

## SCHEDULE 1

Regulation 3

### Amendment of Titles 1 to 15

## PART 1

### Amendment of Title 1: General issues

#### Chapter 1 of Title 1

1. In Article 1(1), omit “on the internal market”.
- 2.—(1) Article 2 is amended as follows.
  - (2) In paragraph 1(a), for “Council Directive 96/29/Euratom” to the end of the point substitute “retained EU law that transposed Council Directive 2013/59/Euratom(1) laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation(2);”.
  - (3) In paragraph 2, for “Directive 2006/12/EC” substitute “Article 3(1) of Directive 2008/98/EC(3)”.
  - (4) After paragraph 2, insert—
    - “**2A.** For the purposes of this Regulation, Directive 2008/98/EC means that Directive as last amended by Council Regulation (EU) 2017/997, and read in accordance with paragraphs 2B and 2C.
    - 2B.** Article 5 is to be read as if paragraph 2 were omitted.
    - 2C.** Article 6 is to be read as if—
      - (a) paragraphs 1 to 3 were omitted;
      - (b) in paragraph 4—
        - (i) in the first sentence, for the words “Where criteria” to “paragraphs 1 and 2” there were substituted “Except where Council Regulation (EU) No 333/2011, Commission Regulation (EU) No 1179/2012 or Commission Regulation (EU) No 715/2013 applies”;
        - (ii) the second sentence were omitted.”.
  - (5) In paragraph 3, for “Member States” substitute “The Secretary of State”.
  - (6) Omit paragraph 4.
  - (7) In paragraph 5—
    - (a) for point (a) substitute—
      - “(a) in medicinal products for human or veterinary use within the scope of the Veterinary Medicines Regulations 2013(4), or the Human Medicines Regulations 2012(5);”;
    - (b) for point (b)(i) substitute—

(1) Different aspects of Council Directive 2013/59/Euratom have been transposed by various pieces of legislation, including the Ionising Radiations Regulations 2017 (S.I. 2017/1075) in Great Britain and the Ionising Radiations Regulations (Northern Ireland) 2017 (S.R. 2017/229) in Northern Ireland.

(2) OJ No. L 13, 17.1.2014, p. 1.

(3) OJ No. L 312, 22.11.2008, p. 3, as last corrected by Corrigendum (OJ No. L 042, 18.2.2017, p. 43).

(4) S.I. 2013/2033, amended by S.I. 2014/599, 2018/761.

(5) S.I. 2012/1916, amended by S.I. 2013/235, 1855, 2593, 2014/490, 1878, 2015/323, 570, 903, 1503, 1862, 1879, 2016/186, 190, 696, 2017/715, 1322, 2018/199, 378.

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- “(i) as a food additive in foodstuffs as defined by Article 3(2)(a) of Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives;”;
- (c) for point (b)(ii) substitute—
  - “(ii) as a flavouring in foodstuffs within the scope of Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods or Commission Implementing Regulation (EU) No 872/2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council;”;
- (d) for point (b)(iv) substitute—
  - “(iv) in animal nutrition within the scope of Article 2(1) of Regulation (EC) No 767/2009.”.
- (8) In paragraph 6—
  - (a) for point (a) substitute—
    - “(a) medicinal products for human or veterinary use within the scope of the Veterinary Medicines Regulations 2013, or the Human Medicines Regulations 2012;”;
  - (b) for point (b) substitute—
    - “(b) cosmetic products as defined in Regulation (EC) No 1223/2009 on cosmetic products;”;
  - (c) for point (c) substitute—
    - “(c) medical devices which are invasive or used in direct physical contact with the human body in so far as legislation relating to the classification and labelling of dangerous substances and mixtures applies to them which ensures the same level of information provision and protection as Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures;”;
  - (d) for point (d)(i) and (ii) substitute—
    - “(i) as a food additive in foodstuffs as defined by Article 3(2)(a) of Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives;
    - (ii) as a flavouring in foodstuffs within the scope of Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods or Commission Implementing Regulation (EU) No 872/2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council;”;
  - (e) for point (d)(iv) substitute—
    - “(iv) in animal nutrition within the scope of Article 2(1) of Regulation (EC) No 767/2009.”.
- (9) In paragraph 7(c)—
  - (a) for “from the Community” substitute “from the United Kingdom”;
  - (b) for “into the Community” substitute “into the United Kingdom”.
- (10) In paragraph 7(d), for “Community” substitute “United Kingdom”.

## Chapter 2 of Title 1

- 3. In Chapter 2 of Title 1, before Article 3 insert—

*“Article 2A*

*The Agency*

1. The functions and powers of the Agency under the REACH legislation are to be functions and powers of the HSE.

Accordingly, any reference to the Agency in the REACH legislation must be read as meaning the HSE.

2. The general incidental powers of the HSE are to be exercisable for the purpose of carrying out the functions of the Agency under the REACH legislation.

But that does not limit the powers which the HSE has under the REACH legislation.

3. The non-REACH functions of the HSE are not limited by the functions of the Agency under the REACH legislation.

Accordingly, the HSE is not prevented from carrying out non-REACH functions in relation to a matter just because any of the functions of the Agency under the REACH legislation is also exercisable, or has been exercised, in relation to that matter.

4. The power of the Secretary of State under section 12(2)(a) of HASWA 1974 to give directions (as read with section 12(4) of HASWA 1974) is to be exercisable with respect to the functions of the Agency under the REACH legislation.

The Secretary of State may not give any such directions with regard to the enforcement of the REACH legislation in any particular case.

The Secretary of State must consider any request made by any of the other appropriate authorities for the Secretary of State to give a direction by virtue of this paragraph.

The function of giving directions by virtue of this section is subject to the consent requirement in Article 4A (whether or not there has been a request under the previous subparagraph).

5. In this Article—

“general incidental powers” means the powers which the HSE has under—

- (a) section 13 of HASWA 1974, and
- (b) Schedule 2 to HASWA 1974;

“HASWA 1974” means the Health and Safety at Work etc. Act 1974<sup>(6)</sup>;

“HSE” means the Health and Safety Executive;

“non-REACH function” means any function which arises otherwise than under the REACH legislation;

“REACH legislation” means—

- (a) this Regulation,
- (b) any instrument made under this Regulation, and
- (c) any retained direct EU legislation that was originally made under EU REACH.

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<sup>(6)</sup> 1974 c. 37. Section 12 was substituted by S.I. 2008/960. Section 13 was substituted by S.I. 2008/960 and amended by section 116 of the Energy Act 2013 (c. 32).

*Status: This is the original version (as it was originally made).*

## Article 2B

### *Advice from Environment Agency or other environmental regulators to Agency*

1. The Agency must comply with paragraph 2 when exercising—
  - (a) its functions under—
    - (i) Article 7(5),
    - (ii) Article 9(4), (7) and (8),
    - (iii) Article 21,
    - (iv) Articles 40(1) and (3), 41(1), (3) and (5), 42(1), 43, 44, 45, 46(1) and (3), 48, 49, 51 and 52,
    - (v) Articles 58(3) and (4) and 59(1), (2), (3), (6) and (7),
    - (vi) Article 64(1), (3), (4), (5) and (6),
    - (vii) Articles 69, 70 and 71, and
  - (b) any of its other functions under this Regulation,

if, and to the extent that, the exercise of the function involves consideration of any relevant environmental issues.

2. The Agency must—
  - (a) obtain the advice of the Environment Agency before exercising the function concerned, and
  - (b) use the advice obtained when exercising the function concerned.

3. Whenever the advice of the Environment Agency is sought by the Agency under this Article, the Environment Agency must collaborate with the other environmental regulators when formulating the advice.

4. If, as part of a collaboration under paragraph 3, one of the other environmental regulators gives advice to the Environment Agency, the Environment Agency must pass that advice on to the Agency if that other environmental regulator requires it to do so.

5. In this Article—

“other environmental regulator” means—

- (a) in relation to Wales, the Natural Resources Body for Wales;
- (b) in relation to Scotland, the Scottish Environment Protection Agency;
- (c) in relation to Northern Ireland, the Department of Agriculture, Environment and Rural Affairs.

“relevant environmental issue” means—

- (a) exposure of the environment to chemicals;
- (b) exposure of humans to chemicals in the environment;
- (c) assessment of the potential effect of chemicals on the environment;
- (d) measures aimed at controlling the release of chemicals into the environment.”.

4.—(1) Article 3 is amended as follows.

(2) Before paragraph 1 insert—

“**A1.** EU REACH: means Regulation (EC) No 1907/2006 of the European Parliament and of the Council(7) as it has effect in EU law;

**A2.** appropriate authority: means—

- (a) the Secretary of State, in relation to England;
- (b) the Scottish Ministers, in relation to Scotland;
- (c) the Welsh Ministers, in relation to Wales;
- (d) the Department of Agriculture, Environment and Rural Affairs and the Department for the Economy, in relation to Northern Ireland (and those Departments’ exercise of their functions under this Regulation is subject to the following provision of this paragraph).

When—

- (a) the function of giving consent under Article 4A is exercisable by the Department of Agriculture, Environment and Rural Affairs and the Department for the Economy, or
- (b) a function under Article 129 is exercisable by the Department of Agriculture, Environment and Rural Affairs and the Department for the Economy as the appropriate authority,

that function is to be exercised by those Departments acting jointly.

When any other function under this Regulation is exercisable by the Department of Agriculture, Environment and Rural Affairs and the Department for the Economy as the appropriate authority, that function is to be exercised either—

- (a) by one of those Departments acting alone, or
- (b) by both of those Departments acting jointly.”.

(3) In paragraph 4, for “Community” substitute “United Kingdom”.

(4) In paragraph 9, for “Community”, in both places it occurs, substitute “United Kingdom”.

(5) In paragraph 10, for “customs territory of the Community” substitute “United Kingdom”.

(6) In paragraphs 11, 13 and 14, for “Community” substitute “United Kingdom”.

(7) For paragraph 18 substitute—

“**18.** Agency: see Article 2A;

**18A.** ECHA: means the European Chemicals Agency established under EU REACH;”.

(8) Omit paragraph 19.

(9) In paragraph 20, in points (b) and (c)—

- (a) for “Community” substitute “European Community”;
- (b) for “the entry into force of this Regulation” substitute “1 June 2007”.

(10) In paragraph 21, for “has been” substitute “was”.

(11) In paragraph 36, at the end insert—

“and, in its application for the purposes of this paragraph, the Annex to that Recommendation has effect with the following modifications—

(a) in Article 2(1)—

- (i) the reference to EUR 50 million has effect as a reference to £43.650 million;

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(7) OJ No. L 396, 30.12.2006, p. 1, as last amended by Regulation (EU) 2018/1513 (OJ No. L 256, 12.10.2018, p. 1).

- (ii) the reference to EUR 43 million has effect as a reference to £37.539 million;
- (b) in Article 2(2) the reference to EUR 10 million has effect as a reference to £8.730 million;
- (c) in Article 2(3) the reference to EUR 2 million has effect as a reference to £1.746 million;
- (d) in Article 3(2)—
  - (i) in point (a), the reference to EUR 1,250,000 has effect as a reference to £1,091,250;
  - (ii) in point (d), the reference to EUR 10 million has effect as a reference to £8.730 million.”.

5. After Article 4 insert—

*“Article 4A*

*The consent requirement*

1. Where any provision of this Regulation states that a function is subject to the consent requirement in this Article, the function may be exercised in a particular instance only if the person exercising it has obtained the consent or consents (if any) required by paragraphs 2 to 4.

2. The consent of the Scottish Ministers is required 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<sup>(8)</sup>), whether or not the exercise of the function also relates to a part of the United Kingdom other than Scotland.

3. The consent of the Welsh Ministers is required 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<sup>(9)</sup>) whether or not the exercise of the function also relates to a part of the United Kingdom other than Wales.

4. The consent of the Department of Agriculture, Environment and Rural Affairs and the Department for the Economy is required if, or to the extent that, the exercise of the function is within devolved competence, whether or not the exercise of the function also relates to a part of the United Kingdom other than Northern Ireland.

The exercise of the function is within devolved competence for the purposes of this paragraph unless it is outside competence by virtue of paragraphs 5 or 6.

5. It is outside devolved competence—

- (a) to make any provision by subordinate legislation which would be outside the legislative competence of the Northern Ireland Assembly if it were included in an Act of the Assembly, or
- (b) to confirm or approve subordinate legislation containing such provision.

6. In the case of any function other than a function of making, confirming or approving subordinate legislation, it is outside devolved competence to exercise the function (or exercise it in any way) 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.

<sup>(8)</sup> 1998 c. 46.

<sup>(9)</sup> 2006 c. 32. Section 58A was inserted by section 19(1) of the Wales Act 2017 (c. 4) and amended by paragraph 33 of Schedule 3 to the European Union (Withdrawal) Act 2018.

7. References in paragraphs 5 and 6 to provision being outside the legislative competence of the Northern Ireland Assembly are to be read in accordance with section 6 of the Northern Ireland Act 1998<sup>(10)</sup>.

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 paragraphs 5 and 6, as outside legislative competence.

8. Article 3(A2) includes provision about the exercise by the Department of Agriculture, Environment and Rural Affairs and the Department for the Economy of the function of giving consent under this Article.”.

## PART 2

### Amendment of Title 2: Registration of substances

#### Chapter 1 of Title 2

6. In Article 5—

- (a) for “, 21 and 23” substitute “and 21”;
- (b) for “Community” substitute “United Kingdom”.

7.—(1) Article 7 is amended as follows.

- (2) In paragraph 7, for “From 1 June 2011 paragraphs” substitute “Paragraphs”.
- (3) For paragraph 8 substitute—

“8. Any measures for the implementation of paragraphs 1 to 7 shall be adopted by regulations made by the Secretary of State. Regulations under this paragraph are to be made by statutory instrument; and a statutory instrument containing regulations under this paragraph is subject to annulment in pursuance of a resolution of either House of Parliament.

The function of making regulations under this paragraph is subject to the consent requirement in Article 4A.”.

8.—(1) Article 8 is amended as follows.

- (2) In the heading, for “non-Community” substitute “non-United Kingdom”.
- (3) In paragraph 1, for “Community”, in each place it occurs, substitute “United Kingdom”.
- (4) In paragraph 3, for “non-Community” substitute “non-United Kingdom”.

9.—(1) Article 9 is amended as follows.

