
STATUTORY INSTRUMENTS

2019 No. 720

**EXITING THE EUROPEAN UNION
ENVIRONMENTAL PROTECTION
FEES AND CHARGES
HEALTH AND SAFETY
PESTICIDES**

The Chemicals (Health and Safety) and
Genetically Modified Organisms (Contained Use)
(Amendment etc.) (EU Exit) Regulations 2019

Made - - - - 27th March 2019

Coming into force in accordance with regulation 1(2)

The Secretary of State makes the following Regulations with the consent of the Treasury in exercise of the powers conferred by section 8(1) of, and paragraphs 1 and 7 of Schedule 4 and paragraph 21(b) of Schedule 7 to, the European Union (Withdrawal) Act 2018⁽¹⁾.

In accordance with paragraphs 1(1) and 12(1) of Schedule 7 to that Act a draft of these Regulations has been laid before Parliament and approved by a resolution of each House of Parliament.

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019.

(2) These Regulations come into force on exit day.

(3) Except as provided by paragraph (4), these Regulations extend to England and Wales, Scotland and Northern Ireland.

(4) An amendment or revocation made by Schedule 1 has the same extent as the provision amended or revoked.

⁽¹⁾ 2018 c. 16. Treasury consent has been obtained pursuant to paragraph 3(1) of Schedule 4.

Amendments to retained EU law

- 2.—(1) Schedule 1 contains amendments to the following subordinate legislation—
- (a) the Health and Safety (Enforcing Authority) Regulations 1998**(2)**;
 - (b) the Health and Safety (Enforcing Authority) Regulations (Northern Ireland) 1999**(3)**;
 - (c) the Control of Substances Hazardous to Health Regulations 2002**(4)**;
 - (d) the Dangerous Substances and Explosive Atmospheres Regulations 2002**(5)**;
 - (e) the Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003**(6)**;
 - (f) the Dangerous Substances and Explosive Atmospheres Regulations (Northern Ireland) 2003**(7)**;
 - (g) the Plant Protection Products (Fees and Charges) Regulations 2011**(8)**;
 - (h) the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013**(9)**;
 - (i) the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013**(10)**;
 - (j) the Genetically Modified Organisms (Contained Use) Regulations 2014**(11)**;
 - (k) the Control of Major Accident Hazards Regulations 2015**(12)**;
 - (l) the Explosives (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2015**(13)**;
 - (m) the Biocidal Products (Fees and Charges) Regulations (Northern Ireland) 2015**(14)**;
 - (n) the Control of Major Accident Hazards Regulations (Northern Ireland) 2015**(15)**;
 - (o) the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015**(16)**;
 - (p) the Health and Safety and Nuclear (Fees) Regulations 2016**(17)**.
- (2) Schedule 2 contains amendments to the following retained direct EU legislation—
- (a) Regulation [\(EC\) No 1907/2006](#) of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH);
 - (b) Regulation [\(EC\) No 1272/2008](#) of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures;
 - (c) [Commission Regulation \(EU\) No 544/2011](#) of 10 June 2011 implementing Regulation [\(EC\) No 1107/2009](#) of the European Parliament and of the Council as regards the data requirements for active substances;

(2) S.I. 1998/494, amended by S.I. 2015/21.
(3) S.R. 1999 No. 90, amended by S.R. 2015 No. 265.
(4) S.I. 2002/2677, amended by S.I. 2015/21.
(5) S.I. 2002/2776, amended by S.I. 2015/21.
(6) S.R. 2003 No. 34, amended by S.R. 2015 No. 265.
(7) S.R. 2003 No. 152, amended by S.R. 2015 No. 265.
(8) S.I. 2011/2132, amended by S.I. 2016/254.
(9) S.I. 2013/1506.
(10) S.R. 2013 No.206.
(11) S.I. 2014/1663, amended by S.I. 2015/1637.
(12) S.I. 2015/483.
(13) S.R. 2015 No. 236.
(14) S.R. 2015 No. 254.
(15) S.R. 2015 No. 325.
(16) S.R. 2015 No. 339.
(17) S.I. 2016/253.

- (d) [Commission Regulation \(EU\) No 545/2011](#) of 10 June 2011 implementing Regulation [\(EC\) No 1107/2009](#) of the European Parliament and of the Council as regards the data requirements for plant protection products;
 - (e) [Commission Regulation \(EU\) No 547/2011](#) of 8 June 2011 implementing Regulation [\(EC\) No 1107/2009](#) of the European Parliament and of the Council as regards labelling requirements for plant protection products;
 - (f) Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products;
 - (g) Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals;
 - (h) [Commission Regulation \(EU\) No 283/2013](#) of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation [\(EC\) No 1107/2009](#) of the European Parliament and of the Council concerning the placing of plant protection products on the market;
 - (i) [Commission Regulation \(EU\) No 284/2013](#) of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation [\(EC\) No 1107/2009](#) of the European Parliament and of the Council concerning the placing of plant protection products on the market;
 - (j) Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council;
 - (k) Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of some biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council;
 - (l) Commission Implementing Regulation (EU) No 88/2014 of 31 January 2014 specifying a procedure for the amendment of Annex I to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products;
 - (m) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council.
- (3) Schedule 3 contains amendments to Part 2 of Annex II to the EEA agreement.

Revocation of [Commission Regulation \(EU\) No 440/2010](#)

3. [Commission Regulation \(EU\) No 440/2010](#) of 21 May 2010 on the fees payable to the European Chemicals Agency pursuant to Regulation [\(EC\) No 1272/2008](#) of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures is revoked.

Transitional provision in relation to Regulation [\(EC\) No 1272/2008](#)

4. A classification which, immediately before exit day, is set out in Table 3 of Annex VI to Regulation [\(EC\) No 1272/2008](#) of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures⁽¹⁸⁾ is treated as if it were approved by the Secretary of State in accordance with Article 37A of Regulation [\(EC\) No 1272/2008](#).

(18) OJ No. L 353, 31.12.2008, p. 1, as amended.

Transitional provision in relation to Regulation (EU) No 649/2012

5.—(1) A chemical which, immediately before exit day, is listed in Annex I or Annex V of Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals⁽¹⁹⁾ is treated as having been included in the UK PIC list and assigned to one or more of five groups of chemicals in the UK PIC list by the Secretary of State on exit day in accordance with Article 7 of Regulation (EU) No 649/2012.

(2) In paragraph (1), “UK PIC list” means the list established and maintained in accordance with Articles 7 and 23 of Regulation (EU) No 649/2012 as amended by Schedule 2.

