

## SCHEDULE 3

### Amendment of the Annexes and Appendices to the REACH Regulation

## PART 1

### The Annexes

#### Annex 1

1.—(1) Annex 1 (general provisions for assessing substances and preparing chemical safety reports) is amended as follows.

(2) In point 0.5, in the first paragraph, for “Community” substitute “United Kingdom or European Union”.

(3) In point 1.1.2, for the words from “test methods laid down” to “Article 13(3)” substitute “Council Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to REACH”.

(4) In point 1.3.1, in the first paragraph, omit “and Articles 4 to 7 of Directive 1999/45/EC”.

(5) In point 5.1.1, in the second paragraph, for “Community” substitute “United Kingdom”.

#### Annex 2

2.—(1) Annex 2 (requirements for the compilation of safety data sheets) is amended as follows.

(2) In point 0.2.2, after “set out in” insert “retained EU law that transposed”.

(3) In point 1.1—

(a) in the first paragraph, for the words from “the official language(s)” to the end of the paragraph substitute “English”;

(b) in the third paragraph, in point (b), omit the words “Member State”.

(4) In point 1.3—

(a) omit the second paragraph;

(b) in the fourth paragraph, for “non-Union” substitute “non-United Kingdom”.

(5) In point 1.4, omit from “in the Member State” to “on the market”.

(6) In point 2.1, in the first paragraph, omit “to the classification and labelling inventory”.

(7) In point 3.2.2(a)(ii), omit “Union”.

(8) In point 3.2.3, omit “Union”.

(9) In point 3.2.4, in point (b), omit the words “Member State”.

(10) In point 7, in the second paragraph, after “measures according to” insert “retained EU law that transposed”.

(11) In point 8.1.1, omit “in the Member State in which the safety data sheet is being provided”.

(12) For points 8.1.1.1 to 8.1.1.5 substitute—

“8.1.1.1. the workplace exposure limit within the meaning of—

(a) the Control of Substances Hazardous to Health Regulations 2002 (S.I. 2002/2677), as respects Great Britain, or

(b) the Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003 (S.R. 2003 No. 34), as respects Northern Ireland;

**8.1.1.2.** the occupational exposure limit within the meaning of—

- (a) the Control of Lead at Work Regulations 2002 (S.I. 2002/2676), as respects Great Britain, or
  - (b) the Control of Lead at Work Regulations (Northern Ireland) 2003 (S.R. 2003 No. 35), as respects Northern Ireland.”.
- (13) In point 8.2.1, after “in accordance with” insert “the retained EU law that transposed”.
- (14) In point 8.2.2.2, for “Council Directive 89/686/EEC” substitute “Regulation (EU) 2016/425(1)”.
- (15) In point 8.2.3, omit “Union”.
- (16) In point 13, in the first paragraph—
- (a) after “the requirements of” insert “the retained EU law that transposed”;
  - (b) omit “by the Member State in which the safety data sheet is being supplied”.
- (17) In point 13.1, in the second paragraph, for the words from “Union” to “force” substitute “legislation relating to waste”.
- (18) In point 14, omit from “, all three” to “of the Council”.
- (19) In point 15.1, in the first paragraph—
- (a) omit “Union”;
  - (b) for “for example,” substitute “including relevant EU provisions transposed through retained EU law, such as the”;
  - (c) for “Council Directive 96/82/EC” substitute “Directive 2012/18/EU”;
  - (d) omit the second sentence.

## Annex 5

3. In Annex 5 (exemptions from the obligation to register in accordance with Article 2(7)(b)), in paragraph 8, for “dangerous” substitute “hazardous”.

## Annex 7

4. In Annex 7 (standard information requirements for substances manufactured or imported in quantities of one tonne or more), in footnote (2), for the words from “the appropriate” to “specified in” substitute “regulations under”.

## Annex 8

5. In Annex 8 (standard information requirements for substances manufactured or imported in quantities of 10 tonnes or more), in footnote (2), for the words from “the appropriate” to “specified in” substitute “regulations under”.

## Annex 9

6.—(1) Annex 9 (standard information requirements for substances manufactured or imported in quantities of 100 tonnes or more) is amended as follows.