- (2) In paragraph 1—
  - (a) for “a period of five years” substitute “a five-year exemption period”;
  - (b) for “Community” substitute “United Kingdom”.
- (3) After paragraph 1, insert—

“1A. In paragraph 1 “five-year exemption period” means a period of five years beginning when Articles 5, 6, 7, 17, 18 and 21 would otherwise apply to the substance (if it were not manufactured or imported as mentioned in paragraph 1).”.

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<sup>(10)</sup> 1998 c. 47. Section 6 was amended by section 12(5) of the European Union (Withdrawal) Act 2018 and S.I. 2011/1043.

*Status: This is the original version (as it was originally made).*

(4) In paragraph 3, in the final sentence, for “competent authority of the Member State(s) concerned” substitute “appropriate authorities that request it”.

(5) In paragraph 8—

(a) in the first subparagraph, for the words from “competent” to the end substitute “appropriate authorities that request them”;

(b) in the second subparagraph, for “such competent authorities” substitute “the appropriate authorities”.

(6) In paragraph 9, for “competent authorities of the Member States concerned” substitute “appropriate authorities”.

**10.** In Article 10(a), in the final subparagraph, for “, Article 27(6) or Article 30(3)” substitute “or Article 27(6)”.

**11.** In Article 11(1), for “Community” substitute “United Kingdom”.

**12.—**(1) Article 13 is amended as follows.

(2) In paragraph 2—

(a) in the second sentence—

(i) for “The Commission,” substitute “The Secretary of State,”;

(ii) for “Commission Regulation on test methods adopted in accordance with the procedure referred to in Article 133(4)” substitute “Test Methods Regulation”;

(b) for the third sentence substitute—

“Amendments to the Test Methods Regulation may be made by regulations made by the Secretary of State. Amendments to the Annexes of this Regulation may be made by regulations made by the Secretary of State. Regulations under this paragraph are to be made by statutory instrument; and a statutory instrument containing regulations under this paragraph is subject to annulment in pursuance of a resolution of either House of Parliament. The functions of making regulations under this paragraph are subject to the consent requirement in Article 4A.”.

(3) In paragraph 3, in the first subparagraph—

(a) in the first sentence—

(i) for “a Commission Regulation” substitute “the Test Methods Regulation”;

(ii) omit “the Commission or”;

(b) omit the second sentence.

(4) In paragraph 4—

(a) for “[Directive 2004/10/EC](#)” substitute “the Good Laboratory Practice Regulations 1999(**11**)”;

(b) omit “the Commission or”;

(c) for “[Directive 86/609/EC](#)” substitute “the Animals (Scientific Procedures) Act 1986(**12**)”.

(11) [S.I. 1999/3106](#). The definition of “principles of good laboratory practice” was substituted by, and Schedules 1 and 2 were amended by, [S.I. 2004/994](#).

(12) [1986 c. 14](#), amended by paragraph 66 of Schedule 10 to the Courts and Legal Services Act [1990 \(c. 41\)](#), the Schedule to the Protection of Badgers Act [1992 \(c. 51\)](#), paragraph 59 of Schedule 4 to the Criminal Procedure (Consequential Provisions) (Scotland) Act [1995 \(c. 40\)](#), Part 9 of Schedule 37 to the Criminal Justice Act [2003 \(c. 44\)](#), paragraph 5 of Schedule 11 to the Constitutional Reform Act [2005 \(c. 4\)](#), paragraph 12 of Schedule 3 and Schedule 4 to the Animal Welfare Act [2006 \(c. 45\)](#), paragraph 18 of Schedule 10 to the Tribunal, Courts and Enforcement Act [2007 \(c. 15\)](#), and paragraph 3 of Schedule 4 and Schedule 5 to the Welfare of Animals Act (Northern Ireland) [2011 \(c. 16\)](#); [S.I. 1993/2013](#), [1996/3278](#), [1998/1674](#), [1974, 2006/2407](#), [2012/3039](#), [2014/2124](#), [2015/1782](#), [2018/486](#); [S.S.I 2006/536](#); and [S.R. 1993/407](#), [1997/226](#), [1998/331](#).



(5) At the end insert—

“6. In this Article “Test Methods Regulation” means [Commission Regulation \(EU\) No 440/2008](#).”.

**13.**—(1) Article 14 is amended as follows.

(2) In paragraph 1, for “without prejudice to Article 4 of [Directive 98/24/EC](#), a” substitute “A”.

(3) In paragraph 5(b), for “[Directive 76/768/EEC](#)” substitute “[Regulation \(EC\) No 1223/2009](#) on cosmetic products”.

### **Chapter 2 of Title 2**

**14.**—(1) Article 16 is amended as follows.

(2) In the heading, omit “the Commission, the Agency and”.

(3) Omit paragraph 1.

(4) In paragraph 2, for “28” substitute “27”.

### **Chapter 3 of Title 2**

**15.** In Articles 17(2) and 18(2), in the second subparagraph, for “, Article 27(6) or Article 30(3)” substitute “or Article 27(6)”.

**16.** In Article 19(1), for “Community” substitute “United Kingdom”.

### **Chapter 4 of Title 2**

**17.**—(1) Article 20 is amended as follows.

(2) In paragraph 2—

(a) in the second subparagraph, omit the words from “, or within” to the end;

(b) in the third subparagraph, in the first sentence, omit “or three-month”.

(3) In paragraph 4—

(a) in the first subparagraph, for “competent authority of the relevant Member State” substitute “appropriate authorities that request the notification”;

(b) omit the second and third subparagraphs;

(c) in the fourth subparagraph, for “competent authority of the relevant Member State(s)” substitute “appropriate authorities that request the notification”.

**18.** In Article 21(1), omit the second subparagraph.

**19.**—(1) Article 22 is amended as follows.

(2) In the following provisions, for “competent authority of the relevant Member State” substitute “appropriate authorities that request it”—

(a) paragraph 1, the final subparagraph;

(b) paragraph 2, the final sentence.

### **Chapter 5 of Title 2**

**20.** Omit Article 23.

**21.** In Article 24, omit paragraph 1.

## PART 3

### Amendment of Title 3: Data sharing and avoidance of unnecessary testing

#### Chapter 1 of Title 3

22. In Article 25(3), after “this Regulation” insert “, or under EU REACH before exit day”.

#### Chapter 2 of Title 3

23. For the title of Chapter 2 substitute “Rules for registrants of substances”.

- 24.—(1) Article 26 is amended as follows.

(2) In paragraph 1, omit “of a non-phase-in substance, or potential registrant of a phase-in substance who has not pre-registered in accordance with Article 28,”.

- (3) In paragraph 3—

- (a) in the first subparagraph, for “the same substance has previously been registered less than 12 years earlier” substitute “there is a previous registration of the same substance that is less than 12 years old”;

- (b) after the first subparagraph, insert—

“A registration of a substance is less than 12 years old if—

- (a) in a case where the registration came into existence under Article 127A, the existing EU registration (as defined in Article 127D) began less than 12 years before the potential registrant’s enquiry to the Agency;
- (b) in any other case, the registration under this Regulation began less than 12 years before the potential registrant’s enquiry to the Agency.”.

- 25.—(1) Article 27 is amended as follows.

(2) In paragraph 1, for “a substance has previously been registered less than 12 years earlier” substitute “there is a previous registration of a substance that is less than 12 years old”.

- (3) For paragraph 2 substitute—

“2. Within one month of a request for information being made according to paragraph 1, the owner of the study shall provide proof of the cost of the information to the potential registrant(s) requesting it. The potential and the previous registrant(s) as referred to in paragraph 1 shall make every effort to reach an agreement on the sharing of the information requested by the potential registrant(s) with respect to Article 10(a)(vi) and (vii). Such an agreement may be replaced by submission of the matter to an arbitration board and acceptance of the arbitration order.”.

(4) In paragraph 4, after “the previous registrant shall” insert “, within two weeks of receipt of payment,”.

- (5) For paragraph 5 substitute—

“5. If the previous registrant as referred to in paragraph 1 refuses to provide either proof of the cost of that study or the study itself to a potential registrant, or there is failure to reach an agreement referred to in paragraph 4, the potential registrant(s) shall inform the Agency and the previous registrant(s) thereof at the earliest one month after receipt, from the Agency, of the name and address of the previous registrant(s).”.

### **Chapter 3 of Title 3**

26. Omit Articles 28 to 30.

## **PART 4**

### **Amendment of Title 4: Information in the supply chain**

27.—(1) Article 31 is amended as follows.

(2) In paragraph 3(c), for “for which there are Community” substitute “in relation to which the law of any part of the United Kingdom provides”.

(3) In paragraph 5, for the words from “an official language” to the end substitute “English and may also be supplied in any other language.”

(4) Omit paragraph 10.

28. In Article 32(2), omit “after 1 June 2007”.

29. In Article 36(1)—

(a) omit “to any competent authority of the Member State in which he is established or”;

(b) after “Agency” insert “or to any appropriate authority”.

## **PART 5**

### **Amendment of Title 5: Downstream Users**

#### **Title 5**

30. In Article 37(3), omit the second subparagraph.

## **PART 6**

### **Amendment of Title 6: Evaluation**

#### **Chapter 1 of Title 6**

31.—(1) Article 41 is amended as follows.

(2) In paragraph 2, for “Member States competent authorities” substitute “the appropriate authorities that request it”.

(3) In paragraph 5(c), omit “Community”.

(4) Omit paragraph 6.

(5) For paragraph 7 substitute—

“7. The Secretary of State may, by regulations, make provision to modify the effect of paragraph 5 by—

(a) modifying the percentage of dossiers to be selected;

(b) modifying the criteria which determine the dossiers to which priority is to be given.

Regulations under this paragraph may amend paragraph 5.

*Status: This is the original version (as it was originally made).*

The Secretary of State must consult the Agency before making regulations under this paragraph.

Regulations under this paragraph are to be made by statutory instrument; and a statutory instrument containing regulations under this paragraph is subject to annulment in pursuance of a resolution of either House of Parliament.

The function of making regulations under this paragraph is subject to the consent requirement in Article 4A.”.

**32.** In Article 42(2)—

- (a) in the first sentence, for “Commission and the competent authorities of the Member States” substitute “appropriate authorities that request the notification”;
- (b) omit the second sentence.

**33.**—(1) Article 43 is amended as follows.

(2) In paragraph 2—

- (a) omit points (a) and (b);
- (b) in point (c)—
  - (i) for “2022” substitute “2023”;
  - (ii) after “received” insert “by ECHA”.

(3) In paragraph 3, for “Member States” substitute “appropriate authorities that request it”.

## **Chapter 2 of Title 6**

**34.**—(1) Article 44 is amended as follows.

(2) In the first sentence of paragraph 1—

- (a) for “In order to ensure a harmonised approach, the” substitute “The”;
- (b) for “Member States” substitute “appropriate authorities”.

(3) In paragraph 2—

- (a) in the first subparagraph—
  - (i) in the first sentence omit “Community”;
  - (ii) for the last two sentences substitute—

“The Agency must submit its draft rolling action plan to the appropriate authorities by 31 May 2020 and give the appropriate authorities the opportunity to comment on it. The Agency must submit a draft annual update to its rolling action plan by 31 May each year after 2020 and give the appropriate authorities the opportunity to comment on it. The Agency must adopt a final rolling annual action plan for each year (after taking account of any comments made on the draft by the appropriate authorities) and must publish it on its website.”;

- (b) omit the last subparagraph.

**35.**—(1) Article 45 is amended as follows.

(2) For the heading substitute “Evaluation of substances on the rolling action plan”.

(3) In paragraph 1—

- (a) in the first sentence omit—
  - (i) “coordinating the substance evaluation process and”;

- (ii) “Community”;
  - (b) omit the last two sentences.
  - (4) Omit paragraphs 2 to 5.
- 36.**—(1) Article 46 is amended as follows.
- (2) In paragraph 1—
    - (a) in the first sentence for “competent authority” substitute “Agency”;
    - (b) in the second sentence, omit “Community”.
  - (3) In paragraph 3, for “competent authority” substitute “Agency”.
  - (4) In paragraph 4, in the first sentence—
    - (a) for “competent authority” substitute “Agency”;
    - (b) omit “, and notify the Agency accordingly”.
- 37.** Omit Article 47(2).
- 38.** For Article 48 substitute—

*“Article 48*

*Follow-up to substance evaluation*

Once the substance evaluation has been completed, the Agency must consider how to use the information obtained from this evaluation for the purposes of Article 59(3) and Article 69(4). The Agency must inform the appropriate authorities and the registrant of its conclusions as to whether or how to use the information obtained.”.

**Chapter 3 of Title 6**

- 39.** In Article 49—
- (a) in the first subparagraph for “competent authority of the Member State in whose territory the site is located” substitute “Agency”;
  - (b) for the second subparagraph substitute—

“Where the appropriate authority in relation to the part of the United Kingdom where the site is located considers that a risk to human health or the environment, equivalent to the level of concern arising from the use of substances meeting the criteria in Article 57, arises from the use of an on-site isolated intermediate and that risk is not properly controlled, that appropriate authority may request the Agency to take the steps set out in points (a) and (b) of the first paragraph.

The Agency must inform the appropriate authorities that request them of the results of an assessment under this Article.”.

**Chapter 4 of Title 6**

- 40.**—(1) Article 50 is amended as follows.
- (2) In paragraph 1, omit the last two sentences.
  - (3) In paragraphs 2 and 3, in the last sentence, for the words from “competent authority” to the end substitute “appropriate authorities that request it, when a registrant has informed the Agency in accordance with this paragraph”.
  - (4) In paragraph 4(a), for “competent authority” substitute “Agency”.

*Status: This is the original version (as it was originally made).*

**41.** For Article 51 substitute—

*“Article 51*

*Adoption of decisions under dossier evaluation*

1. This Article applies where the Agency has notified its draft decision in accordance with Article 40 or 41.
2. If the Agency receives no comments from the registrant or downstream user, the Agency must make its decision in the version notified under paragraph 1.
3. If the Agency receives any comments from the registrant or downstream user, the Agency must—
  - (a) take the comments into account, and
  - (b) make its decision (whether that is to make the decision in the version notified or vary the decision notified).
4. The Agency must notify the registrant or downstream user and the appropriate authorities of the decision made under paragraph 2 or 3.
5. An appeal may be brought, in accordance with Articles 91, 92 and 93 against a decision made under paragraph 2 or 3.”.

