + \Sigma c \text{ H411} + \Sigma c \text{ H412} + \Sigma c \text{ H413} \geq 25 \text{ \%}]$$

Where: Σ = sum and c = concentrations of the substances.

(*) 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, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).;

(2) the note below the entry for HP 15 is deleted.

COMMISSION IMPLEMENTING REGULATION (EU) 2017/998**of 12 June 2017****amending for the 268th time Council Regulation (EC) No 881/2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the ISIL (Da'esh) and Al-Qaida organisations**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 881/2002 of 27 May 2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the ISIL (Da'esh) and Al-Qaida organisations ⁽¹⁾, and in particular Article 7(1)(a) and Article 7a(5) thereof,

Whereas:

- (1) Annex I to Regulation (EC) No 881/2002 lists the persons, groups and entities covered by the freezing of funds and economic resources under that Regulation.
- (2) On 7 June 2017, the Sanctions Committee of the United Nations Security Council decided to amend one entry in its list of persons, groups and entities to whom the freezing of funds and economic resources should apply. Annex I to Regulation (EC) No 881/2002 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 881/2002 is amended in accordance with the Annex to this Regulation.

*Article 2*This Regulation shall enter into force on the 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, 12 June 2017.

*For the Commission,
On behalf of the President,
Head of the Service for Foreign Policy Instruments*

⁽¹⁾ OJ L 139 29.5.2002, p. 9.

ANNEX

The identifying data for the entry 'Al-Nusra Front for the People of the Levant (alias (a) the Victory Front; (b) Jabhat al-Nusra; (c) Jabhet al-Nusra; (d) Al-Nusra Front; (e) Al-Nusra Front; (f) Ansar al-Mujahideen Network); (g) Levantine Mujahideen on the Battlefields of Jihad). Other information: (a) Operates in Syria; (b) Previously listed between 30 May 2013 and 13 May 2014 as an aka of Al-Qaida in Iraq. Date of designation referred to in Article 2a(4)(b): 14.5.2014.' under the heading 'Legal persons, groups and entities' in Annex I to Regulation (EC) No 881/2002 is replaced by the following:

'Al-Nusra Front for the People of the Levant (alias (a) the Victory Front; (b) Jabhat al-Nusra; (c) Jabhet al-Nusra; (d) Al-Nusra Front; (e) Al-Nusra Front; (f) Ansar al-Mujahideen Network); (g) Levantine Mujahideen on the Battlefields of Jihad; (h) Jabhat Fath al Sham; (i) Jabhat Fath al-Sham; (j) Jabhat Fatah al-Sham; (k) Jabhat Fateh Al-Sham; (l) Fatah al-Sham Front; (m) Fateh al-Sham Front); (n) Conquest of the Levant Front; (o) The Front for the Liberation of al Sham; (p) Front for the Conquest of Syria/the Levant; (q) Front for the Liberation of the Levant; (r) Front for the Conquest of Syria. Other information: (a) Operates in Syrian Arab Republic (b) Iraq; (c) Previously listed between 30 May 2013 and 13 May 2014 as an aka of Al-Qaida in Iraq. Date of designation referred to in Article 7d(2)(i): 14.5.2014.'

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.
- (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.

⁽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).

- (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, 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.
- (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 ⁽¹⁾ and 1 July 2015 ⁽²⁾, 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 be 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.

⁽¹⁾ http://echa.europa.eu/documents/10162/13640/5th_a_xiv_recommendation_06feb2014_en.pdf

⁽²⁾ http://echa.europa.eu/documents/10162/13640/6th_a_xiv_recommendation_01july2015_en.pdf

- (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.
- (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 socio-economic 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 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:

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, 13 June 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

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

1. The following entries are added:

Entry Nr	Substance	Intrinsic property(ies) referred to in Article 57	Transitional arrangements		Exempted (categories of) uses	Review periods
			Latest application date ⁽¹⁾	Sunset date ⁽²⁾		
'32.	1-Bromopropane (n-propyl bromide) EC No: 203-445-0 CAS No: 106-94-5	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020	—	—
33.	Diisopentylphthalate EC No: 210-088-4 CAS No: 605-50-5	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020	—	—
34.	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7 rich EC No: 276-158-1 CAS No: 71888-89-6	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020	—	—
35.	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters EC No: 271-084-6 CAS No: 68515-42-4	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020	—	—
36.	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear EC No: 284-032-2 CAS No: 84777-06-0	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020	—	—
37.	Bis(2-methoxyethyl) phthalate EC No: 204-212-6 CAS No: 117-82-8	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020	—	—
38.	Dipentylphthalate EC No: 205-017-9 CAS No: 131-18-0	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020	—	—