(2) In footnote (2), for the words from “the appropriate” to “specified in” substitute “regulations under”.

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(1) Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJNo. L 81, 31.3.2016, p. 51).

(3) In point 8.7.2, in the first column, for “as specified in” substitute “made under”.

(4) In point 8.7.3, in the first column, for “as specified in” substitute “made under”.

#### **Annex 10**

7.—(1) Annex 10 (standard information requirements for substances manufactured or imported in quantities of 1,000 tonnes or more) is amended as follows.

(2) In footnote (2), for the words from “the appropriate” to “specified in” substitute “regulations under”.

(3) In point 8.7.3, in the first column, for “as specified in” substitute “made under”.

#### **Annex 11**

8.—(1) Annex 11 (general rules for adaptation of the standard testing regime set out in Annexes 7 to 10) is amended as follows.

(2) In point 1.2, in the second paragraph, omit “the Commission or”.

(3) In point 1.3, in the second paragraph, omit “the Commission, Member States and”.

(4) In point 1.4, in the first paragraph—

(a) omit “(e.g. the European Centre for the Validation of Alternative Methods (ECVAM)) criteria”;

(b) for “process” substitute “process”.

(5) In point 1.5, in the first paragraph, omit “sufficiently in advance of the first registration deadline for phase-in substances”.

#### **Annex 12**

9. In Annex 12 (general provisions for downstream users to assess substances and prepare chemical safety reports), in the introduction, in the second paragraph, for “Community” substitute “other”.

#### **Annex 14**

10. In Annex 14 (list of substances subject to authorisation), in entry Nr 4, in the entry for the column headed “exempted (categories of) uses”, for “[Directive 2001/82/EC](#), and/or [Directive 2001/83/EC](#)” substitute “the Veterinary Medicines Regulations 2013 or the Human Medicines Regulations 2012”.

#### **Annex 15**

11.—(1) Annex 15 (dossiers) is amended as follows.

(2) In Part 1 (introduction and general provisions), in the first paragraph, in the second indent, omit “within the Community”.

(3) In Part 2 (content of dossiers), in section 3 (Dossiers for restrictions proposal)—

(a) in the heading “Justification for Restrictions at Community Level”, omit “at Community level”;

(b) in the paragraph that follows that heading—

(i) in the first indent omit “on a Community-wide basis”;

(ii) in the second indent omit “Community wide”.

## Annex 17

12. Annex 17 (restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles) is amended as follows.

13. Immediately before the Table insert—

“1. In this Annex “competent appropriate authority”, in relation to the exercise of a function under this Annex, means—

- (a) the Secretary of State if, or to the extent that, the exercise of the function—
  - (i) relates to England;
  - (ii) relates to Scotland and is not within devolved competence (within the meaning of section 54 of the Scotland Act 1998);
  - (iii) relates to Wales and is not within devolved competence (within the meaning of section 58A(7) and (8) of the Government of Wales Act 2006);
  - (iv) relates to Northern Ireland and is not within devolved competence in Northern Ireland;
- (b) the Scottish Ministers if, or to the extent that, the exercise of the function is within devolved competence (within the meaning of section 54 of the Scotland Act 1998);
- (c) the Welsh Ministers if, or to the extent that, the exercise of the function is within devolved competence (within the meaning of section 58A(7) and (8) of the Government of Wales Act 2006);
- (d) the Department of Agriculture, Environment and Rural Affairs and the Department for the Economy if, or to the extent that, the exercise of the function is within devolved competence in Northern Ireland.

2. For the purposes of paragraph 1(d), the exercise of a function (or its exercise in any way) is within devolved competence in Northern Ireland except so far as a provision of an Act of the Northern Ireland Assembly conferring the function (or, as the case may be, conferring it so as to be exercisable in that way) would be outside the legislative competence of the Assembly.

The reference in this paragraph to provision being outside the legislative competence of the Northern Ireland Assembly is to be read in accordance with section 6 of the Northern Ireland Act 1998.

Any provision that would be outside the legislative competence of the Northern Ireland Assembly unless the Secretary of State consented to it is to be regarded, for the purposes of this paragraph, as outside legislative competence.