**42.** For Article 52 substitute—

*“Article 52*

*Adoption of decisions under substance evaluation*

1. This Article applies where the Agency has circulated its draft decision in accordance with Article 46.
2. If the Agency receives no comments from the registrant or the downstream user, the Agency must make its decision in the version circulated under paragraph 1.
3. If the Agency receives any comments from the registrant or the downstream user, the Agency must—
  - (a) take the comments into account, and
  - (b) make its decision (whether that is to make the decision in the version circulated or vary the decision circulated).
4. The Agency must notify the registrant or the downstream user, and the appropriate authorities, of the decision made under paragraph 2 or 3.
5. An appeal may be brought, in accordance with Articles 91, 92 and 93 against a decision made under paragraph 2 or 3.”.

## PART 7

### Amendment of Title 7: Authorisation

#### Chapter 1 of Title 7

- 43.** In Article 55, for “internal market” substitute “market in the United Kingdom”.

**44.**—(1) Article 56 is amended as follows.

(2) In paragraph 4—

- (a) in point (a), for “[Directive 91/414/EEC](#)” substitute “[Regulation \(EC\) No 1107/2009](#)”;
- (b) in point (b), for “[Directive 98/8/EC](#)” substitute “[Regulation \(EU\) No 528/2012](#)”;
- (c) in point (c), for “[Directive 98/70/EC](#)” to the end substitute “the Motor Fuel (Composition and Content) Regulations 1999**(13)**”.

(3) In paragraph 5(a), for “[Directive 76/768/EEC](#)” substitute “[Regulation \(EC\) No 1223/2009](#)”.

**45.**—(1) Article 58 is amended as follows.

(2) In paragraph 1, for the subparagraph before point (a) substitute—

“**1.** The Secretary of State may, by regulations, include in Annex 14 substances referred to in Article 57. The regulations must specify for each substance:”.

(3) In paragraph 2, omit “Community”.

(4) In paragraph 3—

- (a) in the first subparagraph, omit “, taking into account the opinion of the Member State Committee,”;
- (b) in the second subparagraph, in the second sentence, for “1 June 2009” substitute “1 June 2020”.

(5) In paragraph 4, for “Commission” substitute “appropriate authorities”.

(6) In paragraph 7, omit “Community”.

(7) For paragraph 8 substitute—

“**8.** The Secretary of State may, by regulations, remove from Annex 14 substances which as a result of new information no longer meet the criteria of Article 57.”.

(8) After paragraph 8, insert—

“**9.** Regulations under paragraph 1 or 8 are to be made by statutory instrument; and a statutory instrument containing regulations under paragraph 1 or 8 is subject to annulment in pursuance of a resolution of either House of Parliament.

The function of making regulations under paragraph 1 or 8 is subject to the consent requirement in Article 4A.”.

**46.**—(1) Article 59 is amended as follows.

(2) After paragraph 1, insert—

“**1A.** The Agency must include in its candidate list every substance that is included in ECHA’s candidate list under Article 59(1) of EU REACH immediately before exit day.”.

(3) In paragraph 2—

- (a) for “The Commission” substitute “An appropriate authority”;
- (b) in the last sentence for “Member States” substitute “appropriate authorities”.

(4) In paragraph 3—

- (a) for “Any Member State” substitute “The Agency”;
- (b) omit “and forward it to the Agency”;

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(13) 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.

*Status: This is the original version (as it was originally made).*

- (c) in the last sentence for “within 30 days of receipt to the other Member States” substitute “to the appropriate authorities”.
- (5) Omit paragraph 5.
- (6) In paragraph 6, omit “or make”.
- (7) In paragraph 7—
  - (a) omit “made or”;
  - (b) for the words from “shall” to the end substitute “must consider the comments and make a decision on the identification of the substance within 45 days of the deadline specified in paragraph 4”.
- (8) Omit paragraphs 8 and 9.

## **Chapter 2 of Title 7**

**47.**—(1) Article 60 is amended as follows.

- (2) In paragraph 1—
  - (a) for “Commission” substitute “Secretary of State”;
  - (b) at the end, insert—

“That responsibility of the Secretary of State is subject to the provisions of this Title which make the exercise of certain functions subject to the consent requirement in Article 4A.”.
- (3) In paragraph 2—
  - (a) for “Committee for Risk Assessment” substitute “Agency so far as the opinion relates to the elements”;
  - (b) for “Commission”, in each place it occurs, substitute “Secretary of State”;
  - (c) in the second subparagraph, for “Council [Directive 90/385/EEC](#)” to the end substitute “the Medical Devices Regulations 2002(14)”.
- (4) In paragraph 4, for “the opinions of the Committee for Risk Assessment and the Committee for Socio-economic Analysis” substitute “the elements”.
- (5) In paragraph 5, for “Commission” substitute “Secretary of State”.

**48.**—(1) Article 61 is amended as follows.

- (2) In paragraph 1—
  - (a) for “Commission” substitute “Secretary of State”;
  - (b) after the fifth subparagraph, insert—

“The function of deciding under this paragraph whether to amend or withdraw the authorisation is subject to the consent requirement in Article 4A.”.
- (3) In paragraph 2—
  - (a) in the second subparagraph, for “Commission” substitute “Secretary of State”;
  - (b) after the second subparagraph, insert—

“Any of the other appropriate authorities may request the Secretary of State to carry out a review of an authorisation under this paragraph.”.
- (4) In paragraph 3—

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(14) [S.I. 2002/618](#), amended by [S.I. 2003/1400](#), [1697](#), [2005/2759](#), [2909](#), [2007/400](#), [610](#), [803](#), [2008/530](#), [2936](#), [2009/383](#), [2010/557](#), [2012/1426](#), [2013/525](#), [2327](#), [2017/207](#).



- (a) for “Commission”, in each place it occurs, substitute “Secretary of State”;
- (b) after the second subparagraph, insert—

“Where the Secretary of State is carrying out a review of an authorisation under this paragraph, any of the other appropriate authorities may request the Secretary of State to suspend the authorisation while the review is being carried out.

The function of deciding under the first subparagraph whether to amend or withdraw the authorisation, and the function of deciding under the second subparagraph whether to suspend the authorisation, are subject to the consent requirement in Article 4A.”

- (5) In paragraph 4, omit “referred to in [Directive 96/61/EC](#)”.

- (6) In paragraph 5—

- (a) after “If the” insert “river basin”;
- (b) omit “as referred to in Article 4(1) of [Directive 2000/60/EC](#)”.

- (7) In paragraph 6, for “Commission” substitute “Secretary of State”.

- (8) After paragraph 6, insert—

“7. In this Article—

- (a) “environmental quality standard” means the set of requirements which must be fulfilled at a given time in relation to a given environment or particular part thereof, as set out in retained EU law;
- (b) “river basin district in Northern Ireland” means a river basin district as defined by the Water Environment (Water Framework Directive) Regulations (Northern Ireland) 2017(**15**);
- (c) “river basin district in Scotland” means an area designated as a river basin district by order under section 4(1) of the Water Environment and Water Services (Scotland) Act 2003(**16**);
- (d) “river basin environmental objectives” means—
  - (i) in relation to the Northumbria River Basin District, the environmental objectives referred to in the WFD Regulations as applied by regulation 5 of the Water Environment (Water Framework Directive) (Northumbria River Basin District) Regulations 2003(**17**);
  - (ii) in relation to the Solway Tweed River Basin District, the environmental objectives as defined in regulation 2 of the Water Environment (Water Framework Directive) (Solway Tweed River Basin District) Regulations 2004(**18**);
  - (iii) in relation to any other river basin district within the meaning of the WFD Regulations, the environmental objectives referred to in those Regulations;
  - (iv) in relation to a river basin district in Scotland, the environmental objectives set under section 9(1)(a)(**19**) of the Water Environment and Water Services (Scotland) Act 2003;
  - (v) in relation to a river basin district in Northern Ireland, the environmental objectives set under regulation 12, in accordance with regulation 13, of the

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(15) [S.I. 2017/81](#).

(16) [2003 asp 3](#).

(17) [S.I. 2003/3245](#), amended by [S.I. 2016/139](#), [2017/407](#); there are other amending instruments but none is relevant.

(18) [S.I. 2004/99](#), amended by [S.I. 2016/139](#); there are other amending instruments but none is relevant.

(19) Section 9(1)(a) was amended by section 54(4)(a) of the Aquaculture and Fisheries (Scotland) Act 2013 ([asp 7](#)). Section 9 was applied with modifications by [S.I. 2003/3245](#) and [2004/99](#).

*Status: This is the original version (as it was originally made).*

Water Environment (Water Framework Directive) Regulations (Northern Ireland) 2017; and

(e) “the WFD Regulations” means the Water Environment (Water Framework Directive) (England and Wales) Regulations 2017<sup>(20)</sup>.”

**49.**—(1) Article 62 is amended as follows.

(2) In paragraph 5—

(a) in point (b)(i), for “was granted in accordance with [Directive 96/61/EC](#)” substitute “to carry out an activity referred to in Annex I to [Directive 2010/75/EU](#) was granted in accordance with retained EU law”;

(b) for point (b)(ii) substitute—

“(b) (ii) discharges of a substance from a point source governed by retained EU law that transposed the requirement for prior regulation referred to in Article 11(3)(g) of [Directive 2000/60/EC](#)<sup>(21)</sup> and [Directive 2008/105/EC](#) of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy<sup>(22)</sup>.”

(3) In paragraph 6, for “Directives [90/385/EEC](#), [93/42/EEC](#) or [98/79EC](#)” substitute “the Medical Devices Regulations 2002”.

**50.**—(1) Article 64 is amended as follows.

(2) In paragraph 1, for the second sentence substitute “The Agency must give its draft opinion within ten months of the date of receipt of the application”.

(3) For paragraph 3 substitute—

“**3.** In preparing its opinion, the Agency must first check that the application includes all the information specified in Article 62 that is relevant to its remit. If necessary, the Agency must request additional information to bring the application into conformity with the requirements of Article 62. The Agency may, if it deems it necessary, require the applicant or request third parties to submit, within a specified time period, additional information on possible alternative substances or technologies. The Agency, and any scientific adviser providing the Agency with scientific knowledge and advice in relation to the opinion, must take into account any information submitted by third parties.”

(4) After paragraph 3 insert—

“**3A.** In paragraph 3 “scientific adviser” means a person who the Agency has commissioned (in compliance with the duty imposed by Article 77(A1)) to provide it with scientific knowledge and advice.”

(5) In paragraph 4—

(a) in the first sentence, for “opinions” substitute “opinion”;

(b) in point (a), omit “Committee for Risk Assessment.”;

(c) in point (b), omit “Committee for Socio-economic Analysis.”

(6) In paragraph 5—

(a) in the first subparagraph, for “these draft opinions” substitute “its draft opinion”;

<sup>(20)</sup> [S.I. 2017/407](#), to which there are amendments not relevant to these Regulations.

<sup>(21)</sup> Article 11(3)(g) has been transposed by various pieces of legislation, including the Environmental Permitting (England and Wales) Regulations 2016 ([S.I. 2016/1154](#)).

<sup>(22)</sup> OJ No. L 348, 24.12.2008, p. 84, as last amended by [Directive 2013/39/EU](#) (OJ No. L 226, 24.8.2013, p. 1).

- (b) in the second subparagraph, for “these opinions to the Commission, the Member States” substitute “its final opinion to the appropriate authorities”;
- (c) in the third subparagraph—
  - (i) for “Committees” substitute “Agency”;
  - (ii) for “their” substitute “its”;
  - (iii) for “opinions”, in both places it occurs, substitute “opinion”;
  - (iv) for “Commission, the Member States” substitute “appropriate authorities”.
- (7) In paragraph 6, for “opinions” substitute “opinion”.
- (8) For paragraph 8 substitute—

**“8.** The Secretary of State must make a decision granting or refusing the authorisation within six months of receipt of the opinion from the Agency.

The function in this paragraph of deciding whether to grant or refuse the authorisation is subject to the consent requirement in Article 4A.”.
- (9) In paragraph 9—
  - (i) for “Commission decisions” substitute “decisions of the Secretary of State”;
  - (ii) for “in the Official Journal of the European Union” substitute “by the Secretary of State”.

### **Chapter 3 of Title 7**

- 51.** In Article 65, in the first sentence, omit the words from “without prejudice” to the end of that sentence.
- 52.** In Article 66(2), in the second sentence, for “competent authorities of the Member States” substitute “appropriate authorities”.

## **PART 8**

### **Amendment of Title 8: Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles**

#### **Chapter 1 of Title 8**

- 53.**—(1) Article 67 is amended as follows.
- (2) In paragraph 2—
  - (a) for “**Directive 76/768/EEC**” substitute “Regulation 1223/2009”;
  - (b) for “Directive”, in the second place it occurs, substitute “Regulation”.
- (3) Omit paragraph 3.

#### **Chapter 2 of Title 8**

- 54.**—(1) Article 68 is amended as follows.
- (2) In paragraph 1—
  - (a) in the first sentence—
    - (i) omit “which needs to be addressed on a Community wide basis,”;

*Status: This is the original version (as it was originally made).*

- (ii) for “in accordance with the procedure referred to in Article 133(4) by adopting new restrictions or amending” substitute “by regulations made by the Secretary of State which provide for the adoption of new restrictions or the amendment of”;
- (b) in the second sentence, for “Any such decision” substitute “In exercising the power to make regulations under this paragraph, the Secretary of State”.
- (3) In paragraph 2, for the words from “and for which” to “Article 133(4).” substitute “the Secretary of State may propose restrictions. The function of proposing restrictions is subject to the consent requirement in Article 4A. The Secretary of State may, by regulations, amend Annex 17 to give effect to a proposed restriction.”.
- (4) After paragraph 2 insert—
  - “3. Regulations under paragraph 2 of this Article are to be made by statutory instrument; and a statutory instrument containing regulations made under paragraph 2 of this Article is subject to annulment in pursuance of a resolution of either House of Parliament.
  - The function of making regulations under paragraph 2 of this Article is subject to the consent requirement in Article 4A.”.