25th March 2019

Justin Tomlinson
Parliamentary Under Secretary of State
Department for Work and Pensions

We consent

27th March 2019

Rebecca Harris
Craig Whittaker
Two of the Lords Commissioners of Her
Majesty’s Treasury

(19) OJ No. L 201, 27.07.2012, p. 60, as amended.

SCHEDULE 1

Regulation 2(1)

AMENDMENTS TO SUBORDINATE LEGISLATION

Health and Safety (Enforcing Authority) Regulations 1998

1.—(1) The Health and Safety (Enforcing Authority) Regulations 1998(20) are amended as follows.

(2) In regulation 2(1), in the definition of “hazardous substance or mixture”, for “laid down” substitute “as provided for”.

Health and Safety (Enforcing Authority) Regulations (Northern Ireland) 1999

2.—(1) The Health and Safety (Enforcing Authority) Regulations (Northern Ireland) 1999(21) are amended as follows.

(2) In regulation 2(1), in the definition of “hazardous substance or mixture”, for “laid down” substitute “as provided for”.

Control of Substances Hazardous to Health Regulations 2002

3.—(1) The Control of Substances Hazardous to Health Regulations 2002(22) are amended as follows.

(2) In regulation 2(1), in paragraph (a) of the definition of “substance hazardous to health”, for “laid down” substitute “as provided for”.

Dangerous Substances and Explosive Atmospheres Regulations 2002

4.—(1) The Dangerous Substances and Explosive Atmospheres Regulations 2002(23) are amended as follows.

(2) In regulation 2, in paragraph (a) of the definition of “dangerous substance”, for “laid down” substitute “as provided for”.

Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003

5.—(1) The Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003(24) are amended as follows.

(2) In regulation 2(1), in paragraph (a) of the definition of “substance hazardous to health”, for “laid down” substitute “as provided for”.

Dangerous Substances and Explosive Atmospheres Regulations (Northern Ireland) 2003

6.—(1) The Dangerous Substances and Explosive Atmospheres Regulations (Northern Ireland) 2003(25) are amended as follows.

(2) In regulation 2, in paragraph (a) of the definition of “dangerous substance”, for “laid down” substitute “as provided for”.

(20) S.I. 1998/494, amended by S.I. 2015/21.

(21) S.R. 1999 No. 90; amended by S.R. 2015 No. 265.

(22) S.I. 2002/2677, amended by S.I. 2015/21.

(23) S.I. 2002/2776, amended by S.I. 2015/21.

(24) S.R. 2003 No. 34, amended by S.R. 2015 No. 265.

(25) S.R. 2003 No. 152, amended by S.R. 2015 No. 265.

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Plant Protection Products (Fees and Charges) Regulations 2011

7. The Plant Protection Products (Fees and Charges) Regulations 2011⁽²⁶⁾ are amended in accordance with paragraphs 8 to 16.

8.—(1) Regulation 2(1) is amended as follows.

(2) Omit the definition of “the Directive”.

(3) After the definition of “liability period” insert—

““MRL compliance” means compliance with the requirements of Article 18 of the MRL Regulation;”.

(4) After the definition of “the MRL Regulation” insert—

““MRL supplementary information requirement” means information requested in accordance with Article 14(3) of the MRL Regulation;”.

(5) After the definition of “Regulation 1107/2009” insert—

““standalone MRL application” means an application which is only for the setting, modification or deletion of a maximum residue level of an active substance;”.

9. Omit regulation 3.

10.—(1) Regulation 4 is amended as follows.

(2) In paragraph (2) after “applications for import tolerances” insert “and standalone MRL applications”.

(3) After paragraph (2) insert—

“(2A) A United Kingdom competent authority may charge fees for the evaluation of supplementary information provided in accordance with Article 14(3) of the MRL Regulation and such fees are payable in accordance with Schedule 3.”

11. In regulation 6—

(a) for the heading substitute “Charge for work under the Plant Protection Products (Sustainable Use) Regulations 2012”;

(b) for “within the scope of the Directive” substitute “under the Plant Protection Products (Sustainable Use) Regulations 2012⁽²⁷⁾”.

12. In regulation 7(2)—

(a) omit “or”;

(b) at the end insert “or regulation 4(2A) and Schedule 3”.

13. In regulation 8(6) in the definition of “total costs incurred”—

(a) omit “or”;

(b) at the end insert “or regulation 4(2A) and Schedule 3”.

14.—(1) Schedule 1 is amended as follows.

(2) In paragraph 1—

(a) in the table—

(i) in item 4 in the second column, after “application⁽²⁾” omit “(3)”;

(ii) omit items 5, 5a and 5b;

⁽²⁶⁾ S.I. 2011/2132, amended by S.I. 2016/254.

⁽²⁷⁾ S.I. 2012/1657, amended by S.I. 2016/765, 2018/942.

- (iii) in item 11 in the second column, for “for lead zonal re-registration and new product applications” substitute “to discuss potential product applications”;
- (iv) omit item 12;
- (b) in the notes following the table—
 - (i) omit notes (3), (5) and (6);
 - (ii) in note (7) for “items 1-5, 10, 11 and 12” substitute “items 1-4, 10 and 11”;
 - (iii) in note (16) omit “to the United Kingdom to act as lead zonal rapporteur”;
 - (iv) omit note (17);
 - (v) in note (18) for “the United Kingdom” substitute “a United Kingdom competent authority”.
- (3) In paragraph 2—
 - (a) in the heading, for “or synergist” substitute “, synergist or basic substance”;
 - (b) in the first sentence, for “or synergist” substitute “, synergist or basic substance”;
 - (c) in the table—
 - (i) in the heading before item 1, for “or synergist” substitute “, synergist or basic substance”;
 - (ii) omit item 2;
 - (iii) in item 3 for the words in the second column substitute “Co-ordination of scientific advice and public consultation and finalising the draft assessment report”;
 - (iv) in items 7 and 10, for the words in the second column substitute “Co-ordination of scientific advice and public consultation, and finalising the draft assessment report”;
 - (v) in item 12, in the second column, after “synergist,” insert “basic substance,”;
 - (d) in the notes following the table—
 - (i) omit note (2);
 - (ii) in note (3)—
 - (aa) at the beginning insert “In relation to active substances, safeners or synergists,”;
 - (bb) after the first sentence insert “In relation to basic substances, a full data package comprises the complete dossier (the information referred to in Article 23(3) of Regulation 1107/2009) to support one or more uses of the basic substance.”;
 - (cc) in the second sentence after “the product” insert “or basic substance”;
 - (iii) in note (4)—
 - (aa) omit paragraph (c);
 - (bb) in paragraph (d) at the beginning insert “in relation to active substances, safeners or synergists,”;
 - (cc) omit paragraph (e);
 - (dd) in paragraphs (f) and (g), at the beginning insert “in relation to active substances, safeners or synergists,”;
 - (ee) after paragraph (g) insert—
 - “(h) in relation to basic substances, resubmissions (for example where the previous application for approval under Regulation 1107/2009 has been unsuccessful and a new application is made

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in an attempt to address all the concerns raised from that earlier submission);

(i) in relation to basic substances, data to support a change to the conditions of approval of the basic substance.”;

(iv) for the final sentence substitute—

“The evaluation of scientific peer reviewed open literature on the active substance or basic substance and its relevant metabolites will be treated as a partial data package.”