When any function under this Annex is exercisable by the Department of Agriculture, Environment and Rural Affairs and the Department for the Economy as the competent appropriate authority, that function is to be exercised by both of those Departments acting jointly.”.

14.—(1) In entry 3 in the table (liquid substances or mixtures regarded as dangerous or fulfilling the criteria for certain hazard classes or categories), the second column is amended as follows.

(2) In paragraph 4, for the words from “European Standard” to “(CEN)” substitute “British Standard Specification on Decorative oil lamps (BS EN 14059) adopted by the British Standards Institute”.

(3) In paragraph 5, for “Community provisions” substitute “legislation”.

(4) Omit paragraph 6.

- (5) In paragraph 7, for the words from “competent” to “Commission” substitute “Agency”.
- 15.** In entry 5 in the table (benzene), in the second column, in paragraph (4), in point (a), for “[Directive 98/70/EC](#)” substitute “the Motor Fuel (Composition and Content) Regulations 1999(2)”.
- 16.—**(1) In entry 6 in the table (asbestos fibres), the second column is amended as follows.
- (2) In paragraph 1, omit the second, third and fourth subparagraphs.
- (3) In paragraph 2—
- (a) in the first subparagraph, for “Member States may” substitute “the competent appropriate authority may, after having consulted the other appropriate authorities”;
- (b) in the second subparagraph—
- (i) for “Member States may” substitute “The competent appropriate authority may, after having consulted the other appropriate authorities,”;
- (ii) omit the second and third sentences.
- (4) In paragraph 3, for “Community provisions” substitute “legislation”.
- 17.** In entries 16 (lead carbonates) and 17 (lead sulphates) in the table, in the second column—
- (a) for “Member States may” substitute “the competent appropriate authority may, after having consulted the other appropriate authorities”;
- (b) omit “on their territory”;
- (c) omit the final sentence.
- 18.** In entry 18a in the table (mercury), in the second column, in paragraph 2, for “Member States may” substitute “the competent appropriate authority may, after having consulted the other appropriate authorities,”.
- 19.—**(1) In entry 19 in the table (arsenic compounds), the second column is amended as follows.
- (2) In paragraph 4—
- (a) in point (a), for “Article 5(1) of [Directive 98/8/EC](#)” substitute “Articles 19 or 26 of Regulation (EU) No 528/2012”;
- (b) in point (c), for “Community provisions” substitute “legislation”.
- (3) In paragraph 7, for “Member States may” substitute “The competent appropriate authority may, after having consulted the other appropriate authorities,”.
- 20.** In entry 23 in the table (cadmium), in the second column—
- (a) in the first paragraph, after “2658/87” insert “, as it has effect in EU law immediately before exit day. For the purposes of this entry that Regulation has effect as if the references to Euratom were omitted”;
- (b) in paragraph 1—
- (i) omit the penultimate subparagraph (which begins “The first and second subparagraphs”);
- (ii) omit the final subparagraph (which begins “By 19 November 2012,”);
- (c) in paragraph 4, omit the final subparagraph (which begins “In accordance with Article 69”).

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(2) [S.I. 1999/3107](#), amended by [S.I. 2001/3896](#), [2003/3078](#), [2007/1608](#), [2010/3035](#), [2012/2567](#), [2013/2897](#), [2014/3076](#), [2015/1630](#), [1796](#).

**21.** In entry 24 in the table (monomethyl – tetrachlorodiphenyl methane), in the second column, in paragraph 2, in the second subparagraph, for “Member States may” substitute “the competent appropriate authority may, after having consulted the other appropriate authorities”.

**22.—**(1) In entries 28 to 30 of the table (certain substances that are carcinogens, cell mutagens or toxic to reproduction) the second column is amended as follows.

(2) In paragraph 1, in the second subparagraph, for “Community provisions” substitute “legislation”.

(3) In paragraph 2—

(a) for point (a) substitute—

“(a) medicinal or veterinary medicinal products as defined by the Veterinary Medicines Regulations 2013 and the Human Medicines Regulations 2012;”;

(b) in point (b), for “[Directive 76/768/EEC](#)” substitute “Regulation 1223/2009”;

(c) in point (c), in the first indent, for “[Directive 98/70/EC](#)” substitute “the Motor Fuel (Composition and Content) Regulations 1999”.