**55.**—(1) Article 69 is amended as follows.

- (2) In paragraph 1, for “the Commission” substitute “an appropriate authority”;
- (3) In paragraph 3—
  - (a) for “the Commission” substitute “an appropriate authority”;
  - (b) omit “on a Community wide basis”.
- (4) For paragraph 4 substitute—
  - “4. If the Agency considers that the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed, the Agency must prepare a dossier which conforms to the requirements and format of the relevant sections of Annex 15. If this dossier demonstrates that action is necessary, beyond any measures already in place, the Agency must initiate the restrictions process and must inform those who submitted a registration for that substance.
  - The Agency must refer to any dossier, chemical safety report or risk assessment submitted to it under this Regulation. The Agency must also refer to any relevant risk assessment submitted for other regulatory purposes. To this end other public bodies carrying out a similar task must provide information to the Agency on request.”.
- (5) For paragraph 5 substitute—
  - “5. The Agency must maintain a list of substances for which a dossier conforming to the requirements of Annex 15 is planned or underway for the purposes of a proposed restriction.”.
- (6) After paragraph 5, insert—
  - “5A. The Agency or an appropriate authority may propose the re-examination of an existing restriction listed in Annex 17.

If the Agency is proposing the re-examination, it must notify the appropriate authorities of the proposal. If an appropriate authority is proposing a re-examination, it must notify the Agency and the other appropriate authorities of the proposal. Where a re-examination is proposed (by the Agency or an appropriate authority), the Secretary of State must decide, on the basis of evidence presented by whoever proposed the re-examination, whether the re-examination should take place. That function of deciding whether the re-examination

should take place is subject to the consent requirement in Article 4A. If the Secretary of State decides that the re-examination should take place, the Agency must carry out the re-examination.”.

**56.**—(1) Article 70 is amended as follows.

(2) In the heading, for “Committee for Risk Assessment” substitute “risk assessment”.

(3) In the Article—

(a) for “Committee for Risk Assessment” substitute “Agency”;

(b) for the words from “Member State” to “Commission” substitute “dossier”.

**57.**—(1) Article 71 is amended as follows.

(2) In the heading for “Committee for Socio-economic Analysis” substitute “socio-economic analysis”.

(3) In paragraphs 1 and 2, for “Committee for Socio-economic Analysis” substitute “Agency”.

(4) Omit paragraph 3.

**58.**—(1) Article 72 is amended as follows.

(2) In the heading, for “Commission” substitute “appropriate authorities”.

(3) In paragraph 1—

(a) in the first sentence—

(i) for “Commission” substitute “appropriate authorities”;

(ii) for “the opinions of the Committee for Risk Assessment and Socio-economic Analysis” substitute “its opinions on risk assessment and socio-economic analysis”;

(b) in the last sentence—

(i) for “one or both of the Committees do” substitute “the Agency does”;

(ii) for “Commission” substitute “appropriate authorities”.

(4) In paragraph 2, for “the opinions of the two Committees” substitute “its opinions”.

(5) In paragraph 3, for “Commission and/or Member State on request” substitute “appropriate authorities that request them”.

**59.**—(1) Article 73 is amended as follows.

(2) For the heading substitute “Restriction decisions”.

(3) In paragraph 1—

(a) in the first subparagraph—

(i) for “Commission shall prepare” substitute “Secretary of State must propose”;

(ii) for the words from “the opinion of the Committee for Socio-economic Analysis” to “whichever is the earlier” substitute “the Agency’s opinions”;

(iii) at the end, insert “The functions of deciding whether to propose a draft amendment, and of proposing a draft amendment, are subject to the consent requirement in Article 4A.”;

(b) in the second subparagraph, for “Commission” substitute “Secretary of State”.

(4) For paragraph 2 substitute—

“2. The Secretary of State may, by regulations, amend Annex 17 to include the draft amendment.

*Status: This is the original version (as it was originally made).*

Regulations under this paragraph are to be made by statutory instrument; and a statutory instrument containing regulations made under this paragraph is subject to annulment in pursuance of a resolution of either House of Parliament.

The function of making regulations under this Article is subject to the consent requirement in Article 4A.”.

## PART 9

### Amendment of Title 9: Fees and charges

#### Title 9

**60.**—(1) Article 74 is amended as follows.

(2) In paragraph 1—

(a) for “The fees” substitute “The Secretary of State may, by regulations, specify the fees”;

(b) for “, Article 62(7) and Article 92(3)” to the end substitute “and Article 62(7)”.

(3) After paragraph 1 insert—

“Regulations under this paragraph are to be made by statutory instrument; and a statutory instrument containing regulations made under this paragraph is subject to annulment in pursuance of a resolution of either House of Parliament.

The function of making regulations under this Article is subject to the consent requirement in Article 4A.”

(4) In paragraph 3, omit the first subparagraph.

(5) Omit paragraph 4.

## PART 10

### Amendment of Title 10: Agency

#### Title 10

**61.** Omit Articles 75 and 76.

**62.**—(1) Article 77 is amended as follows.

(2) Before paragraph 1, insert—

**A1.** When forming opinions the Agency must take relevant scientific knowledge and advice into account (including any relevant knowledge and advice relating to socio-economic matters).

**A2.** The Agency may take any such knowledge or advice into account when forming an opinion only if—

(a) the knowledge or advice has been commissioned by the Agency, from one or more suitably qualified or experienced persons who are independent of the Agency, for the purposes of forming the opinion concerned, or

(b) the knowledge or advice—

(i) is already in existence (whether within the Agency or externally),

- (ii) is produced within the Agency for the purposes of forming the opinion concerned, or
- (iii) is, in accordance with Article 2B, produced by the Environment Agency or one of the other environmental regulators in connection with the Agency forming the opinion concerned and then passed on to the Agency, and the Agency considers that it is appropriate to take it into account, rather than to commission knowledge or advice in compliance with point (a).

The knowledge or advice that the Agency may take into account in compliance with point (b) (i) includes knowledge or advice which has previously been commissioned by the Agency from one or more suitably qualified or experienced persons who are independent of the Agency for the purposes of forming a previous opinion on any matter.

**A3.** The Agency must comply with this paragraph if —

- (a) it is forming—
  - (i) an opinion in connection with deciding whether to grant an authorisation under Article 60,
  - (ii) an opinion under Article 70 as to whether suggested restrictions are appropriate in reducing the risk to human health or the environment, or
  - (iii) an opinion under Article 71 on suggested restrictions and on the related socio-economic impact, and
- (b) it only takes into account knowledge or advice that is not commissioned in compliance with paragraph A2(a) for the purposes of forming that opinion.

The Agency must—

- (a) produce an explanation of why it considered that it was appropriate to take only that knowledge or advice into account,
- (b) publish the explanation, and
- (c) send a copy of the explanation to the appropriate authorities.

**A4.** When exercising its functions, the Agency must act in a way that ensures a high degree of transparency.

**A5.** The Agency must produce and publish a statement of how it will comply with paragraphs A1, A2 and A4.

The Agency must produce and publish the first statement within the period of 3 months beginning with the day after exit day.

The Agency must consult such persons as it considers appropriate before producing the first, or any subsequent, statement.

**A6.** The statement must include—

- (a) information about the qualifications or relevant experience that are suitable in order for persons to be commissioned to provide knowledge or advice to the Agency,
- (b) examples of situations in which the Agency envisages that it might be appropriate to take existing knowledge or advice (rather than knowledge or advice commissioned as mentioned in paragraph A2(a)) into account.

**A7.** Paragraphs A1 to A6 do not limit the Agency’s duties under Article 2B.”.

(3) In paragraph 1, for “Member States and the institutions of the Community” substitute “appropriate authorities”.

*Status: This is the original version (as it was originally made).*

- (4) In paragraph 2—
  - (a) in the words before point (a), for “The Secretariat” substitute “The Agency”;
  - (b) omit points (a) to (d);
  - (c) in point (e)—
    - (i) in the first sentence omit the words from “, the classification” to the end;
    - (ii) omit the final sentence.
  - (d) omit point (h);
  - (e) in point (i), omit “including Member State competent authorities”;
  - (f) in point (l)—
    - (i) omit “Commission’s”;
    - (ii) after “request” insert “of any appropriate authority”;
    - (iii) for “between the Community, its Member States,” substitute “with”;
  - (g) in point (m), omit “based on conclusions from the Member State Committee”.
- (5) Omit paragraphs 3 and 4.
- 63.** Omit Articles 78 to 82.
- 64.**—(1) Article 83 is amended as follows.
  - (2) For the heading substitute “Annual report by the Agency to the appropriate authorities”.
  - (3) Omit paragraphs 1 and 2.
  - (4) In paragraph 3—
    - (a) in the words before point (a)—
      - (i) for “Executive Director” substitute “Agency”;
      - (ii) for “Management Board” substitute “Secretary of State”;
    - (b) in point (a)—
      - (i) for “received by the Agency and opined upon” substitute “prepared by the Agency”;
      - (ii) after “restricted;” insert “the Agency’s compliance with Article 77(A1) by taking into account scientific knowledge and advice (including knowledge and advice relating to socio-economic matters);”;
      - (iii) omit “; an overview of the activities of the Forum”.
    - (c) for the last two subparagraphs substitute—

“The Agency must provide any draft submitted to the Secretary of State under points (a) to (e) to the other appropriate authorities at the same time it is submitted to the Secretary of State.

The Secretary of State must consult the other appropriate authorities before giving approval to any draft submitted under points (a) to (e).”.
- 65.** Omit Articles 84 to 87.
- 66.**—(1) Article 88 is amended as follows.
  - (2) For paragraph 1 substitute—

“**1.** The details of the suitably qualified or experienced persons that provide advice to the Agency under Article 77(A2)(a) must be made public. Individuals may request that their names not be made public if they believe that such publication could place them at risk.



The Agency must decide whether to agree to such requests. When details are published, the professional qualifications of each suitably qualified or experienced person must be specified.”

(3) In paragraph 2, in the first sentence, for the words from “Members of the Management Board” to “the Forum” substitute “Suitably qualified or experienced persons that provide advice to the Agency pursuant to Article 77(A2)(a)”.

(4) Omit paragraph 3.

**67.** Omit Articles 89 and 90.

**68.**—(1) Article 91 is amended as follows.

(2) In paragraph 1, for “Article 30(2) and (3) and Article 51” substitute “Article 51 and Article 52”.

(3) After paragraph 1 insert—

“**1A.** An appeal pursuant to paragraph 1 lies to the First-tier Tribunal.”

(4) After paragraph 2 insert—

“**3.** On an appeal pursuant to paragraph 1, the First-tier Tribunal—

(a) may dismiss the appeal, or

(b) if it allows the appeal may—

(i) quash the decision and (if appropriate) remit the matter to the Agency, or

(ii) substitute for the decision any other decision which could have been made by the Agency.”

**69.**—(1) Article 92 is amended as follows.

(2) In the heading, omit “, time-limits, fees and form”.

(3) Omit paragraphs 2 and 3.

**70.**—(1) Article 93 is amended as follows.

(2) For the heading substitute “Change of decision where appeal made”.

(3) For paragraph 1 substitute—

“**1.** If—

(a) an appeal against a decision is brought pursuant to Article 91, and

(b) the Agency considers the appeal to be admissible and well founded,

the Agency may rectify the decision within the period of 30 days beginning with the day when the appeal is brought.”

(4) Omit paragraphs 2 to 4.

**71.** Omit Article 94.

**72.**—(1) Article 95 is amended as follows.

(2) In paragraph 1, for “bodies established under Community Law, including Community Agencies,” substitute “public bodies”;

(3) In paragraph 3—

(a) omit “and the body concerned is a Community Agency or a scientific committee”;

(b) for “Commission” substitute “appropriate authorities”.

*Status: This is the original version (as it was originally made).*

73. Omit Articles 96 to 107.

74. In Article 108, for the words from “Management Board” to “and” substitute “Agency must develop appropriate contacts with”.

75. In Article 109, for the words from “Management Board” to “Commission,” substitute “Agency must”.

76.—(1) Article 110 is amended as follows.

(2) In the heading and in paragraph 1, for “Community” substitute “public”;

(3) In paragraph 2—

(a) in the first subparagraph—

(i) for the words from “Executive” to “Authority,” substitute “Agency, having consulted the Food Standards Agency(23) and Food Standards Scotland(24),”;

(ii) omit the last sentence;

(b) in the second subparagraph, for “European Food Safety Authority” substitute “Food Standards Agency and Food Standards Scotland”.

(4) In paragraph 3, for “European Medicines Agency” substitute “Medicines and Healthcare products Regulatory Agency(25)”.

(5) Omit paragraph 4.

77. In Article 111, for “Member States, manufactures” substitute “Manufacturers”.

## PART 11

### Amendment of Title 12: Information

#### Title 12

78.—(1) Article 117 is amended as follows.

(2) Omit paragraph 1.

(3) In paragraph 2—

(a) in the first subparagraph—

(i) in the first sentence, for “Commission” substitute “appropriate authorities”;

(ii) in the second sentence, after “its report” insert “sections on evaluation and enforcement,”;

(b) in the second subparagraph, for “1 June 2011” substitute “1 April 2022”.

(4) In paragraph 3—

(a) in the first subparagraph, for “Commission” substitute “appropriate authorities”;

(b) in the second subparagraph, for “1 June 2011” substitute “1 April 2022”.

(5) In paragraph 4—

(a) in the first subparagraph—

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(23) The Food Standards Agency was established by section 1 of the Food Standards Act 1999 (c. 28).

(24) Food Standards Scotland was established by section 1 of the Food (Scotland) Act 2015 (asp 1).

(25) The Medicines and Healthcare products Regulatory Agency was created on 1 April 2003 through the merger of the Medicines Control Agency and the Medical Devices Agency.

- (i) for “Commission shall” substitute “Secretary of State, in cooperation with the other appropriate authorities, must”;
- (ii) in point (b), for “Commission” substitute “appropriate authorities”;
- (b) in the second subparagraph, for “1 June 2012” substitute “1 April 2023”.

**79.**—(1) Article 118 is amended as follows.

- (2) Omit paragraph 1.
- (3) In paragraph 3—
  - (a) for “Management Board” substitute “Agency”;
  - (b) omit “implementing Regulation (EC) No 1049/2001, including”;
  - (c) omit “, by 1 June 2008”.
- (4) Omit paragraph 4.

**80.**—(1) Article 120 is amended as follows.

- (2) In the heading, for “third” substitute “other”.
- (3) In the words before point (a)—
  - (a) for the words from “a third” to “Treaty,” substitute “another country or an international organisation in accordance with an agreement concluded between the United Kingdom and the other country or international organisation,”;
  - (b) in point (b), for “third party” substitute “other country or international organisation concerned”.