(4) Omit paragraph 4 (including the table, and the notes following the table, in that paragraph).

15.—(1) Schedule 2 is amended as follows.

(2) In the Schedule heading, for “fee” substitute “fees and standalone MRL application fees”.

(3) After the Schedule heading insert the paragraph heading “Fees for import tolerances”.

(4) The existing content of the Schedule (after the Schedule heading) becomes paragraph 1.

(5) In that paragraph—

(a) in the first sentence, for “product-related applications” substitute “import tolerances”;

(b) in the table, before item 1 insert—

“A1	Preliminary consideration of an application to determine whether the application can proceed further	229
A2	Co-ordination of applications	1,872”

(c) in the notes following the table—

(i) for note (1) substitute—

“(1) This category is mainly for active substances not currently approved in respect of the part of the United Kingdom to which the application relates. In certain cases it may also include active substances still being reviewed if toxicological endpoints have not yet been agreed and accepted in respect of that part of the United Kingdom.”;

(ii) in note (2)—

(aa) for “plant protection products” substitute “active substances”;

(bb) for “at a European level” substitute “and accepted in respect of the part of the United Kingdom to which the application relates”;

(iii) in note (3)—

(aa) for “plant protection products” substitute “active substances”;

(bb) for “at European level” substitute “and accepted in respect of the part of the United Kingdom to which the application relates”;

(iv) after note (3) insert—

“Fees for multiple import tolerances for the same active substance are calculated on a modular basis with a charge applied for each crop.”

(6) After that paragraph insert—

“Fees for standalone MRL applications

2. Fees for standalone MRL applications are in accordance with the following table.

<i>Item</i>	<i>Category</i>	<i>Fee (£)</i>
1	Preliminary consideration of an application to determine whether the application can proceed further	229
2	Co-ordination of applications	1,872
3	Full human health description ⁽¹⁾	16,224
4	Metabolism and residues evaluation ⁽²⁾	6,760
5	Residues evaluation ⁽³⁾	2,028

Notes

(1) This category is mainly for active substances not currently approved in respect of the part of the United Kingdom to which the application relates. In certain cases it may also include active substances still being reviewed if toxicological endpoints have not yet been agreed and accepted in respect of that part of the United Kingdom.

(2) This category is for active substances where toxicological endpoints have already been agreed and accepted in respect of the part of the United Kingdom to which the application relates but the residue definition has only been established for crop groups unrelated to the intended use.

(3) This category is for active substances where relevant toxicological endpoints and residue definition have already been agreed and accepted in respect of the part of the United Kingdom to which the application relates.

Fees for multiple standalone applications for the same active substance are calculated on a modular basis with a charge applied for each crop or combination of maximum residue levels.”

16. After Schedule 2 insert—

“SCHEDULE 3

Regulation 4(2A)

Maximum residue level supplementary information fees

Fees for the evaluation of supplementary information provided in accordance with Article 14(3) of the MRL Regulation are in accordance with the following table.

<i>Item</i>	<i>Category</i>	<i>Fee (£)</i>
1	Preliminary consideration of application to determine whether the application can proceed further	229
2	Co-ordination of applications	1,872
3	Simple reasoned case ⁽¹⁾	416
4	Analytical method ⁽²⁾	416
5	Toxicology ⁽³⁾	3,120
6	Metabolism and residues evaluation ⁽⁴⁾	6,760
7	Residues evaluation ⁽⁵⁾	2,028

Notes

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

(1) This category is for an MRL supplementary information requirement to provide additional information on aspects of the data already evaluated or to provide evidence of the commercial availability of standards for MRL compliance.

(2) This category is for an MRL supplementary information requirement to provide an analytical method for MRL compliance.

(3) This category is for an MRL supplementary information requirement to address the toxicological relevance of a metabolite identified in plants or products of animal origin.

(4) This category is for an MRL supplementary information requirement to address plant or livestock metabolism or any other nature of residue study.

(5) This category is for an MRL supplementary information requirement to provide additional residue trials or any other magnitude of residue study including monitoring data.

Fees for multiple submissions to address MRL supplementary information for the same active substance are calculated on a modular basis with a charge applied for each MRL supplementary information requirement. Large or novel studies to address MRL supplementary information requirements will incur an additional fee, as a multiple of the original fee, if significant extra work is required over and above the usual level for the module in question.”

Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013

17. The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013(28) are amended in accordance with paragraphs 18 to 29.

18. In regulation 4(1)—

- (a) in the definition of “the Biocides Regulation”, for “Annexes I to IV” substitute “Annexes II to IV”;
- (b) omit the definition of “the Commission”;
- (c) in the definition of “competent authority”, for “a Member State” substitute “the United Kingdom”;
- (d) after the definition of “devolved administration” insert—
 - ““Devolved Authority” means—
 - (a) the Scottish Ministers,
 - (b) the Welsh Ministers, or
 - (c) a Northern Ireland department;”
- (e) in the definition of “the PIC Regulation”, for “Annexes I, II, V and VI” substitute “Annexes II and VI”.

19. In regulation 6(1) omit “of Article 43”.

20. For regulation 7 substitute—

“7.—(1) For the purposes of the PIC Regulation, the Designated National Authority is—

- (a) in England, Scotland and Wales, the Great Britain Executive;
- (b) in Northern Ireland, the Northern Ireland Executive.

(2) The Designated National Authority is responsible for controlling the export and import of chemicals listed in Parts 1, 2 and 3 of the UK PIC list, in accordance with Article 18 of the PIC Regulation.

(28) S.I. 2013/1506.

(3) In paragraph (2), the “UK PIC list” means the list established and maintained in accordance with Articles 7 and 23 of the PIC Regulation.”