Entry Nr	Substance	Intrinsic property(ies) referred to in Article 57	Transitional arrangements		Exempted (categories of) uses	Review periods
			Latest application date ⁽¹⁾	Sunset date ⁽²⁾		
39.	N-pentyl-isopentylphthalate EC No: — CAS No: 776297-69-9	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020	—	—
40.	Anthracene oil EC No: 292-602-7 CAS No: 90640-80-5	Carcinogenic (category 1B)***, PBT, vPvB	4 April 2019	4 October 2020	—	—
41.	Pitch, coal tar, high temp. EC No: 266-028-2 CAS No: 65996-93-2	Carcinogenic (category 1B), PBT, vPvB	4 April 2019	4 October 2020	—	—
42.	4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated (covering well-defined substances and UVCB substances, polymers and homologues) EC No: — CAS No: —	Endocrine disrupting properties (Article 57(f) — environment)	4 July 2019	4 January 2021	—	—
43.	4-Nonylphenol, branched and linear, ethoxylated (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) EC No: — CAS No: —	Endocrine disrupting properties (Article 57(f) — environment)	4 July 2019	4 January 2021	—	—

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

⁽²⁾ Date referred to in Article 58(1)(c)(i).

- The sign '(*)' is inserted next to the date indicated in the 'Latest application date' column for the following substance entry numbers: 4, 5, 6, 7, 10, 11, 12, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 25, 27, 28, 29, 30 and 31.
- The sign '(**)' is inserted next to the date indicated in the 'Sunset date' column for the following substance entry numbers: 4, 5, 6, 7, 10, 11, 12, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 25, 27, 28, 29, 30 and 31.

4. The following notes are inserted after the table:

- '(*) 1 September 2019 for the use of the substance in the production of spare parts for the repair of articles the production of which ceased or will cease before the sunset date indicated in the entry for that substance, where that substance was used in the production of those articles and the latter cannot function as intended without that spare part, and for the use of the substance (on its own or in a mixture) for the repair of such articles where that substance on its own or in a mixture was used in the production of those articles and the latter cannot be repaired otherwise than by using that substance.
 - (**) 1 March 2021 for the use of the substance in the production of spare parts for the repair of articles the production of which ceased or will cease before the sunset date indicated in the entry for that substance, where that substance was used in the production of those articles and the latter cannot function as intended without those spare parts, and for the use of the substance (on its own or in a mixture) for the repair of such articles, where that substance was used in the production of those articles and the latter cannot be repaired otherwise than by using that substance.
 - (***) Does not meet the criteria for identification as a carcinogen if it contains < 0,005 % (w/w) benzo[a]pyrene (Einecs No 200-028-5)
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COMMISSION REGULATION (EU) 2017/1000**of 13 June 2017****amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards perfluorooctanoic acid (PFOA), its salts and PFOA-related substances****(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 Article 68(1) thereof,

Whereas:

- (1) Perfluorooctanoic acid ('PFOA'), its salts and PFOA-related substances ⁽²⁾ have some specific properties such as high friction resistance, dielectricity, resistance to heat and chemical agents, and low surface energy. They are used in a wide variety of applications such as in the fluoropolymer and fluoroelastomer production, as surfactants in fire-fighting foams, and in textile and paper production to provide water, grease, oil and/or dirt repellency.
- (2) On 14 June 2013, the Member State Committee, referred to in Article 76(1)(e) of Regulation (EC) No 1907/2006, identified PFOA as a persistent, bioaccumulative and toxic substance ('PBT') in accordance with Article 57(d) of that Regulation. On 20 June 2013, PFOA was included in the Candidate List of Substances of Very High Concern ('SVHC') for possible inclusion in Annex XIV to Regulation (EC) No 1907/2006.
- (3) On 17 October 2014, Germany and Norway submitted to the European Chemicals Agency ('the Agency') a dossier ⁽³⁾ pursuant to Article 69(4) of Regulation (EC) No 1907/2006 ('the Annex XV dossier'), proposing to restrict the manufacture, placing on the market and use of PFOA, its salts and PFOA-related substances, in order to address the risks to human health and the environment. Germany and Norway proposed a concentration limit of 2 ppb for the presence of these substances in other substances, mixtures or articles, and did not propose exemptions except for second-hand articles for which an end-use in the Union can be demonstrated before the date of application of the restriction.
- (4) On 8 September 2015, the Agency's Committee for Risk Assessment ('RAC') adopted its opinion concluding that subject to modification of the scope and conditions proposed in the Annex XV dossier, a general restriction on manufacture, use and placing on the market of PFOA, its salts and PFOA-related substances, is the most appropriate Union-wide measure to address the identified risks in terms of effectiveness in reducing those risks. RAC proposed two different concentration limits, namely 25 ppb for PFOA and its salts and 1 000 ppb for one or a combination of PFOA-related substances, in other substances, mixtures or articles, reflecting the possible presence of unavoidable impurities and unintended contaminants, and taking account of the capabilities of analytical methods. RAC proposed to exempt from the restriction photographic coatings applied to films, papers or printing plates, implantable medical devices and substances or mixtures used in semiconductor and photolithography processes, considering the relatively low environmental impact and long substitution timeframes. RAC also proposed to exempt the use of substances as transported isolated intermediates in order to allow the manufacture of alternatives, as well as the placing on the market of second-hand articles.