## PART 12

### Amendment of Title 13: Competent authorities

#### **Title 13**

- 81.** For the heading of Title 13 substitute “provision of information”.
- 82.** Omit Articles 121 and 122.
- 83.** In Article 123—
  - (a) for “competent authorities of the Member States” substitute “Agency”;
  - (b) for “competent authorities” substitute “the appropriate authorities”;
  - (c) omit “, with a view to coordinating Member States in these activities”.
- 84.** In Article 124—
  - (a) omit the first paragraph;
  - (b) in the second paragraph, for “Member States shall establish national helpdesks” substitute “The Agency must establish a national helpdesk”.

## PART 13

### Amendment of Title 14: Enforcement

#### **Title 14**

- 85.** Omit Articles 125 and 126.
- 86.** In Article 127—
- (a) in the first sentence—
    - (i) for “117(1)” substitute “117(2)”;
    - (ii) omit “pursuant to Articles 125 and 126”;
  - (b) omit the last two sentences.

## PART 14

### Amendment of Title 15: Transitional and final provisions

- 87.** In the heading of Title 15 omit “transitional and”.
- 88.** Omit Article 128.
- 89.—**(1) For Article 129 substitute—

#### *“Article 129*

#### *Safeguard clause*

- 1.** An appropriate authority may impose an appropriate provisional restriction in respect of a substance if that authority—
  - (a) has justifiable grounds for believing that urgent action is essential to protect human health or the environment in respect of the substance, on its own, in a mixture or in an article, even if satisfying the requirements of this Regulation, and
  - (b) has competence to impose the provisional restriction.
- 2.** If an appropriate authority imposes a provisional restriction in accordance with paragraph 1, it must—
  - (a) immediately inform the Agency and the other appropriate authorities, giving reasons for its decision and submitting the scientific or technical information on which the provisional restriction is based, and
  - (b) within three months of its decision, request the Agency to initiate the procedure under Article 69.
- 3.** When a decision has been reached under Article 73 (as part of the procedure under Article 69) the appropriate authority must revoke the provisional measure.
- 4.** In this Article “restriction” means a restriction on the placing on the market or use of a substance.
- 5.** The Secretary of State has competence to impose a provisional restriction if, or to the extent that, the exercise of that function to impose that restriction—
  - (a) relates to England;

- (b) relates to Scotland and is not within devolved competence (within the meaning of section 54 of the Scotland Act 1998);
- (c) 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);
- (d) relates to Northern Ireland and is not within devolved competence in Northern Ireland.

6. The Scottish Ministers have competence to impose a provisional restriction if, or to the extent that, the exercise of that function to impose that restriction is within devolved competence (within the meaning of section 54 of the Scotland Act 1998).

7. The Welsh Ministers have competence to impose a provisional restriction if, or to the extent that, the exercise of that function to impose that restriction is within devolved competence (within the meaning of section 58A(7) and (8) of the Government of Wales Act 2006).

8. The Department of Agriculture, Environment and Rural Affairs and the Department for the Economy in Northern Ireland have competence to impose a provisional restriction if, or to the extent that, the exercise of that function to impose that restriction is within devolved competence in Northern Ireland.

9. For the purposes of paragraph 8, the exercise of the function of imposing a provisional restriction is within devolved competence in Northern Ireland except so far as a provision of an Act of the Northern Ireland Assembly conferring the function of imposing that provisional restriction 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.

Article 3(A2) includes provision about the exercise by the Department of Agriculture, Environment and Rural Affairs and the Department for the Economy of the function of giving consent under this Article.”.

90. In Article 130—

- (a) for “competent authorities,” substitute “appropriate authorities and”;
- (b) omit “and the Commission”.

91. For Article 131 substitute—

### *“Article 131*

#### *Amendments to the Annexes*

1. The Secretary of State may, by regulations, make such amendments of the Annexes as the Secretary of State considers appropriate.

The Secretary of State must consider any request made by any of the other appropriate authorities for amendments of the Annexes to be made.

2. Regulations under this Article are to be made by statutory instrument; and a statutory instrument containing regulations under this Article is subject to annulment in pursuance of a resolution of either House of Parliament.

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The function of making regulations under this Article is subject to the consent requirement in Article 4A.”.

**92.** For Article 132 substitute—

*“Article 132*

*Implementing legislation*

**1.** The Secretary of State may, by regulations, make such provision as the Secretary of State considers appropriate for putting the provisions of this Regulation efficiently into effect.

The Secretary of State must consider any request made by any of the other appropriate authorities for such provision to be made.

**2.** Regulations under this Article are to be made by statutory instrument; and a statutory instrument containing regulations under this Article is subject to annulment in pursuance of a resolution of either House of Parliament.

The function of making regulations under this Article is subject to the consent requirement in Article 4A.”.

**93.** After Article 132, insert—

*“Article 132A*

*Regulations under this Regulation*

Any power to make regulations under this Regulation includes power to make supplementary, incidental, consequential, transitional, transitory or saving provision.”.

**94.** Omit Articles 133 to 137.

**95.**—(1) Article 138 is amended as follows.

(2) For “Commission”, in each place it occurs, substitute “Secretary of State”.

(3) In paragraph 1—

(a) in the first sentence, for “June 2019” substitute “December 2020”;

(b) omit the second sentence;

(c) after point (c) insert—

“(d) the views of any appropriate authority.”;

(d) in the final sentence, for “present legislative” substitute “formulate”.

(4) In paragraphs 2 and 3, for “present legislative” substitute “formulate”.

(5) Omit paragraphs 4 to 7.

(6) In paragraph 8—

(a) in the first sentence, for “June 2019” substitute “December 2020”;

(b) in the last sentence, for “present legislative” substitute “formulate”.

(7) In paragraph 9—

(a) for “June 2019” substitute “December 2020”;

(b) for the final sentence substitute—

“The Secretary of State may, by regulations, amend Annex 8 if the Secretary of State considers that it is appropriate to do so on the basis of this review, while ensuring a high level of protection of health and the environment.

Regulations under this paragraph are to be made by statutory instrument; and a statutory instrument containing regulations under this paragraph is subject to annulment in pursuance of a resolution of either House of Parliament.

The function of making regulations under this Article is subject to the consent requirement in Article 4A.”

96. Omit Articles 140 and 141.

## SCHEDULE 2

Regulation 4

### Transitional provision

1. After Article 127 of the REACH Regulation insert—

## “TITLE 14A

### EU withdrawal: transitional provision

#### *Article 127A*

##### *Existing EU registrations which have effect as UK registrations*

1. An existing EU registration under Articles 6, 7(1), 7(5) or 24(1) of EU REACH has effect on and after exit day as a UK registration (the “transferred UK registration”) if the registration—
  - (a) has a current connection with the United Kingdom, or
  - (b) has a relevant past connection with the United Kingdom (but does not have a current connection with the United Kingdom).
2. A registration has a current connection with the United Kingdom if—
  - (a) the registrant immediately before exit day is a person established in the United Kingdom (a “current UK registrant”), and
  - (b) a registration of the substance concerned by the current UK registrant is a registration of a kind that could be submitted on exit day under Article 6 or 7(1) or (5) of this Regulation.
3. A registration has a relevant past connection with the United Kingdom if—
  - (a) the registrant at any time during the 2 year period before exit day was a person established in the United Kingdom (a “former UK registrant”), and
  - (b) a registration of the substance concerned by the former UK registrant is a registration of a kind that could be submitted on exit day under Article 6 or 7(1) or (5) of this Regulation.
4. Where an existing EU registration has effect by virtue of this Article as a transferred UK registration, it has effect—

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- (a) if it is an existing EU registration under Article 6 of EU REACH, as a transferred UK registration under Article 6 of this Regulation;
- (b) if it is an existing EU registration under Article 7(1) of EU REACH, as a transferred UK registration under Article 7(1) of this Regulation;
- (c) if it is an existing EU registration under Article 7(5) of EU REACH, as a transferred UK registration under Article 7(5) of this Regulation;
- (d) if it is an existing EU registration that existed by virtue of Article 24(1) of EU REACH, as a transferred UK registration that exists by virtue of Article 6 of this Regulation.

5. Where a registration that has a current connection with the United Kingdom has effect as a transferred UK registration by virtue of this Article, the current UK registrant becomes the registrant in relation to the transferred UK registration on exit day.

6. Where a registration that has a relevant past connection with the United Kingdom has effect as a transferred UK registration by virtue of this Article, the former UK registrant becomes the registrant in relation to the transferred UK registration on exit day.

If two or more persons have been former UK registrants at different times during the 2 year period before exit, only the person who was the former UK registrant most recently before exit day is to become registrant in relation to the transferred UK registration by virtue of this paragraph.

#### *Article 127B*

##### *Application of this Regulation to transferred UK registrations*

1. The other Titles of this Regulation apply to a transferred UK registration as they would apply to the registration—

- (a) if it had been submitted on exit day to the Agency under Article 6 or 7(1) or (5) (as the case may be);
- (b) in a case where the existing EU registration came into existence by virtue of Article 24(1) of EU REACH, if it had been submitted on exit day to the Agency under Article 6.

Accordingly, no registration under that Article needs to be submitted.

2. But, in their application to the transferred UK registration, the other Titles of this Regulation have effect with the modifications set out in the following provisions of this Article.

3. In the case of—

- (a) a transferred UK registration under Article 6, no fee is payable under Article 6(4);
- (b) a transferred UK registration under Article 7, no fee is payable under Article 7(1) or (5).

4. The registrant must submit—

- (a) the Article 10 information referred to in Article 10(a)(i), (ii), and (iii), and any relevant indication under Article 10(a)(viii), to the Agency within the 120 day post-exit period;
- (b) the other Article 10 information to the Agency within the 2 year post-exit period.



Where the existing EU registration existed by virtue of Article 24(1) of EU REACH, the duty under this paragraph does not apply in relation to a transferred UK registration unless Article 24(2) applied in relation to the notified substance concerned before exit day.

5. The technical dossier that is submitted in accordance with point (a) in Article 10 does not need to include the proposals for testing mentioned in paragraph (ix) if, before exit day, ECHA has made a decision under Article 40(3) of EU REACH in relation to the testing proposals included in the technical dossier that was included in the existing EU registration.

For further provision about certain cases where there is an existing EU decision on a testing proposal, see Article 127I.

6. The registrant must submit the registration number and registration date assigned to the existing EU registration by ECHA in accordance with Article 20(3) of EU REACH, and such other evidence as the Agency may require of the existing EU registration, to the Agency within the 120 day post-exit period.

7. Article 20 has effect with the following provision substituted for paragraphs 1 to 3—

“1. The Agency must assign a submission date to each transferred UK registration, which must be the date on which the registrant complies with paragraph 4(a) or (b) of Article 127B.

2. The Agency may undertake a completeness check of each registration in order to ascertain that all the elements required under Articles 10 and 12 have been provided. The completeness check must not include an assessment of the quality or the adequacy of any data or justifications submitted.

If a registration is incomplete, the Agency must inform the registrant as to what further information is required in order for the registration to be complete, while setting a reasonable deadline for this. The registrant must complete his registration and submit it to the Agency within the deadline set. The Agency must confirm the submission date of the further information to the registrant. The Agency must perform a further completeness check, considering the further information submitted.

3. Once the registrant has complied with paragraph 4(a) of Article 127B, the Agency must assign a registration number to the substance concerned and a registration date, which must be the same as the registration date for the existing EU registration.”

8. Article 21 has effect with the following provision substituted for the first subparagraph of paragraph 1—

“1. A registrant of a transferred UK registration may continue the manufacture or import of a substance or production or import of an article from exit day, subject to any indication to the contrary from the Agency in accordance with Article 20(2).”

9. The Agency is not required by Article 41(5) to carry out compliance checking of dossiers relating to transferred UK registrations in the tonnage bands of over 100 to 1,000 tonnes or over 1,000 tonnes.

10. The reference in Article 43(1) to the preparation of a draft decision within 180 days of receiving a registration has effect as a reference to the preparation of a draft decision within 180 days of receipt of the information required by Article 10(a)(ix) under paragraph 4.

*Status: This is the original version (as it was originally made).*

### *Article 127C*

#### *Decisions of ECHA relating to existing EU registrations*

1. This Article applies in relation to an existing EU registration which has effect as a transferred UK registration under Article 127A.
2. Any existing ECHA decision which relates to the registration has effect on and after exit day as a decision of the Agency which relates to the transferred UK registration.
3. The registrant must—
  - (a) notify the Agency, within the 120 day post-exit period, of any existing ECHA decision which relates to the registration, and
  - (b) if required to do so by the Agency, supply the Agency, within the period specified by the Agency, with copies of any existing ECHA decision which relates to the registration.
4. The Agency may extend any period of time specified in an existing ECHA decision.
5. The other Titles of this Regulation apply to the decision as they would apply to it if it had been made by the Agency on exit day.
6. In this Article “existing ECHA decision” means a decision which has been made by ECHA under any provision of EU REACH and which is valid immediately before exit day.

### *Article 127D*

#### *Interpretation of Articles 127A to 127C*

1. In Articles 127A to 127C—
  - “Article 10 information” means the information which a registration is required to include by virtue of Article 10;
  - “existing EU registration” means a registration of a substance with ECHA which is subsisting immediately before exit day;
  - “transferred UK registration” has the meaning given in Article 127A(1);
  - “UK registration” means a registration of a substance with the Agency.