21. In regulation 8—

- (a) in paragraph (2) omit “or Member State”;
- (b) for paragraph (4) substitute—

“(4) The duties referred to in paragraph (3) are those contained in Articles 6(1), 7(1), 13(1) and (2)(b), 20(1), 26(1), 29(1), 31(1), 50(2), 54(1) and (2), 59(2), 62(1), 63(1), (2) and (3), 64(2), 71(3), the second subparagraph of 89(3), 93 and 95(1) of the Biocides Regulation.”

22. In regulation 13—

- (a) for paragraph (1) substitute—

“(1) In this regulation, “essential use active substance” means an active substance in respect of which the Secretary of State or a Devolved Authority has granted a derogation for essential use under Article 22 of Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council.”;

- (b) in paragraph (5)(c), for “Commission” substitute “Secretary of State or Devolved Authority”;
- (c) in paragraph (6), for “Commission makes a decision or adopts a regulation” substitute “Secretary of State or Devolved Authority issues a decision”.

23.—(1) Regulation 14 is amended as follows.

(2) In paragraph (2)—

- (a) omit sub-paragraphs (f), (g), (k) and (l);
- (b) before paragraph (m) insert—

“(la) to reject an application for non-payment of fees under Article 54(3);

(lb) to establish technical equivalence under Article 54(4);

(lc) to reject an application for failure to provide additional information under Article 54(5);”;

- (c) after paragraph (n) insert—

“(na) to give a prospective applicant data under Article 63(3);”.

(3) Omit paragraph (3).

(4) In paragraph (4)—

- (a) in sub-paragraph (a)—
 - (i) for “(g)” substitute “(e)”;
 - (ii) after “(j),” insert “(la), (lc),”;
- (b) in sub-paragraph (b) omit “and 2(l)”;
- (c) in sub-paragraph (d) omit “, (k)”.

(5) In paragraph (7), for “Commission or another competent authority” substitute “Secretary of State or a Devolved Authority”.

24. In regulation 17, for “Member State” substitute “Secretary of State”.

25. In regulation 21—

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- (a) for the heading, substitute “Duties on the Designated National Authority and the Secretary of State”;
 - (b) for “a designated national authority or the Member State” substitute “the Designated National Authority or the Secretary of State”.
- 26.** In regulation 30(1)—
- (a) in sub-paragraph (a), omit “or”;
 - (b) omit sub-paragraph (b).
- 27.** In regulation 38 omit paragraph (2).
- 28.** In Schedule 2—
- (a) in paragraph 1, in the definition of “Plant protection product”, after “91/414/EEC” insert “as it had effect immediately before exit day”;
 - (b) after paragraph 10 insert—
 - “**11.** For the purposes of regulation 13 of these Regulations, essential use derogations granted by the Commission before exit day (under either Regulation 1062/2014 or its predecessor Regulation 1451/2007 on the second phase of the 10-year work programme referred to in Article 16(2) of [Directive 98/8/EC](#) of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market) are deemed to have been granted by the Secretary of State subject to the same terms and conditions.”
- 29.** In Schedule 3, in paragraph 7, omit sub-paragraphs (c) and (d).

Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013

30. The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013(**29**) are amended in accordance with paragraphs 31 to 39.

- 31.** In regulation 4(1)—
- (a) in the definition of “the Biocides Regulation”, for “Annexes I to IV” substitute “Annexes II to IV”;
 - (b) omit the definition of “the Commission”;
 - (c) in the definition of “competent authority”, for “a Member State” substitute “the United Kingdom”;
 - (d) after the definition of “the Department concerned” insert—
 - ““Devolved Authority” means—
 - (a) the Scottish Ministers,
 - (b) the Welsh Ministers, or
 - (c) a Northern Ireland department;”.
- 32.** In regulation 6 omit “of Article 43”.
- 33.** In regulation 7—
- (a) in paragraph (2) omit “or Member State”;
 - (b) for paragraph (4) substitute—

(29) [S.R. 2013 No.206](#).

“(4) The duties referred to in paragraph (3) are those contained in Articles 6(1), 7(1), 13(1) and (2)(b), 20(1), 26(1), 29(1), 31(1), 50(2), 54(1) and (2), 59(2), 62(1), 63(1), (2) and (3), 64(2), 71(3), the second sub-paragraph of 89(3), 93 and 95(1) of the Biocides Regulation.”

34. In regulation 12—

(a) for paragraph (1) substitute—

“(1) In this regulation, “essential use active substance” means an active substance in respect of which the Secretary of State or a Devolved Authority has granted a derogation for essential use under Article 22 of Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and the Council.”;

(b) in paragraph (5)(c), for “Commission” substitute “Secretary of State or Devolved Authority”;

(c) in paragraph (6), for “Commission makes a decision or adopts a regulation” substitute “Secretary of State or Devolved Authority issues a decision”.

35.—(1) Regulation 13 is amended as follows.

(2) In paragraph (2)

(a) omit sub-paragraphs (f), (g), (k) and (l);

(b) before paragraph (m) insert—

“(la) to reject an application for non-payment of fees under Article 54(3);

(lb) to establish technical equivalence under Article 54(4);

(lc) to reject an application for failure to provide additional information under Article 54(5);”;

(c) after paragraph (n) insert—

“(na) to give a prospective applicant data under Article 63(3)”.

(3) Omit paragraph (3).

(4) In paragraph (4)—

(a) in sub-paragraph (a)—

(i) for “(g)” substitute “(e)”;

(ii) after “(j),” insert “(la), (lc),”;

(b) in sub-paragraph (b) omit “and 2(1)”;

(c) in sub-paragraph (d) omit “, (k)”.

(5) In paragraph (7), for “Commission or another competent authority” substitute “Secretary of State or a Devolved Authority”.

36. In regulation 16 for “Member State” substitute “Secretary of State”.

37. In regulation 18(1)—

(a) in sub-paragraph (a), omit “or”;

(b) omit sub-paragraph (b).

38. In Schedule 1—

(a) in paragraph 1, in the definition of “Plant protection product”, after “94/414/EEC” insert “as it had effect immediately before exit day”;

(b) after paragraph 10 insert—

“**11.** For the purposes of regulation 12 of these Regulations, essential use derogations granted by the Commission before exit day (under either Regulation 1062/2014 or its predecessor Regulation 1451/2007 on the second phase of the 10-year work programme referred to in Article 16(2) of [Directive 98/8/EC](#) of the European Parliament and the Council concerning the placing of biocidal products on the market) are deemed to have been granted by the Secretary of State subject to the same terms and conditions.”