⁽¹⁾ OJ L 396, 30.12.2006, p. 1.

⁽²⁾ PFOA-related substances are substances that, based on their molecular structure, are considered to have the potential to degrade or be transformed to PFOA.

⁽³⁾ <http://echa.europa.eu/documents/10162/e9cddee6-3164-473d-b590-8fcf9caa50e7>

- (5) On 4 December 2015, the Agency's Committee for Socio-Economic Analysis ('SEAC') adopted its opinion, indicating that the restriction proposed in the Annex XV dossier, as modified by RAC and SEAC, is the most appropriate Union-wide measure to address the identified risks in terms of its socioeconomic benefits and socioeconomic costs.
- (6) SEAC agreed with the exemptions proposed by RAC. In addition, SEAC suggested a three year deferral of the restriction, instead of the eighteen months proposed in the Annex XV dossier, to allow stakeholders to take the necessary compliance measures. Based on socioeconomic considerations, such as high costs, significant economic burden, lack of alternatives, relatively low emissions to the environment, critical uses with high societal benefits, SEAC suggested longer deferrals of the restriction for latex printing inks, textiles for the protection of workers, membranes intended for medical textiles, filtration in water treatment, production processes, and effluent treatment, certain plasma nano-coatings and non-implantable medical devices.
- (7) SEAC also suggested to exempt from the proposed restriction fire-fighting foams already placed on the market before the date of application of the restriction, and semiconductor manufacturing equipment.
- (8) The Agency's Forum for Exchange of Information on Enforcement, referred to in Article 76(1)(f) of Regulation (EC) No 1907/2006, was consulted during the restriction process and its opinion has been taken into account.
- (9) On 12 January 2016, the Agency submitted the opinions of the RAC and the SEAC ⁽¹⁾ to the Commission.
- (10) Based on those opinions, the Commission concluded that an unacceptable risk to human health and the environment arises from the manufacture, use or placing on the market of PFOA, its salts and PFOA-related substances on their own, as a constituent of other substances, in mixtures and in articles. The Commission considers that those risks need to be addressed on a Union wide basis.
- (11) Perfluorooctane sulfonic acid ('PFOS') and its derivatives should be exempted from the proposed restriction, since those substances are already regulated by Regulation (EC) No 850/2004 of the European Parliament and of the Council ⁽²⁾. The unavoidable production of PFOA during the manufacture of fluorochemicals with a carbon chain equal to or shorter than six atoms should also be exempted from the proposed restriction.
- (12) As advised by SEAC, the application of the restriction should be deferred generally for a period of three years and for longer periods in relation to specified sectors in order to enable stakeholders to comply with the proposed restriction. While a standard analytical method is available for the determination of extractable PFOS in coated and impregnated solid articles, liquids and firefighting foams (CEN/TS 15968:2010), which most likely can be adjusted to also include PFOA and PFOA-related substances with a relevant detection limit, at present no such standard method is available for extraction and chemical analysis of those substances. The deferral period for the restriction should allow the further development of suitable analytical methods that can be applied to all matrices.
- (13) Regulation (EC) No 1907/2006 should therefore be amended accordingly.
- (14) 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 XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

⁽¹⁾ <https://echa.europa.eu/documents/10162/2f0dfce0-3dcf-4398-8d6b-2e59c86446be>

⁽²⁾ Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC (OJ L 158, 30.4.2004, p. 7).