**23.** In entry 31 of the table (creosotes etc.), in the second column, in paragraph 2(a)—

(a) in the first subparagraph omit “Community”;

(b) in the third subparagraph, for “Community provisions” substitute “legislation”.

**24.** In entries 32 to 38 of the table (chloroform etc.), in the second column, in paragraph 2—

(a) for “Community provisions” substitute “legislation”;

(b) for point (a) substitute—

“(a) medicinal or veterinary medicinal products as defined by the Veterinary Medicines Regulations 2013 and the Human Medicines Regulations 2012;”;

(c) in point (b), for “[Directive 76/768/EEC](#)” substitute “Regulation 1223/2009”.

**25.** In entry 40 of the table (certain flammable substances etc.), in the second column, in paragraph 2, for “Community provisions” substitute “legislation”.

**26.** In entry 45 of the table (diphenylether, octabromo derivative), in the second column, in paragraph 3, for “[Directive 2002/95/EC](#)” substitute “the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012(3)”.

**27.** In entry 47 of the table (chromium VI compounds), in the second column, in paragraph 2, for “Community provisions” substitute “legislation”.

**28.—**(1) In entry 50 of the table (polycyclic-aromatic hydrocarbons), the second column is amended as follows.

(2) In paragraph 1, in the second subparagraph, for “EN” substitute “BS EN”.

(3) For paragraph 4 substitute—

“4. For the purpose of this entry ‘tyres’ shall mean tyres for vehicles covered by:

— the Road Vehicles (Approval) Regulations 2009(4);

— Regulation (EU) No 167/2013 of the European Parliament and of the Council on the approval and market surveillance of agricultural and forestry vehicles(5);

(3) [S.I. 2012/3032](#), amended by [S.I. 2014/1771](#), [2018/942](#).

(4) [S.I. 2009/717](#), amended by [S.I. 2011/1043](#), [1946](#), [2013/602](#), [2018/235](#), [236](#), [673](#), [984](#).

(5) OJ No. L 60, 2.3.2013, p. 1, as last amended by Regulation (EU) 2018/830 (OJ No. L 140, 6.6.2018, p. 15).

- Regulation (EU) No 168/2013 of the European Parliament and of the Council on the approval and market surveillance of two- or three-wheel vehicles and quadricycles<sup>(6)</sup>.

**29.** In entry 55 of the table (2-(2-butoxyethoxy)ethanol), in the second column, in paragraph 3, omit “Community”.

**30.**—(1) In entry 56 of the table (methylenediphenyl diisocyanate), the second column is amended as follows.

(2) In paragraph 1(a), for “Council [Directive 89/686/EEC](#)” substitute “Regulation (EU) 2016/425”.

(3) In paragraph 1(b)—

(a) omit “Community”;

(b) in the third indent, for “EN” substitute “BS EN”.

**31.** In entry 57 of the table (cyclohexane), in the second column, in paragraph 3, omit “Community”.

**32.**—(1) In entry 58 of the table (ammonium nitrate), the second column is amended as follows.

(2) In paragraph 2(a), for “Council [Directive 93/15/EEC](#)” substitute “the retained EU law that transposed [Directive 2014/28/EU](#)<sup>(7)</sup>”.

(3) In paragraph 2(b)—

(a) in the definition of “farmer”—

(i) omit “by national law”;

(ii) for the words from “Community” to “Treaty” substitute “the United Kingdom”;

(b) in the definition of “agricultural activity”, omit from “as established” to the end of the definition.

(4) Omit paragraph 3.

**33.**—(1) In entry 59 of the table (dichloromethane), the second column is amended as follows.

(2) In paragraph 2—

(a) in the first subparagraph—

(i) for “Member States may” substitute “the competent appropriate authority may, after having consulted the other appropriate authorities,”;

(ii) omit “on their territories and”.

(b) in the second subparagraph—

(i) for “Member States making use of this” substitute “A”;

(ii) omit “and shall inform the Commission thereof”;

(c) in the third subparagraph—

(i) omit “that is accepted by the Member State in which that professional operates”;

(ii) omit “or be otherwise approved by that Member State,”;

(d) omit the fourth subparagraph.