39. In Schedule 2, in paragraph 7, omit sub-paragraphs (c) and (d).

Genetically Modified Organisms (Contained Use) Regulations 2014

40.—(1) The Genetically Modified Organisms (Contained Use) Regulations 2014⁽³⁰⁾ are amended as follows.

(2) In regulation 3(2)—

- (a) in sub-paragraph (a) omit paragraph (iii);
- (b) in sub-paragraph (b), for paragraph (i) substitute—

“(i) a medicinal product for veterinary use marketed in accordance with the Veterinary Medicines Regulations 2013⁽³¹⁾”.

(3) After regulation 33 insert—

“Transitional provision in relation to the withdrawal of the United Kingdom from the European Union

33A.—(1) Subject to paragraphs (2) and (3), these Regulations do not apply to any activity which is covered by a written consent given by a competent authority of an EEA State in accordance with Article 15(3), 17(6) or 18(2) of [Directive \(EC\) No 2001/18](#) of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms⁽³²⁾.

(2) The written consent referred to in paragraph (1) must be valid immediately before exit day.

(3) Any activity covered by the consent referred to in paragraph (1) must be conducted in accordance with any obligations, conditions or limitations attached to that consent.

(4) Subject to paragraphs (5) and (6), these Regulations do not apply to any genetically modified organisms which are cultured, stored, transported, destroyed, disposed of or used, where such organisms are, or are contained in, a medicinal product for human or veterinary use marketed in accordance with an authorisation under [Regulation \(EC\) No 726/2004](#) of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

(5) The marketing authorisation referred to in paragraph (4) must be valid immediately before exit day.

(6) Any marketing authorisation referred to in paragraph (4) must be conducted in accordance with any obligations, conditions, restrictions, requirements or limitations attached to that authorisation.”

(4) In Schedule 3, in paragraph 3 for sub-paragraph (d) substitute—

⁽³⁰⁾ [S.I. 2014/1663](#), amended by [S.I. 2015/1637](#).

⁽³¹⁾ [S.I. 2013/2033](#), amended by [S.I. 2014/599](#), [2018/761](#).

⁽³²⁾ OJ No. L 106, 17.04.2001, p.1.

- “(d) consideration of relevant legislation, including legislation on the protection of workers from risks related to exposure to biological agents at work, other classification schemes referring to plant and animal pathogens, and other international and national classification schemes for genetically modified micro-organisms;”.

Control of Major Accident Hazards Regulations 2015

41.—(1) The Control of Major Accident Hazards Regulations 2015(**33**) are amended as follows.

(2) In regulation 2(1), in the definition of “the CLP Regulation”, for “Annex VI, Part 3 Table 3.1” substitute “the UK mandatory classification and labelling list established under Article 38A (which for the purposes of these Regulations is deemed to be part of Regulation (EC) No. 1272/2008)”.

Explosives (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2015

42.—(1) The Explosives (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2015(**34**) are amended as follows.

(2) In regulation 3—

- (a) in the definition of “the CLP Regulation” omit the words from “, of which” to the end;
- (b) in the definition of “competent authority”, for “a Member State” substitute “the United Kingdom”.

(3) In regulation 4 omit “of Article 43”.

(4) In regulation 5(1) for “Member State” substitute “the Secretary of State”.

(5) In regulation 7(1)—

- (a) at the end of sub-paragraph (a), omit “or”;
- (b) omit sub-paragraph (b).

(6) In Schedule 1 in paragraph 7 omit sub-paragraphs (c) and (d).

Biocidal Products (Fees and Charges) Regulations (Northern Ireland) 2015

43.—(1) The Biocidal Products (Fees and Charges) Regulations (Northern Ireland) 2015(**35**) are amended as follows.

(2) In regulation 2(1), after the definition of “the Executive” insert—

““Regulation 354/2013” means Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council;

“Regulation 1062/2014” means Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council.”

(3) Omit regulation 3.

(4) In regulation 4, for paragraph (1) substitute—

“(1) The Executive shall charge fees for—

(33) S.I. 2015/483.

(34) S.R. 2015 No. 236.

(35) S.R. 2015 No. 254

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

- (a) work it carries out within the scope of the Biocides Regulation which relates to the activities listed in column 1 of the Table in the Schedule;
- (b) work it carries out in order to evaluate an application for a change to an authorised product under Regulation 354/2013;
- (c) work it carries out in order to determine an application to be a participant for the review of an active substance/product-type combination under Article 17 of Regulation 1062/2014; and
- (d) work it carries out in order to evaluate an application under regulation 12 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013(36).”
- (5) In the Schedule, for the table substitute—

“Table

<i>I</i>	<i>2</i>
<i>Activity</i>	<i>Fee per person per day worked</i>
(a) Validation of an application for approval of an active substance	£447
(b) Evaluation of an application to approve an active substance	£447
(c) Evaluation of an application to renew an active substance approval	£447
(d) Validation of an application to amend the conditions of approval of an active substance	£447
(e) Evaluation of an application to amend the conditions of approval of an active substance	£447
(f) Work relating to a request for inclusion of an active substance in the Simplified Active Substance List made on behalf of an economic operator	£447
(g) Validation of an application to amend the conditions of inclusion of an active substance in the Simplified Active Substance List	£447
(h) Evaluation of an application to amend the conditions of inclusion of an active substance in the Simplified Active Substance List	£447
(i) Meetings with applicants and prospective applicants	£447
(j) Evaluation of an application to authorise a biocidal product under the simplified procedure	£393
(k) Validation of an application for a national authorisation of a biocidal product	£393
(l) Evaluation of an application for a national authorisation of a biocidal product	£393
(m) Evaluation of an application to renew a national authorisation of a biocidal product	£393
(n) Determination of an application to amend an existing biocidal product authorisation	£393
(o) Evaluation of an application for an emergency use permit	£393

(36) S.R. 2013 No. 206.

<i>I</i>	<i>2</i>
<i>Activity</i>	<i>Fee per person per day worked</i>
(p) Assessment of an application to be included in the list of suppliers maintained under Article 95 of Regulation 528/2012	£447
(q) Determination of a request that information on an active substance or product is not made publicly available	£447
(r) Determination of the classification of a proposed change to an authorised product in accordance with Regulation 354/2013	£393
(s) Determination of an application to be a participant for the review of an active substance/product-type combination under Article 17 of Regulation 1062/2014	£447
(t) Assessment of technical equivalence	£447
(u) Evaluation of an application under regulation 12 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013	£393”

The Control of Major Accident Hazards Regulations (Northern Ireland) 2015

44.—(1) The Control of Major Accident Hazards Regulations (Northern Ireland) 2015(37) are amended as follows.