### *Article 127E*

#### *Pre-exit downstream users that are to continue to be regarded as downstream users*

1. This Article applies to a person that is—
  - (a) an existing UK downstream user under EU REACH, or
  - (b) an existing UK distributor under EU REACH,
 in relation to a substance (the “UK user or distributor”).
2. In any case where the transitional protection conditions are met, the UK user or distributor is to be treated for the purposes of this Regulation—
  - (a) as a downstream user as respects the substance concerned (if they are an existing UK downstream user under EU REACH), or
  - (b) as a distributor as respects the substance concerned (if they are an existing UK distributor under EU REACH).
3. The transitional protection conditions are met in any case where—

- (a) the substance is imported to the United Kingdom from an EEA state,
  - (b) the existing UK user or distributor is the importer in relation to the import,
  - (c) the import occurs during the 2 year post-exit period, and
  - (d) the person who supplies the substance to the UK user or distributor for the import (the “relevant supplier”) is either a registrant or a downstream user under EU REACH as respects the substance concerned.
4. If the relevant supplier meets the requirement in paragraph 3(d), it does not matter whether they are—
- (a) the person from which the UK user or distributor obtained supplies of the substance before exit day (and therefore the person in relation to which the UK user was a downstream user or distributor under EU REACH), or
  - (b) a different person.
5. Where paragraph 3 applies in the case of an import of the substance concerned, the provisions of this Regulation that apply to importers do not apply to the UK user or distributor in relation to that import.
6. If the UK user or distributor imports the substance into the United Kingdom in quantities of 1 to 10 tonnes per year, they must within the 180 day post-exit period—
- (a) supply the Agency with the information referred to in point (a)(i) of Article 10;
  - (b) supply the Agency with the information referred to in points (ii) and (iv) of Article 10 to the extent that information is available to the UK user or distributor;
  - (c) supply the Agency with the information referred to in points (a) to (d) of Article 32(1) and otherwise comply with Article 32;
  - (d) supply the Agency with the relevant registration number for the substance under EU REACH to the extent that information is available to the UK user or distributor, and such other evidence as the Agency may require demonstrating that the information supplied in accordance with paragraph (c) above complies with the requirements of Articles 10, 12 and 14 (as they apply to the tonnage of the substance which the UK user or distributor imports into the United Kingdom).
7. If the UK user or distributor imports the substance into the United Kingdom in quantities of 10 tonnes or more per year, they must within the 180 day post-exit period—
- (a) supply the agency with the information referred to in point (a)(i) of Article 10;
  - (b) supply the Agency with the information referred to in points (ii) and (iv) of Article 10 to the extent that information is available to the UK user or distributor;
  - (c) supply the Agency with the information referred to in—
    - (i) Article 14(6) to the extent that information is available to the UK user or distributor,
    - (ii) Article 31, and
    - (iii) Article 32(1)(a) to (d);
  - (d) otherwise comply with Articles 14(6), 31 and 32;
  - (e) supply the Agency with the relevant registration number for the substance under EU REACH to the extent that information is available to the UK user or distributor, and such other evidence that the Agency may require demonstrating that the information supplied in accordance with paragraph (c) above complies with the requirements of Articles 10, 12 and 14 (as they apply to the tonnage of the substance which the UK user or distributor imports into the United Kingdom).

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8. The UK user or distributor must provide the Agency with updated information of the kind required by paragraph 6 or 7, in particular where the UK user or distributor begins to import the substance concerned from a different relevant supplier.

9. In this Article—

“existing UK distributor under EU REACH” means a person who was, at any time in the 2 year period before exit day, a distributor under EU REACH established in the United Kingdom in relation to a substance;

“existing UK downstream user under EU REACH” means a person who was, at any time in the 2 year period before exit day, a downstream user under EU REACH established in the United Kingdom in relation to a substance;

“relevant supplier” has the meaning given in paragraph 3(d).

#### *Article 127F*

##### *Existing EU authorisations*

1. The holder of an existing EU authorisation which has the relevant connection with the United Kingdom must, before the end of the 60 day post-exit period, supply the Agency with the required technical information relating to the authorisation.

2. An existing EU authorisation which does not have the relevant connection with the United Kingdom ceases to have effect (as retained EU law) on exit day.

3. An existing EU authorisation has the relevant connection with the United Kingdom if the holder of the authorisation is established in the United Kingdom.

4. In this Article—

“existing EU authorisation” means an authorisation granted in accordance with Articles 60 to 64 of EU REACH which is subsisting immediately before exit day;

“holder”, in relation to an existing EU authorisation, means the person to whom the authorisation has been granted;

“required technical information”, in relation to an existing EU authorisation, means—

(a) the information included in the application for the authorisation in accordance with Article 62(4) and (5) of EU REACH,

(b) any other information provided to ECHA by the applicant for the authorisation which was material to the formation of ECHA’s opinion in relation to the application for the authorisation, and

(c) any information required to be submitted or recorded before exit day under any condition under which the authorisation is granted.

#### *Article 127G*

##### *Existing applications for EU authorisations*

1. The Secretary of State must decide an existing application for an EU authorisation (as mentioned in Article 64(8)) if—

(a) the application—

(i) is at the final decision stage on exit day,

(ii) has the relevant connection with the United Kingdom; and

(b) the person who made the application—

- (i) notifies the Secretary of State of the existence of the application,
  - (ii) provides the Secretary of State with copies of the application, the information included in it under Article 62(4) and (5) of EU REACH, and any other information provided to ECHA by the applicant for the authorisation which was material to the formation of ECHA’s opinion in relation to the application for the authorisation, and
  - (iii) provides the Secretary of State with copies of the final opinions of ECHA referred to in Article 64(5) of EU REACH.
2. An application for an EU authorisation is at the final decision stage if—
- (a) ECHA has adopted the final opinions referred to in Article 64(5) of EU REACH, but
  - (b) the Commission has not made a final decision granting or refusing the application.
3. An application for an EU authorisation has the relevant connection with the United Kingdom if the person making the application is established in the United Kingdom.
4. The period of six months for the Secretary of State to make an authorisation decision in accordance with Article 64(8) of this Regulation begins with the day on which paragraph 1(b) is complied with.
5. Where, immediately before exit day, a person may place a substance on the market for a use or use it himself in reliance on Article 56(1)(d) of EU REACH, the person may continue to do so on and after exit day in reliance on Article 56(1)(d) of this Regulation.
- But this paragraph ceases to apply at the end of the 180 day post-exit period if the person does not comply with paragraph 1(b) of this Article before the end of that period.
6. In this Article “existing application for an EU authorisation” means an application made before exit day for the grant of an authorisation in accordance with Articles 60 to 64 of EU REACH.

#### *Article 127H*

##### *Existing authorised downstream users under EU law*

1. On and after exit day, a person who—
- (a) is established in the United Kingdom, and
  - (b) is an existing authorised downstream user under EU law in relation to a substance,
- is authorised to use that substance in accordance with Article 56(2).
2. Where Article 56(2) applies to the use of a substance by virtue of paragraph 1, a reference in Article 56(2) to an authorisation granted to a person up a supply chain is a reference to an existing EU authorisation relating to that use of the substance.
3. Accordingly, paragraph 1 ceases to apply to a person if the existing EU authorisation relating to that use of the substance ceases to have effect.
4. A person to whom paragraph 1 applies must, before the end of the 60 day post-exit period—
- (a) confirm to the Agency that they are an existing authorised downstream user under EU law in relation to the substance, and
  - (b) notify the Agency of—
    - (i) the existing EU authorisation;

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- (ii) any conditions set out in the existing EU authorisation (as referred to in Article 56(2) of EU REACH);
  - (iii) the identity of the supplier of the substance to the person.
5. Article 66(1) does not apply to the use of a substance in accordance with Article 56(2) by virtue of this Article.
6. In this Article—
- “existing authorised downstream user under EU law” means a person who, immediately before exit day, is authorised to use a substance in accordance with Article 56(2) of EU REACH;
  - “existing EU authorisation” means an authorisation granted to a person up a supply chain (as referred to in Article 56(2) of EU REACH) which is subsisting immediately before exit day, as it has effect in EU law;

#### *Article 127I*

##### *Existing examinations of testing proposals*

1. On and after exit day, an existing EU decision on a testing proposal which has the relevant connection with the United Kingdom has effect as a decision by the Agency under Article 40(3) of this Regulation.
2. An existing EU decision on a testing proposal has the relevant connection with the United Kingdom if the registrant, or downstream user, concerned is established in the United Kingdom.
3. The Agency may extend any deadline specified in an existing EU decision on a testing proposal.
4. In this Article, “existing EU decision on a testing proposal” means a decision taken by ECHA—
  - (a) in accordance with Article 40(3)(a), (b), (c) or (e) of EU REACH, if the requirements of the decision have not been fulfilled, or
  - (b) in accordance with Article 40(3)(d) of EU REACH.

#### *Article 127J*

##### *Existing Article 7(2) notifications*

1. This Article applies if—
  - (a) before exit day, a producer of articles established in the United Kingdom, or an importer of articles established in the United Kingdom, has given ECHA a notification under Article 7(2) of EU REACH in relation to a substance, and
  - (b) immediately before exit day, that person is not a registrant in relation to the substance concerned.
2. The person that gave the notification to ECHA must submit to the Agency, within the 60 day post-exit period, the information notified to ECHA in accordance with Article 7(2) and (4) of EU REACH.

### *Article 127K*

#### *Existing Article 9 exemptions*

1. This Article applies if—

- (a) a five year exemption under Article 9(1) of EU REACH, or
- (b) an extended exemption under Article 9(7) of EU REACH,

applies in relation to a substance immediately before exit day where the research and development concerned takes place in the United Kingdom.

2. On and after exit day—

- (a) a five year exemption under Article 9(1) of this Regulation, or,
- (b) an extended exemption under Article 9(7) of this Regulation,

(as the case may be) applies in relation to the substance, subject to the same conditions (if any) imposed by ECHA under Article 9(4) in relation to the corresponding exemption under EU REACH.

3. That exemption under Article 9(1) or (7) of this Regulation is to end on the same date that the corresponding exemption under EU REACH would have ended.

4. Where an exemption under Article 9(1) or (7) of this Regulation applies to a substance by virtue of this Article, the following duties must be complied with in relation to the exemption of the substance within the 120 day post-exit period—

- (a) Article 9(2) must be complied with by the manufacturer or importer or producer, as the case may be (the “notifier”);
- (b) the notifier must also notify the Agency of the number and notification date assigned by ECHA under Article 9(3) of EU REACH;
- (c) the notifier must give the Agency copies of any additional necessary information given to ECHA under Article 9(4) of EU REACH.

Where the notifier complies with Article 9(2) in accordance with this paragraph, no fee is payable under Article 9(2).

### *Article 127L*

#### *Existing Article 17 registrations*

1. This Article applies if a registration with ECHA under Article 17 of EU REACH which relates to an on-site isolated intermediate that is manufactured in the United Kingdom is—

- (a) subsisting immediately before exit day, and
- (b) either—
  - (i) has a current connection with the United Kingdom, or
  - (ii) has a relevant past connection with the United Kingdom (but does not have a current connection with the United Kingdom).

2. On and after exit day, the registration has effect as a registration with the Agency under Article 17 of this Regulation.

3. Where paragraph 2 operates on a registration the manufacturer concerned must give the Agency—

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- (a) the information referred to in Article 17(2)(a), (b), (e) and (f) and the confirmation referred to in Article 17(3), within the 120 day post-exit period, and
  - (b) the information referred to in Article 17(2)(c) and (d) within the 2 year post-exit period.
4. Article 19(1) does not apply to the giving of information in accordance with paragraph 3 of this Article.
5. The manufacturer concerned must submit the registration number and registration date assigned to the existing EU registration by ECHA in accordance with Article 20(3) of EU REACH, and such other evidence as the Agency may require of the existing EU registration, to the Agency within the 120 day post-exit period.
6. Where paragraph 2 operates on a registration, the other Titles of this Regulation apply to that registration as they would apply to the registration if it had been submitted to the Agency under Article 17 on exit day, but with the modifications set out in the following provisions of this Article.
7. No fee is payable under Article 17(2).
8. Article 20 has effect with the following provision substituted for paragraphs 1 to 3—
- “1. The Agency must assign a submission date to each registration which has effect under Article 127L, which must be the date on which the registrant complies with paragraph 3(a) or (b) of Article 127L.
  - 2. The Agency may undertake a completeness check of each registration in order to ascertain that all the elements required under Article 17 have been provided. The completeness check must not include an assessment of the quality or the adequacy of any data or justifications submitted.
- If a registration is incomplete, the Agency must inform the registrant as to what further information is required in order for the registration to be complete, while setting a reasonable deadline for this. The registrant must complete his registration and submit it to the Agency within the deadline set. The Agency must confirm the submission date of the further information to the registrant. The Agency must perform a further completeness check, considering the further information submitted.
- 3. Once the registrant has complied with paragraph 3(a) of Article 127L, the Agency must assign a registration number to the substance concerned and a registration date, which must be the same as the registration date for the existing EU registration.”
9. Article 21 has effect with the following provision substituted for the first subparagraph of paragraph 1—
- “1. A registrant may continue the manufacture of a substance from exit day, subject to any indication to the contrary from the Agency in accordance with Article 20(2).”

#### *Article 127M*

##### *Existing Article 18 registrations*

1. This Article applies if a registration with ECHA under Article 18 of EU REACH which relates to a transported isolated intermediate that is manufactured in or imported into the United Kingdom is—



- (a) subsisting immediately before exit day, and
  - (b) either—
    - (i) has a current connection with the United Kingdom, or
    - (ii) has a relevant past connection with the United Kingdom (but does not have a current connection with the United Kingdom).
2. On and after exit day, the registration has effect as a registration with the Agency under Article 18 of this Regulation.
3. Where paragraph 2 operates on a registration, the manufacturer or importer concerned must give the Agency—
- (a) the information referred to in Article 18(2)(a), (b), (e) and (f) and the confirmation referred to in Article 18(4), within the 120 day post-exit period, and
  - (b) the information referred to in Article 18(2)(c) and (d) and 18(3) within the 2 year post-exit period.
4. Article 19(1) does not apply to the giving of information in accordance with paragraph 3 of this Article.
5. The manufacturer or importer concerned must submit the registration number and registration date assigned to the existing EU registration by ECHA in accordance with Article 20(3) of EU REACH, and such other evidence as the Agency may require of the existing EU registration, to the Agency within the 120 day post-exit period.
6. Where paragraph 2 operates on a registration, the other Titles of this Regulation apply to that registration as they would apply to the registration if it had been submitted to the Agency under Article 18 on exit day, but with the modifications set out in the following provisions of this Article.
7. No fee is payable under Article 18(2).
8. Article 20 has effect with the following provision substituted for paragraphs 1 to 3—
- “1. The Agency must assign a submission date to each registration which has effect under Article 127M, which must be the date on which the registrant complies with paragraph 3(a) or (b) of Article 127M.
  - 2. The Agency may undertake a completeness check of each registration in order to ascertain that all the elements required under Article 18 have been provided. The completeness check must not include an assessment of the quality or the adequacy of any data or justifications submitted.
- If a registration is incomplete, the Agency must inform the registrant as to what further information is required in order for the registration to be complete, while setting a reasonable deadline for this. The registrant must complete his registration and submit it to the Agency within the deadline set. The Agency must confirm the submission date of the further information to the registrant. The Agency must perform a further completeness check, considering the further information submitted.
- 3. Once the registrant has complied with paragraph 3(a) of Article 127M, the Agency must assign a registration number to the substance concerned and a registration date, which must be the same as the registration date for the existing EU registration.”.
9. Article 21 has effect with the following provision substituted for the first subparagraph of paragraph 1—

*Status: This is the original version (as it was originally made).*

“1. A registrant may continue the manufacture or import of a substance from exit day, subject to any indication to the contrary from the Agency in accordance with Article 20(2).”.