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, 13 June 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

In Annex XVII to Regulation (EC) No 1907/2006, the following entry is added:

<p>‘68. Perfluorooctanoic acid (PFOA)</p> <p>CAS No 335-67-1</p> <p>EC No 206-397-9</p> <p>and its salts.</p> <p>Any related substance (including its salts and polymers) having a linear or branched perfluoroheptyl group with the formula C_7F_{15}- directly attached to another carbon atom, as one of the structural elements.</p> <p>Any related substance (including its salts and polymers) having a linear or branched perfluorooctyl group with the formula C_8F_{17}- as one of the structural elements.</p> <p>The following substances are excluded from this designation:</p> <p>— C_8F_{17}-X, where X = F, Cl, Br.</p> <p>— C_8F_{17}-C(=O)OH, C_8F_{17}-C(=O)O-X' or C_8F_{17}-CF₂-X' (where X' = any group, including salts).</p>	<ol style="list-style-type: none"> 1. Shall not be manufactured, or placed on the market as substances on their own from 4 July 2020. 2. Shall not, from 4 July 2020, be used in the production of, or placed on the market in: <ol style="list-style-type: none"> (a) another substance, as a constituent; (b) a mixture; (c) an article, <p>in a concentration equal to or above 25 ppb of PFOA including its salts or 1 000 ppb of one or a combination of PFOA-related substances.</p> 3. Points 1 and 2 shall apply from: <ol style="list-style-type: none"> (a) 4 July 2022 to: <ol style="list-style-type: none"> (i) equipment used to manufacture semi-conductors; (ii) latex printing inks. (b) 4 July 2023 to: <ol style="list-style-type: none"> (i) textiles for the protection of workers from risks to their health and safety; (ii) membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment; (iii) plasma nano-coatings. (c) 4 July 2032 to medical devices other than implantable medical devices within the scope of Directive 93/42/EEC. 4. Points 1 and 2 shall not apply to any of the following: <ol style="list-style-type: none"> (a) perfluorooctane sulfonic acid and its derivatives, which are listed in Part A of Annex I to Regulation (EC) No 850/2004; (b) the manufacture of a substance where this occurs as an unavoidable by-product of the manufacture of fluorochemicals with a carbon chain equal to or shorter than 6 atoms; (c) a substance that is to be used, or is used as a transported isolated intermediate, provided that the conditions in points (a) to (f) of Article 18(4) of this Regulation are met; (d) a substance, constituent of another substance or mixture that is to be used, or is used: <ol style="list-style-type: none"> (i) in the production of implantable medical devices within the scope of Directive 93/42/EEC;
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- (ii) in photographic coatings applied to films, papers or printing plates;
 - (iii) in photo-lithography processes for semiconductors or in etching processes for compound semiconductors;
 - (e) concentrated fire-fighting foam mixtures that were placed on the market before 4 July 2020 and are to be used, or are used in the production of other fire-fighting foam mixtures.
5. Point 2(b) shall not apply to fire-fighting foam mixtures which were:
- (a) placed on the market before 4 July 2020; or
 - (b) produced in accordance with point 4(e), provided that, where they are used for training purposes, emissions to the environment are minimised and effluents collected are safely disposed of.
6. Point 2(c) shall not apply to:
- (a) articles placed on the market before 4 July 2020;
 - (b) implantable medical devices produced in accordance with point 4(d)(i);
 - (c) articles coated with the photographic coatings referred to in point 4(d)(ii);
 - (d) semiconductors or compound semiconductors referred to in point 4(d)(iii).
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CORRIGENDA**Corrigendum to Commission Implementing Regulation (EU) 2016/1821 of 6 October 2016 amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff**

(Official Journal of the European Union L 294 of 28 October 2016)

On page 207, in the Annex, in the text replacing Annex I to Council Regulation (EEC) No 2658/87, in Part Two, in Section V, in Chapter 27, in the third paragraph of additional note 2(f):

for: 'The term "diluted colour C" means the colour of a product, as determined by the ISO 2049 method (equivalent to the ASTM D 1500 method), after one part of such product has been mixed with 100 parts by volume of xylene, toluene or another suitable solvent. The colour must be determined immediately after dilution.'

read: 'The term "diluted colour C" means the colour of a product, as determined by the ISO 2049 method (equivalent to the ASTM D 1500 method), after one part of the product has been made up to 100 parts by volume with xylene, toluene or another suitable solvent. The colour must be determined immediately after dilution.'

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