(2) In regulation 2(1), in the definition of “the CLP Regulation”, for “Annex VI, Part 3 Table 3.1” substitute “the UK mandatory classification and labelling list established under Article 38A (which for the purposes of these Regulations is deemed to be part of Regulation (EC) No. 1272/2008)”.

Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015

45.—(1) The Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015(38) are amended as follows.

(2) In regulation 3(2)—

(a) in sub-paragraph (a)—

(i) in paragraph (ii) omit “or”;

(ii) omit paragraph (iii);

(b) in sub-paragraph (b), for paragraph (i) substitute—

“(i) a medicinal product for veterinary use marketed in accordance with the Veterinary Medicines Regulations 2013(39);”.

(3) After regulation 33 insert—

“Transitional provision in relation to the withdrawal of the United Kingdom from the European Union

33A.—(1) Subject to paragraphs (2) and (3), these Regulations do not apply to any activity which is covered by a written consent given by a competent authority of an EEA State in accordance with Article 15(3), 17(6) or 18(2) of Directive (EC) No 2001/18 of the European

(37) S.R. 2015 No. 325.

(38) S.R. 2015 No. 339.

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

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

Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms⁽⁴⁰⁾.

(2) The written consent referred to in paragraph (1) must be valid immediately before exit day.

(3) Any activity covered by the consent referred to in paragraph (1) must be conducted in accordance with any obligations, conditions or limitations attached to that consent.

(4) Subject to paragraphs (5) and (6), these Regulations do not apply to any genetically modified organisms which are cultured, stored, transported, destroyed, disposed of or used, where such organisms are, or are contained in, a medicinal product for human or veterinary use marketed in accordance with an authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

(5) The marketing authorisation referred to in paragraph (4) must be valid immediately before exit day.

(6) Any marketing authorisation referred to in paragraph (4) must be conducted in accordance with any obligations, conditions, restrictions, requirements or limitations attached to that authorisation.”

(4) In Schedule 3, in paragraph 3 for sub-paragraph (d) substitute—

“(d) consideration of relevant legislation, including legislation on the protection of workers from risks related to exposure to biological agents at work, other classification schemes referring to plant and animal pathogens, and other international and national classification schemes for genetically modified micro-organisms;”.

Health and Safety and Nuclear (Fees) Regulations 2016

46.—(1) The Health and Safety and Nuclear (Fees) Regulations 2016⁽⁴¹⁾ are amended as follows.

(2) In regulation 21—

(a) omit paragraph (1);

(b) for paragraph (2) substitute—

“(2) Each competent authority must charge fees for—

(a) work it carries out within the scope of the Biocides Regulation which relates to the activities listed in column 1 of Schedule 15;

(b) work it carries out in order to evaluate an application for a change to an authorised product under Regulation 354/2013;

(c) work it carries out in order to determine an application to be a participant for the review of an active substance/product-type combination under Article 17 of Regulation 1062/2014; and

(d) work it carries out in order to evaluate an application under regulation 13 of the 2013 Biocidal Products and Chemicals Regulations.”;

(c) in paragraph (12), after the definition of “competent authority” insert—

““Regulation 354/2013” means Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council; and

⁽⁴⁰⁾ OJ No L 106, 17.04.2001, p. 1.

⁽⁴¹⁾ S.I. 2016/253.

“Regulation 1062/2014” means Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council.”

(3) After regulation 21 insert—

“Fees payable for activities under the CLP Regulation

21A.—(1) The Agency⁽⁴²⁾ may charge fees for work it carries out within the scope of the CLP Regulation which relates to the activities listed in column 1 of Schedule 16.

(2) Any fee payable under paragraph (1) must be calculated in accordance with paragraphs (3) to (9).

(3) Where a fee is payable under paragraph (1), the Agency must prepare and send to the person referred to in column 2 of Schedule 16 (“the applicant”) an estimate of the fee, which will be at least £5000.

(4) The applicant must pay the Agency the amount of that estimate within 30 days of its issue.

(5) Upon completion of the work, the Agency must prepare a detailed statement of the work carried out and of the cost incurred by the Agency or any person acting on its behalf in carrying out that work.

(6) If the cost referred to in paragraph (5) is greater than the amount estimated in accordance with paragraph (3), the Agency must notify the amount of the difference to the applicant who must pay the amount of the difference, which will be the final fee payable, without delay.

(7) If the cost referred to in paragraph (5) is less than the amount estimated in accordance with paragraph (3), the fee must be adjusted accordingly and the amount of the difference must be paid without delay by the Agency to the applicant.

(8) Subject to paragraph (9), in estimating or stating the cost of carrying out any work, the Agency must determine that cost by reference to the daily rate per person specified in column 3 of Schedule 16 that corresponds to the activity listed in column 1.

(9) The daily rate per person must be adjusted pro rata for a period worked of less than 7.4 hours on any one day by—

- (a) dividing the daily rate by 14.8 to create a half-hourly rate; and
- (b) multiplying that figure by the number of half hours worked, rounded up or down to the nearest half hour.

(10) Any unpaid fees may be recovered by the Agency as a civil debt.

(11) For the purposes of this regulation and Schedule 16 “the CLP Regulation” means Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures.

(12) Expressions used in the CLP Regulation which are also used in this regulation or Schedule 16 have the same meaning in these Regulations as they have in the CLP Regulation.”

(4) In Schedule 15, for the table substitute—

(42) The definition of Agency in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures is being amended to mean the Health and Safety Executive by amendments made elsewhere in these Regulations.