#### *Article 127N*

##### *Registrations under Article 127L and Article 127M*

1. Articles 127L and 127M are to be read in accordance with paragraphs 2 to 5.
2. A registration under Article 17 or 18 of EU REACH (as the case may be) has a current connection with the United Kingdom if—
  - (a) the registrant immediately before exit day is a person established in the United Kingdom (a “current UK registrant”), and
  - (b) a registration of the substance concerned by the current UK registrant is a registration of a kind that could be submitted on exit day under Article 17 or 18 (as the case may be) of this Regulation.
3. A registration under Article 17 or 18 of EU REACH (as the case may be) has a relevant past connection with the United Kingdom if—
  - (a) the registrant at any time during the 2 year period before exit day was a person established in the United Kingdom (a “former UK registrant”), and
  - (b) a registration of the substance concerned by the former UK registrant is a registration of a kind that could be submitted on exit day—
    - (i) under Article 17 of this Regulation if the former UK registrant was the manufacturer of the on-site intermediate concerned on exit day, or
    - (ii) under Article 18 of this Regulation if the former UK registrant was the manufacturer or importer of the transported isolated intermediate concerned on exit day.
4. Where a registration that has a current connection with the United Kingdom has effect as a registration with the Agency by virtue of Article 127L or 127M, the current UK registrant becomes the registrant in relation to the registration with the Agency on exit day.
5. Where a registration that has a relevant past connection with the United Kingdom has effect as a registration with the Agency by virtue of Article 127L or 127M, the former UK registrant becomes the registrant in relation to the registration with the Agency on exit day.

If two or more persons have been former UK registrants at different times during the 2 year period before exit day, only the person who was the former UK registrant most recently before exit day is to become the registrant in relation to the registration with the Agency by virtue of this paragraph.

#### *Article 127O*

##### *Obligation to keep information*

1. This Article applies to a person established in the United Kingdom who, immediately before exit day, is, as respects any information, bound by the obligation imposed by Article 36(1) of EU REACH.
2. On and after exit day, the person is, as respects the information concerned, bound by the obligation imposed by Article 36(1) of this Regulation.

3. Where paragraph 2 applies to a person, the person is not bound by the obligation imposed by Article 36(1) of this Regulation after the end of a 10 year period under Article 36(1) of EU REACH that was running at exit day (and the reference to the 10 year period in Article 36(1) of this Regulation is accordingly to be read as a reference to the remainder of the 10 year period under EU REACH that falls after exit day).

#### *Article 127P*

#### *Periods before exit and post-exit used in this Title*

In this Title—

- (1) “60 day post-exit period” means the period of 60 days beginning with the day after that on which exit day falls;
- (2) “90 day post-exit period” means the period of 90 days beginning with the day after that on which exit day falls;
- (3) “120 day post-exit period” means the period of 120 days beginning with the day after that on which exit day falls;
- (4) “180 day post-exit period” means the period of 180 days beginning with the day after that on which exit day falls;
- (5) “2 year period before exit” means the period of two years ending with exit day;
- (6) “2 year post-exit period” means the period of two years beginning with the day after that on which exit day falls.”.

### SCHEDULE 3

Regulation 5

#### 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”.

*Status: This is the original version (as it was originally made).*

- (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([26](#))”.
- (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”;

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(26) 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](#) (OJ No. L 81, 31.3.2016, p. 51).

- (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”.

(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<sup>(27)</sup>”.

**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”;

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(27) [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](#).

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- (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”).

**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(**28**)”.
- 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(**29**);
  - Regulation (EU) No 167/2013 of the European Parliament and of the Council on the approval and market surveillance of agricultural and forestry vehicles(**30**);
  - 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(**31**).”.
- 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](#)(**32**)”.
- (3) In paragraph 2(b)—

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

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

(30) 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).

(31) 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).

(32) 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](#)).

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- (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.
- (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(**33**)”.
- (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”.

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

(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(34);”;

(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”;

(b) for “[Directive 2006/42/EC](#) of the European Parliament and of the Council” substitute “the Supply of Machinery (Safety) Regulations 2008(35)”.

(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”.

## PART 2

### The Appendices

**38.** In Appendix 7 (special provisions on the labelling of articles containing asbestos)—

(a) in paragraph 1(c), omit the second subparagraph;

(b) in paragraph 5, for “Community provisions” substitute “legislation”;

(c) in paragraph 7, for the words from “the official” to the end substitute “English, and may also be done in other languages”.

**39.** In Appendix 10 (entry 43 – Azocolourants – list of testing methods)—

(a) in the heading of the first column of the table, omit “European”;

(b) in the first column of each entry in the table, for “CEN” substitute “BSI”;

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

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

- (c) in the second column of each entry in the table, for “EN” substitute “BS EN”.

## SCHEDULE 4

Regulation 6

### Amendment of the Test Methods Regulation

1. [Commission Regulation \(EC\) No 440/2008](#) laying down test methods pursuant to the REACH Regulation is amended in accordance with this Schedule.
2. In Article 2, for “Commission” substitute “Secretary of State”.
3. For Article 4 substitute—

#### *“Article 4*

In this Regulation, “Agency” has the meaning given in Article 3(18) of Regulation [\(EC\) No 1907/2006](#) of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency.”.

4.—(1) Part B of the Annex (methods for the determination of toxicity and other health effects) is amended as follows.

(2) In the General Introduction, in section C (alternative testing), for “European Union” substitute “United Kingdom”.

(3) In section B.36 (toxicokinetics), in paragraphs 37 and 38, for “a competent authority” substitute “the Agency”.

(4) In section B.54 (uterotrophic bioassay in rodents: a short-term screening test for oestrogenic properties), in paragraphs 11 and 19, for the words from “local regulations” to “scientific purposes” substitute “, for example, the Animals (Scientific Procedures) Act 1986**(36)**”.

(5) In section B.55 (Hershberger bioassay in rats: a short-term screening assay for (anti)androgenic properties), in paragraphs 10 and 19, for the words from “local regulations” to “scientific purposes” substitute “, for example, the Animals (Scientific Procedures) Act 1986”.

5.—(1) Part C of the Annex (methods for the determination of ecotoxicity) is amended as follows.

(2) In section C.11 (activated sludge, respiration inhibition test (carbon and ammonium oxidation)), in paragraph 3, for the text after the semi-colon substitute “lower limits for the concentration of nitrogen in treated effluents discharged to receiving waters are now in force.”.

(3) In section C.41 (fish sexual development test), in paragraph 39, for the words from “[Directive 2010/63/EU](#)” to “scientific purposes” substitute “the Animals (Scientific Procedures) Act 1986”.

## SCHEDULE 5

Regulation 7

### Amendment of the Data Sharing Regulation

1. Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing in accordance with Regulation [\(EC\) No 1907/2006](#) of the European Parliament and of

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(36) 1986 c. 14.

the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is amended in accordance with this Schedule.

- 2.—(1) Article 2 is amended as follows.
  - (2) In paragraph 1, omit “or participants in a Substance Information Exchange Forum (SIEF)”.
  - (3) In paragraph 2—
    - (a) in the first subparagraph—
      - (i) for “already exists on the date of entry into force of this Regulation” substitute “existed before 25 January 2016”;
      - (ii) after “paragraph 1.” insert “A waiver under Article 2(2) of the EU Implementing Regulation which is in effect immediately before exit day has effect on and after exit day as a waiver under this Article of this Regulation (and here “EU Implementing Regulation” means Commission Implementing Regulation (EU) 2016/9 as it has effect in EU law).”;
    - (b) in the second subparagraph, for “Articles 27 and 30” substitute “Article 27”;
    - (c) in the third subparagraph—
      - (i) in point (a), for “after the date of entry into force of this Regulation” substitute “on or after 25 January 2016”;
      - (ii) in point (b), for the words from “the date” to the end substitute “25 January 2016, that is requested”.
  - (4) In paragraph 3—
    - (a) in the third subparagraph, for “the entry into force of this Regulation” substitute “25 January 2016”;
    - (b) in the fourth subparagraph, after “of a study” insert “(whether to ECHA or the Agency)”;
    - (c) after the fourth subparagraph, insert—

“In this paragraph the term “ECHA” has the same meaning as in Regulation [\(EC\) No 1907/2006](#).”.
3. In Article 3—
  - (a) in paragraph 2, for “Articles 27(6) and 30(3)” substitute “Article 27(6)”;
  - (b) in paragraph 3, for “Articles 26 or 29” substitute “Article 26”.
4. In Article 4—
  - (a) in paragraph 1, for “Articles 27(3) and 30(1)” substitute “Article 27(3)”;
  - (b) in paragraph 3, for “Articles 27 and 30” substitute “Article 27”;
  - (c) in paragraph 5, in the first subparagraph—
    - (i) for “already exists on the date of entry into force of this Regulation” substitute “existed before 25 January 2016”;
    - (ii) after “model.” insert—

“A waiver under Article 4(5) of the EU Implementing Regulation which is in effect immediately before exit day has effect on and after exit day as a waiver under this Article of this Regulation (and here “EU Implementing Regulation” means Commission Implementing Regulation (EU) 2016/9 as it has effect in EU law).”.
5. In Article 5—
  - (a) in paragraph 1, for “Articles 27(5) and 30(3)” substitute “Article 27(5)”;

- (b) omit paragraph 2.
- 6. Omit Article 6.

## SCHEDULE 6

Regulation 8

## Amendment of the Fees and Charges Regulation

1. [Commission Regulation \(EC\) No 340/2008](#) on the fees and charges payable to the European Chemicals Agency is amended in accordance with this Schedule.

2. In Article 1, for “European Chemicals Agency, hereinafter the ‘Agency’, as provided for in” substitute “Agency, within the meaning of”.

3. In Article 2, at the end insert—

“In the application of Recommendation 2003/361/EC for the purposes of this Regulation, the Annex to that Recommendation has effect with the following modifications:

- (a) in Article 2(1)—
  - (i) the reference to EUR 50 million has effect as a reference to £43.650 million;
  - (ii) the reference to EUR 43 million has effect as a reference to £37.539 million;
- (b) in Article 2(2) the reference to EUR 10 million has effect as a reference to £8.730 million;
- (c) in Article 2(3) the reference to EUR 2 million has effect as a reference to £1.746 million;
- (d) in Article 3(2)—
  - (i) in point (a), the reference to EUR 1,250,000 has effect as a reference to £1,091,250;
  - (ii) in point (d), the reference to EUR 10 million has effect as a reference to £8.730 million.”.

4. In Article 3(5), omit the second subparagraph.

5. In Article 4(5), omit the second subparagraph.

6. Omit Article 10.

7.—(1) Article 11 is amended as follows.

(2) In paragraph 1—

- (a) in the second subparagraph, omit the words from “and for” to “1907/2006”;
- (b) in the third subparagraph, omit “Executive Director of the”.

(3) In paragraph 5—

- (a) omit “the Management Board of”;
- (b) for “Commission” substitute “Secretary of State”;
- (c) at the end insert—

“The function of the Secretary of State under this paragraph is subject to the consent requirement in Article 4A of Regulation [\(EC\) No 1907/2006](#).”.

8. In Article 12, for “non-Community”, in both places it occurs, substitute “non-United Kingdom”.

- 9.**—(1) Article 13 is amended as follows.
- (2) In paragraph 1, for “3 to 10” substitute “3 to 9”.
- (3) In paragraph 3, in the second subparagraph—
- (a) for “one of the official languages of the Union” substitute “English”;
- (b) for “any of those official languages” substitute “English”.
- 10.** Omit Articles 14 and 15.
- 11.**—(1) Article 16 is amended as follows.
- (2) In paragraph 1, for “euro” substitute “sterling”.
- (3) In paragraph 2, omit “, with the exception of payments due under Article 10”.
- 12.** In Article 17(1)—
- (a) in the first subparagraph, for the words from “invoice” to “Article 10.” substitute “submission number assigned by the Agency under Article 20 of Regulation (EC) No 1907/2006.”;
- (b) omit the second subparagraph.
- 13.** In Article 19(2), omit “the Management Board of”.
- 14.** In Article 20(1)—
- (a) in the first subparagraph, omit “the Executive Director of”;
- (b) in the second subparagraph, for “EUR 100” substitute “£87”.
- 15.** Omit Article 21.
- 16.** For Article 22 substitute—

*“Article 22*

*Amendment of fees and charges*

**1.** The Secretary of State may, by regulations, amend this Regulation so as to alter the fees and charges provided for in it if the Secretary of State considers that the alterations are appropriate having regard to—

- (a) the change in the relevant prices index, and
- (b) the costs of the Agency (taking one year with another).

**2.** Regulations under this Article are to be made by statutory instrument.

A statutory instrument containing regulations under this Article is subject to annulment in pursuance of a resolution of either House of Parliament.

The Secretary of State must consult the other appropriate authorities before making regulations under this Article.

**3.** In this Article—

- (a) “appropriate authority” has the same meaning as in Article 3 of Regulation (EC) No 1907/2006;
- (b) “relevant prices index” means—
- (i) the all items consumer prices index published by the Statistics Board, or

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(ii) if that index ceases to be available, such other similar general index of prices which the Secretary of State considers appropriate to use for the purposes of this Article.”.

17. Omit Article 23.

18.—(1) Annex 1 is amended as follows.

(2) In Table 1, for the entries which set out the fees substitute—

“£1,518	£1,138
£4,080	£3,061
£10,913	£8,185
£29,419	£22,064”.

(3) In Table 2, for the entries which set out the fees substitute—

“£987	£740	£532	£399	£76	£57
£2,652	£1,990	£1,428	£1,071	£204	£153
£7,094	£5,320	£3,819	£2,865	£546	£409
£19,122	£14,342	£10,297	£7,723	£1,471	£1,103”.

19.—(1) Annex 2 is amended as follows.

(2) In Table 1, for the entries which set out the fees substitute—

“£1,518	£1,138”.
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(3) In Table 2, for the entries which set out the fees substitute—

“£987	£740	£532	£399	£76	£57”.
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20.—(1) Annex 3 is amended as follows.

