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.

"(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), for "from the Community" substitute "from the United Kingdom" and 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.**—(1) 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(**6**);

"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.

(**6**) 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).

*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;

(**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(**8**)), 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(**9**)) 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.

(**8**) 1998 c. 46.
(**9**) 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(**10**).

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).".

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

(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**)".

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(**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.

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 "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".

**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 "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";

(**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.

(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—

(**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

(**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.

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(**20**).".

**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(**21**) 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(**22**).".

(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";

(**20**) S.I. 2017/407, to which there are amendments not relevant to these Regulations.
(**21**) 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).
(**22**) 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,";

(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.

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".

(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 classification and labelling inventory" to "Regulation (EC) No 1272/2008";

(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 77A(2)(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 77A(2)(a)".

(4) Omit paragraph 3.

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

**68.** Article 91 is amended as follows.

(1) in paragraph 1, for "Article 30(2) and (3) and Article 51" substitute "Article 51 and Article 52".

(2) After paragraph 1 insert—

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

(3) 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".

**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.** Article 110 is amended as follows.

(1) In the heading and in paragraph 1, for "Community" substitute "public";

(2) 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".

(3) In paragraph 3, for "European Medicines Agency" substitute "Medicines and Healthcare products Regulatory Agency(**25**)".

(4) 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—

(**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.

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.