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

<i>Activity</i>	<i>Fee per person per day worked</i>
(a) Validation of an application for approval of an active substance	£465
(b) Evaluation of an application to approve an active substance	£465
(c) Evaluation of an application to renew an active substance approval	£465
(d) Validation of an application to amend the conditions of approval of an active substance	£465
(e) Evaluation of an application to amend the conditions of approval of an active substance	£465
(f) Work relating to a request for inclusion of an active substance in the Simplified Active Substance List made on behalf of an economic operator	£465
(g) Validation of an application to amend the conditions of inclusion of an active substance in the Simplified Active Substance List	£465
(h) Evaluation of an application to amend the conditions of inclusion of an active substance in the Simplified Active Substance List	£465
(i) Meetings with applicants and prospective applicants	£465
(j) Evaluation of an application to authorise a biocidal product under the simplified procedure	£409
(k) Validation of an application for a national authorisation of a biocidal product	£409
(l) Evaluation of an application for a national authorisation of a biocidal product	£409
(m) Evaluation of an application to renew a national authorisation of a biocidal product	£409
(n) Determination of an application to amend an existing biocidal product authorisation	£409
(o) Evaluation of an application for an emergency use permit	£409
(p) Assessment of an application to be included in the list of suppliers maintained under Article 95 of the Biocides Regulation	£465
(q) Determination of a request that information on an active substance or product is not made publicly available	£465
(r) Determination of the classification of a proposed change to an authorised product in accordance with Regulation 354/2013	£409
(s) Determination of an application to be a participant for the review of an active substance/product-type combination under Article 17 of Regulation 1062/2014	£465
(t) Assessment of technical equivalence	£465
(u) Evaluation of an application under regulation 13 of the 2013 Biocidal Products and Chemicals Regulations	£409

(5) After Schedule 15 insert—

“SCHEDULE 16

Regulation 21A

FEES FOR ACTIVITIES IN RESPECT OF WHICH A FEE IS
PAYABLE AND DAILY RATE UNDER THE CLP REGULATION

<i>1</i>	<i>2</i>	<i>3</i>
<i>Activity</i>	<i>Person by whom fee is payable</i>	<i>Fee</i>
Consideration of a proposal submitted under sub paragraph (1) of paragraph 3 of Article 37A	Person submitting the application	£465”

SCHEDULE 2

Regulation 2(2)

AMENDMENTS TO RETAINED DIRECT EU LEGISLATION

Regulation (EC) No 1907/2006

1. [Commission Regulation \(EC\) No 1907/2006](#) of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending [Directive 1999/45/EC](#) and repealing [Council Regulation \(EEC\) No 793/93](#) and [Commission Regulation \(EC\) No 1488/94](#) as well as Council [Directive 76/769/EEC](#) and Commission Directives [91/155/EEC](#), [93/67/EEC](#), [93/105/EC](#) and [2000/21/EC](#) is amended in accordance with paragraphs 2 to 11.

2. In Article 3, after paragraph 41 insert—

“42. UK mandatory classification and labelling list: the list of mandatory classification and labelling requirements of substances and groups of substances established and maintained in accordance with Article 38A of Regulation [\(EC\) No 1272/2008](#).

43. UK notification database: the database established in accordance with Article 42 of Regulation [\(EC\) No 1272/2008](#).”

3. In Article 15, for paragraph 2 substitute—

“2. Active substances manufactured or imported for use in biocidal products only and included either in the UK List or the Simplified Active Substance List defined in Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products or Annex II of Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council, subject to the transitional measures detailed in Article 89 of Regulation (EU) No 528/2012, shall be regarded as being registered and the registration as completed for manufacture or import for the use in a biocidal product and therefore as fulfilling the requirements of Chapters 1 and 5 of this Title.”

4. In Article 59, in paragraphs 2 and 3, for “Part 3 of Annex VI to Regulation [\(EC\) No 1272/2008](#)” substitute “the UK mandatory classification and labelling list”.

5. In Annex I—

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

- (a) in point 1.3.1, for “Part 3 of Annex VI to Regulation (EC) No 1272/2008” substitute “the UK mandatory classification and labelling list”;
 - (b) in point 3.2.1, for “Part 3 of Annex VI to Regulation (EC) No 1272/2008” substitute “the UK mandatory classification and labelling list”.
- 6.** In Annex II—
- (a) in point 3.2.1(a)(ii) and (iii), for “Part 3 of Annex VI to Regulation (EC) No 1272/2008” substitute “the UK mandatory classification and labelling list”;
 - (b) in point 3.2.1(a)(iv) and (vi), for “classification and labelling inventory” substitute “UK notification database”.
- 7.** In Annex XVII—
- (a) in entries 28 to 30 of the table (certain substances that are carcinogens, cell mutagens or toxic to reproduction)—
 - (i) for “Part 3 of Annex VI to Regulation (EC) No 1272/2008” wherever it occurs substitute “the UK mandatory classification and labelling list”;
 - (ii) omit “(Table 3.1)” and “(Table 3.2)” wherever they occur;
 - (b) in entry 40 of the table (certain flammable substances etc.), in the first column, for “Part 3 of Annex VI to Regulation (EC) No 1272/2008” substitute “the UK mandatory classification and labelling list”.
- 8.**—(1) The foreword to Appendices 1 to 6 is amended as follows.
- (2) In the first paragraph of the section headed “substances”, for “Part 3 of Annex VI” to the end of the paragraph substitute “the UK mandatory classification and labelling list”.
 - (3) In the section headed “entries for groups of substances”—
 - (a) for “Part 3 of Annex VI to Regulation (EC) No 1272/2008” wherever it occurs substitute “the UK mandatory classification and labelling list”;
 - (b) in the second paragraph, for “elsewhere in Annex VI to Regulation (EC) No 1272/2008” substitute “elsewhere in the UK mandatory classification and labelling list”.
 - (4) In the section headed “Index number”, for “Part 3 of Annex VI to Regulation (EC) No 1272/2008” substitute “the UK mandatory classification and labelling list”.
 - (5) In Note A, for “Part 3 of Annex VI to that Regulation” substitute “the UK mandatory classification and labelling list”.
 - (6) In Note D, for “Part 3 of Annex VI to Regulation (EC) No 1272/2008” substitute “the UK mandatory classification and labelling list”.
- 9.** In the heading of Appendix 1 omit “(Table 3.1)” and “(Table 3.2)”.
- 10.**—(1) Appendix 2 is amended as follows.
- (2) In the heading omit “(Table 3.1)” and “(Table 3.2)”.
 - (3) In the entry for “chromium (VI) compounds”, for “Annex VI to Regulation (EC) No 1272/2008” substitute “the UK mandatory classification and labelling list”.
 - (4) In the entry for “benzidine based azo dyes”, for “Annex VI to Regulation (EC) No 1272/2008” substitute “the UK mandatory classification and labelling list”.
 - (5) In the entry for “o-Dianisidine based azo dyes”, for “Annex VI to Regulation (EC) No 1272/2008” substitute “the UK mandatory classification and labelling list”.
 - (6) In the entry for “o-Tolidine based dyes”, for “Annex VI to Regulation (EC) No 1272/2008” substitute “the UK mandatory classification and labelling list”.