(2) In Table 1, for the entries which set out the fees substitute—

“£2,562	£1,921
£9,395	£7,046
£27,901	£20,926
£6,833	£5,125
£25,339	£19,003
£18,506	£13,879”.

(3) In Table 2, for the entries which set out the fees substitute—



<b>“£1,666</b>	<b>£1,249</b>	<b>£897</b>	<b>£672</b>	<b>£128</b>	<b>£96</b>
£6,107	£4,580	£3,289	£2,466	£470	£353
£18,136	£13,601	£9,765	£7,324	£1,395	£1,046
£4,441	£3,331	£2,391	£1,794	£341	£257
£16,470	£12,353	£8,869	£6,651	£1,267	£950
£12,029	£9,022	£6,477	£4,857	£925	£694”.

(4) In Table 3—

- (a) for “EUR 1 631” in the first place (the fee for a change in the identity of the registrant involving a change in legal personality) substitute “£1,424”;
- (b) for the entries which set out the other fees substitute—

“£4,271	£3,203
£1,424	£1,068
£4,271	£3,203
£2,847	£2,135
£1,424	£1,068
£1,424	£1,068
£1,424	£1,068”.

(5) In Table 4—

- (a) for the first three entries which set out fees (fees for changes of identity of the registrant involving a change in legal personality) substitute—

“£925	£498	£72”.
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- (b) for the other entries which set out fees substitute—

“£2,776	£2,082	£1,495	£1,121	£214	£160
£925	£694	£498	£374	£72	£53
£2,776	£2,082	£1,495	£1,121	£214	£160
£1,851	£1,388	£996	£747	£142	£107
£925	£694	£498	£374	£72	£53
£925	£694	£498	£374	£72	£53
£925	£694	£498	£374	£72	£53”.

**21.**—(1) Annex 4 is amended as follows.

- (2) In Table 1, for the entries which set out the fees substitute—

“£4,271	£3,203
£1,424	£1,068

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£4,271	£3,203
£2,847	£2,135
£1,424	£1,068
£1,424	£1,068
£1,424	£1,068”.

(3) In Table 2, for the entries which set out the fees substitute—

“£2,776	£2,082	£1,495	£1,121	£214	£160
£925	£694	£498	£374	£72	£53
£2,776	£2,082	£1,495	£1,121	£214	£160
£1,851	£1,388	£996	£747	£142	£107
£925	£694	£498	£374	£72	£53
£925	£694	£498	£374	£72	£53
£925	£694	£498	£374	£72	£53”.

**22.**—(1) Annex 5 is amended as follows.

(2) In Table 1, for the entries which set out the fees substitute—

“£475
£308
£166
£24”.

(3) In Table 2, for the entries which set out the charges substitute—

“£949
£617
£332
£47”.

**23.**—(1) Annex 6 is amended as follows.

(2) In Table 1, for the entries which set out the fees substitute—

“£47,229
£9,446
£42,506”.

(3) In Table 2, for the entries which set out the fees substitute—

“£35,422
£7,084
£31,880”.

(4) In Table 3, for the entries which set out the fees substitute—

“£21,253
£4,251
£19,128”.

(5) In Table 4, for the entries which set out the fees substitute—

“£4,723
£945
£4,251”.

**24.**—(1) Annex 7 is amended as follows.

(2) In Table 1, for the entries which set out the charges substitute—

“£47,229
£9,446
£42,506”.

(3) In Table 2, for the entries which set out the charges substitute—

“£35,422
£7,084
£31,880”.

(4) In Table 3, for the entries which set out the charges substitute—

“£21,253
£4,251
£19,128”.

(5) In Table 4, for the entries which set out the charges substitute—

“£4,723
£945
£4,251”.

**25. Omit Annex 8.****SCHEDULE 7**

Regulation 9

**Amendment of an authorisation under Article 60(4) of the REACH Regulation**

**1.** Commission Implementing Decision C(2017) 3439 granting an authorisation for a use of chromium trioxide under REACH (Rimex Metals (UK) Ltd) is amended in accordance with this Schedule.

**2.** In Article 3(d), for “competent authority of the Member State where the authorised use takes place” substitute “Agency (as defined in that Regulation)”.

**SCHEDULE 8**

Regulation 10

**Revocation of retained direct EU legislation**

- 1.** The following retained direct EU legislation is revoked—
  - (a) Commission Regulation (EC) No 506/2007 imposing testing and information requirements on the importers or manufacturers of certain priority substances in accordance with Council Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances;
  - (b) Commission Regulation (EC) No 1238/2007 on laying down rules on the qualifications of the members of the Board of Appeal of the European Chemicals Agency;
  - (c) Commission Regulation (EC) No 465/2008 imposing, pursuant to Council Regulation (EEC) No 793/93, testing and information requirements on importers and manufacturers of certain substances that may be persistent, bioaccumulating and toxic and are listed in the European Inventory of Existing Commercial Chemical Substances;
  - (d) Commission Regulation (EC) No 466/2008 imposing testing and information requirements on the importers and manufacturers of certain priority substances in accordance with Council Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances;
  - (e) Commission Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency;
  - (f) Commission Decision 2010/226/EU on the re-examination of the restriction concerning short-chain chlorinated paraffins (SCCPs) listed in Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council.

**SCHEDULE 9**

Regulation 11

**Amendment of the EEA agreement**

**1.** In Annex 2 to the EEA agreement (Technical Regulations, Standards, Testing and Certification), in Chapter 15 (dangerous substances)—

- (a) in point 12zc, omit—
  - (i) from “The Provisions” to “following adaptations:”;

- (ii) paragraphs (a) to (p);
- (b) omit points 12zca, 12zf, 12zl, 12zm, 12zn, 12zs, 12zx, 12zza.

SCHEDULE 10

Regulation 12

Amendment of the REACH (Enforcement) Regulations 2008

PART 1

Enforcement of requirements under transitional provisions relating to EU exit

**Enforcement of requirements under transitional provisions relating to EU exit**

1.—(1) In regulation 2(1)—

- (a) in the definition of “a listed REACH provision”, for “the REACH table” substitute “a REACH table”;
- (b) for the definition of “the REACH table” substitute—

““a REACH table” means—

- (a) the table in Schedule 1 to these Regulations, or
- (b) the table in Schedule 1A to these Regulations;

“the relevant REACH table” means—

- (a) in relation to a listed REACH provision, the REACH table in which that REACH provision is listed;
- (b) in relation to an enforcement duty, the REACH table under which that enforcement duty arises.”

(2) In regulation 3, for “REACH table”, in each place it occurs, substitute “relevant REACH table”.

(3) In regulation 3A(1), for “in any column” to the end substitute “against any listed REACH provision in any column of the relevant REACH table”.

(4) In the title of Schedule 1, after “of” insert “General”.

(5) After Schedule 1 insert—

“SCHEDULE 1A

Regulation 2(1)

Table of REACH transitional provisions relating to EU exit

Provision of REACH	Subject matter	Enforcing authority			
		England and Wales	Scotland	Northern Ireland	Offshore installations
Article 127B(4) and (6).	Requirement to supply information to the Agency where existing EU registration	The Health and Safety Executive.	The Health and Safety Executive.	The Health and Safety Executive for Northern Ireland.	The Health and Safety Executive.  The Health and Safety

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Provision of REACH	Subject matter	Enforcing authority			
		England and Wales	Scotland	Northern Ireland	Offshore installations
	becomes UK registration.				Executive for Northern Ireland.
Article 127C(3).	Requirement to supply information to the Agency about existing ECHA decisions.	The Health and Safety Executive.	The Health and Safety Executive.	The Health and Safety Executive for Northern Ireland.	The Health and Safety Executive.  The Health and Safety Executive for Northern Ireland.
Article 127E(6), (7) and (8).	Requirement to supply information to the Agency where importer continues to be regarded as downstream user.	The Health and Safety Executive.	The Health and Safety Executive.	The Health and Safety Executive for Northern Ireland.	The Health and Safety Executive.  The Health and Safety Executive for Northern Ireland.
Article 127F(1).	Requirement to supply technical information to the Agency where existing EU authorisation becomes UK authorisation.	The Health and Safety Executive.	The Health and Safety Executive.	The Health and Safety Executive for Northern Ireland.	The Health and Safety Executive.  The Health and Safety Executive for Northern Ireland.
Article 127H(4).	Requirement to supply information to the Agency where authorised downstream user continues to be regarded as such.	The Health and Safety Executive.	The Health and Safety Executive.	The Health and Safety Executive for Northern Ireland.	The Health and Safety Executive.  The Health and Safety Executive for Northern Ireland.
Article 127J(2).	Requirement to supply information where a notification was given under Article 7(2) of EU REACH.	The Health and Safety Executive.	The Health and Safety Executive.	The Health and Safety Executive for Northern Ireland.	The Health and Safety Executive.  The Health and Safety Executive

<i>Provision of REACH</i>	<i>Subject matter</i>	<i>Enforcing authority</i>			
		<i>England and Wales</i>	<i>Scotland</i>	<i>Northern Ireland</i>	<i>Offshore installations</i>
					for Northern Ireland.
Article 127K(4).	Requirement to notify Agency and supply information to it where exemption under Article 9 of EU REACH continues to have effect.	The Health and Safety Executive.	The Health and Safety Executive.	The Health and Safety Executive for Northern Ireland.	The Health and Safety Executive.  The Health and Safety Executive for Northern Ireland.
Article 127L(3) and (5).	Requirement to supply information to the Agency where registration under Article 17 of EU REACH continues to have effect.	The Health and Safety Executive.	The Health and Safety Executive.	The Health and Safety Executive for Northern Ireland.	The Health and Safety Executive.  The Health and Safety Executive for Northern Ireland.
Article 127M(3) and (5).	Requirement to supply information to the Agency where registration under Article 18 of EU REACH continues to have effect.	The Health and Safety Executive.	The Health and Safety Executive.	The Health and Safety Executive for Northern Ireland.	The Health and Safety Executive.  The Health and Safety Executive for Northern Ireland.”

## PART 2

### Other amendments

2. In regulation 2(2), omit the definition of “competent authority”.
- 3.—(1) Regulation 4 is amended as follows.
  - (2) In paragraph (1)—
    - (a) before subparagraph (a) insert—
      - “(za) the Agency;
      - (zb) the appropriate authorities; and”;
    - (b) omit subparagraphs (b) to (d);
    - (c) in the words after subparagraph (d), omit “in the European Union”.

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- (3) In paragraph (2)(b), omit “in the European Union”.
4. In regulation 7(1), omit subparagraph (b) (and the “or” preceding it).
5. Omit regulation 24(2).
- 6.—(1) Schedule 1 (Table of REACH provisions) is amended as follows.
  - (2) In the second column, for “European Chemicals Agency”, in each place it occurs, substitute “Agency”.
  - (3) In the entry relating to Article 8(2) of REACH, in the second column, for “community” substitute “UK”.
  - (4) In the entry relating to Article 26(1) of REACH, in the second column, omit the words from “of a non-phase in” to “pre-registered.”.
  - (5) Omit the entry relating to Article 30(6).
  - (6) In the entry relating to Article 31(2) to (9), in the second column, for “the language of the Member State concerned” substitute “English”.
  - (7) Omit the entry relating to Article 31(10).
  - (8) In the entry relating to Article 32(2) and (3), in the second column, omit “after 1<sup>st</sup> June 2007”.
  - (9) In the entry relating to Article 36(1), in the second column, for “a competent” substitute “an appropriate”.
  - (10) In the entry relating to Article 37(3), omit the row (comprising the second to sixth columns) that relates to requirements providing when a manufacturer, importer or downstream user must comply with Article 14 for a phase-in substance.
  - (11) In the entries relating to Articles 46(2) and 49(a), in the second column, for “competent authority” substitute “Agency”.
7. In Schedule 4, in paragraph 7—
  - (a) before subparagraph (a) insert—
    - “(za) the Agency;
    - (zb) the appropriate authorities;”;
  - (b) omit subparagraphs (b) to (d).

## SCHEDULE 11

Regulation 13

### Amendment and revocation of subordinate legislation

#### **The Environmental Protection (Disposal of Polychlorinated Biphenyls and other Dangerous Substances) (England and Wales) Regulations 2000**

- 1.—(1) Regulation 2 of the Environmental Protection (Disposal of Polychlorinated Biphenyls and other Dangerous Substances) (England and Wales) Regulations 2000<sup>(37)</sup> is amended as follows.
  - (2) In paragraph 1, after the definition of “decontamination” insert—
 

““[Directive 2008/98/EC](#)” means that Directive as last amended by Council Regulation (EU) 2017/997, read in accordance with paragraph (2A).”.
  - (3) After paragraph (2) insert—

<sup>(37)</sup> [S.I. 2000/1043](#), to which there are amendments not relevant to these Regulations.



- “(2A) For the purposes of these Regulations, [Directive 2008/98/EC](#) is to be read as if—
- (a) Article 5(2) were omitted;
  - (b) in Article 6—
    - (i) paragraphs 1 to 3 were omitted;
    - (ii) in paragraph 4—
      - (aa) in the first sentence, for the words from “Where criteria” to “paragraphs 1 and 2” there were substituted “Except where Council Regulation (EU) No 333/2011, [Commission Regulation \(EU\) No 1179/2012](#) or [Commission Regulation \(EU\) No 715/2013](#) applies”;
      - (bb) the second sentence were omitted.”

### **The REACH (Appointment of Competent Authorities) Regulations 2007**

2. The REACH (Appointment of Competent Authorities) Regulations 2007(**38**) are revoked.

### **The Tribunal Procedure (First-tier Tribunal) (General Regulatory Chamber) Rules 2009**

3.—(1) The Tribunal Procedure (First-tier Tribunal) (General Regulatory Chamber) Rules 2009(**39**) are amended as follows.

- (2) In rule 1(3) (interpretation), after the definition of “practice direction”, insert—
- ““REACH Agency” means the “Agency” as defined in Article 3(18) of Regulation ([EC](#)) [No 1907/2006](#) of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency;”.
- (3) In rule 22(6) (the notice of appeal), after subparagraph (f) insert—
- “(g) in an appeal against a decision of the REACH Agency, within 90 days of the date on which the appellant was first notified, or otherwise became aware, of the decision;”.

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(38) [S.I. 2007/1742](#).

(39) [S.I. 2009/1976](#), amended by [S.I. 2010/43](#) and [2018/1053](#); there are other amending instruments but none is relevant.