<sup>(6)</sup> OJ No. L 60, 2.3.2013, p. 52, as amended by Regulation (EU) 134/2014 (OJ No. L 53, 21.2.2014, p. 1).

<sup>(7)</sup> OJ No. L 96, 29.3.2014, p. 1. This Directive has been transposed in Great Britain by the Explosives Regulations 2014 (Amendment) Regulations 2016 ([S.I. 2016/315](#)) and in Northern Ireland by the Making Available on the Market and Supervision of Transfers of Explosives Regulations (Northern Ireland) 2016 ([S.R. 2016/366](#)).

- (3) In paragraph 3, in the first subparagraph—
- (a) omit the first sentence;
  - (b) in point (c), for “[Directive 89/686/EEC](#)” substitute “Regulation (EU) 2016/425”.
- (4) In paragraph 4—
- (a) omit “Community”;
  - (b) in point (d), for “[Directive 89/686/EEC](#)” substitute “Regulation (EU) 2016/425”.
- (5) In paragraph 5—
- (a) for “Community provisions” substitute “legislation”;
  - (b) in the text in quotation marks—
    - (i) after “industrial use and to” insert “approved”;
    - (ii) omit “approved in certain EU Member States”.
- 34.**—(1) In entry 63 of the table (lead), the second column is amended as follows.
- (2) In paragraph 4(a), for the words from “Annex I” to “69/493/EEC” substitute “the Crystal Glass (Descriptions) Regulations 1973<sup>(8)</sup>”.
- (3) In paragraph 4(c), after “2658/87” insert “as it has effect in EU law immediately before exit day”.
- (4) Omit paragraph 6.
- (5) In paragraph 8(b), for the words from “Annex I” to “69/493/EEC” substitute “the Crystal Glass (Descriptions) Regulations 1973”.
- (6) In paragraph 8(c), after “2658/87” insert “as it has effect in EU law immediately before exit day”.
- (7) In paragraph 8(k)—
- (a) in point (i), before “Directive” insert “the retained EU law that transposed”;
  - (b) for point (iii) substitute—
 

“(iii) the Toys (Safety) Regulations 2011<sup>(9)</sup>”;
  - (c) for point (iv) substitute—
 

“(iv) the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012.”.
- (8) In paragraph 9—
- (a) for “Commission” substitute “Agency”;
  - (b) for “modify this entry accordingly” substitute “make recommendations to the Secretary of State”.
- 35.** In entry 65 of the table (inorganic ammonium salts), in the second column—
- (a) omit paragraph 3;
  - (b) in paragraph 4, for “CEN/TS 16516” substitute “BS EN 16516: 2017”.
- 36.**—(1) In entry 67 (Bis(pentabromophenyl)ether), the second column is amended as follows.
- (2) In paragraph 3(b)(ii)—
- (a) for “[Directive 2007/46/EC](#)” substitute “the Road Vehicles (Approval) Regulations 2009”;

(8) [S.I. 1973/1952](#), amended by [S.I. 2011/1043](#) and [2015/1630](#).

(9) [S.I. 2011/1881](#), amended by [S.I. 2015/1630](#).



- (b) for “[Directive 2006/42/EC](#) of the European Parliament and of the Council” substitute “the Supply of Machinery (Safety) Regulations 2008(10)”.
- (3) In paragraph 4(d), for “[Directive 2011/65/EU](#)” substitute “the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012”.
- (4) In paragraph 5, for “Regulation (EU) No 216/2008 of the European Parliament and of the Council” substitute “Regulation (EU) 2018/1139 of the European Parliament and of the Council”.
- 37.** In entry 68 (Perfluorooctanoic acid), in the second column, in paragraphs 3(c) and 4(d)(i), for “[Directive 93/42/EEC](#)” substitute “the Medical Devices Regulations 2002”.

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(10) S.I. 2008/1597, amended by S.I. 2011/1043, 1157, 2014/469, 3248, 2015/1630, 1682, 2016/1105, 2018/235, 236.