11. In the headings of Appendices 3, 4, 5 and 6, omit “(Table 3.1)” and “(Table 3.2)”.

Regulation (EC) No 1272/2008

12. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EEC, and amending Regulation (EC) No 1907/2006 is amended in accordance with paragraphs 13 to 57.

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

(2) In paragraph 1—

- (a) in the first sentence, omit “as well as the free movement of substances, mixtures and articles as referred to in Article 4(8)”;
- (b) in point (a), for “harmonising” substitute “establishing”;
- (c) in point (d), for “harmonised classifications and labelling elements at Community level in Part 3 of Annex VI” substitute “mandatory classifications and labelling elements in the UK mandatory classification and labelling list”;
- (d) in point (e), for “classification and labelling inventory of substances, which is made up of all notifications, submissions and harmonised classification and labelling elements referred to in points (c) and (d)” substitute “UK notification database of substances notified to the Agency after exit day”.

(3) In paragraph 2—

- (a) in point (a), for “Council Directive 96/29/Euratom of 13 May 1996” substitute “the Ionising Radiations Regulations 2017(43) and the Ionising Radiations Regulations (Northern Ireland) 2017(44)”;
- (b) in point (d), omit “Community”.

(4) In paragraph 3, for “Directive 2006/12/EC of the European Parliament and of the Council of 5 April 2006” substitute “Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008”.

(5) Omit paragraph 4.

(6) In paragraph 5—

- (a) in point (a), for “Directive 2001/83/EC” substitute “the Human Medicines Regulations 2012(45)”;
- (b) in point (b), for “Directive 2001/82/EC” substitute “the Veterinary Medicines Regulations 2013(46)”;
- (c) in point (c), for “Directive 76/768/EEC” substitute “Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products”;
- (d) for point (d), substitute—
 - “(d) medical devices as defined in the Medical Devices Regulations 2002(47) which are invasive or used in direct physical contact with the human body, and in vitro diagnostic medical devices, as defined in the same regulations.”;
- (e) in point (e)—

(43) S.I. 2017/1075.

(44) S.R. 2017 No.229.

(45) S.I. 2012/1916.

(46) S.I. 2013/2033.

(47) S.I. 2002/618.

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

- (i) in paragraph (i), for “[Directive 89/107/EEC](#)” substitute “[Regulation \(EC\) No 1333/2008](#) of the European Parliament and of the Council of 16 December 2008 on food additives”;
- (ii) in paragraph (ii), for “[Directive 88/388/EEC](#) and [Decision 1999/217/EC](#)” substitute “[Regulation \(EC\) No 1334/2008](#) of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods or Commission implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances provided for by [Regulation \(EC\) 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 and repealing [Commission Regulation \(EC\) No 1565/2000](#) and Commission Regulation [1999/217/EC](#)”;
- (iii) in paragraph (iv), for “[Directive 82/471/EEC](#)” substitute “[Regulation \(EC\) No 767/2009](#) of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed”.

14. In Article 2—

- (a) in paragraphs 10, 15 (in each place it occurs), 16, 17, 19 and 20, for “Community” substitute “United Kingdom”;
- (b) in paragraph 23, for “European Chemicals Agency established by [Regulation \(EC\) No 1907/2006](#)” substitute “Health and Safety Executive”;
- (c) in paragraph 24, for “established by the Member States to carry out the obligations arising from this Regulation” substitute “appointed to carry out the obligations arising from this Regulation, by the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013⁽⁴⁸⁾ or the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013⁽⁴⁹⁾ or (in relation to explosives) the Explosives (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2015⁽⁵⁰⁾”;
- (d) after paragraph 37, insert—

“**38.** “UK mandatory classification and labelling list” means the list of mandatory classification and labelling requirements of substances and groups of substances established and maintained in accordance with Article 38A;

39. “UK notification database” means the database established in accordance with Article 42;

40. “European Chemicals Agency” means the Agency established by Article 75 of [Regulation \(EC\) No 1907/2006](#)⁽⁵¹⁾ as it has effect in EU law as amended from time to time;

41. “EU CLP Regulation” means [Regulation \(EC\) No 1272/2008](#) of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing [Directives 67/548/EEC](#) and [1999/45/EEC](#), and amending [Regulation \(EC\) No 1907/2006](#)⁽⁵²⁾, as it has effect in EU law as amended from time to time.

42. ‘Devolved Authority’ means:

⁽⁴⁸⁾ S.I. 2013/1506.

⁽⁴⁹⁾ S.R. 2013 No. 206.

⁽⁵⁰⁾ S.R. 2015 No.236.

⁽⁵¹⁾ OJ No. L 396, 30.12.2006, p.1.

⁽⁵²⁾ OJ No. L 353, 31.12.2008, p.1.

- (a) the Scottish Ministers,
- (b) the Welsh Ministers, or
- (c) a Northern Ireland department.”

15. In Article 4, in paragraph 3—

- (a) in the first subparagraph, for “harmonised” substitute “mandatory”, and for “Part 3 of Annex VI”, substitute “the UK mandatory classification and labelling list”;
- (b) in the second subparagraph, for “Part 3 of Annex VI”, substitute “the UK mandatory classification and labelling list”.

16. In Article 7, in paragraph 1, for “within the meaning of [Directive 86/609/EEC](#)” substitute “to which the Animals (Scientific Procedures) Act 1986(53) applies”.

17. In Article 10—

- (a) in paragraph 3, for “harmonised” substitute “mandatory” and for “Part 3 of Annex VI” substitute “the UK mandatory classification and labelling list”;
- (b) in paragraph 4—
 - (i) in the first subparagraph, for “harmonised” substitute “mandatory” and for “Part 3 of Annex VI” substitute “the UK mandatory classification and labelling list”;
 - (ii) in the second subparagraph, for “Part 3 of Annex VI” substitute “the UK mandatory classification and labelling list”;
- (c) in paragraph 5, for “classification and labelling inventory” substitute “UK notification database”.

18. In Article 15—

- (a) in paragraph 4, for “harmonised” substitute “mandatory” and for “Part 3 of Annex VI” substitute “the UK mandatory classification and labelling list”;
- (b) in paragraph 5, for “[Directive 91/414/EEC](#) or [Directive 98/8/EC](#)” substitute “[Regulation \(EC\) No 1107/2009](#) or [Regulation \(EC\) No 528/2012](#)”, and for “Directives” substitute “Regulations”.

19. Omit Article 16.

20. In Article 17, in paragraph 2—

- (a) in the first subparagraph, for “the official language(s) of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise” substitute “English”;
- (b) in the second subparagraph, for “those required by the Member States” substitute “English”.

21. In Article 18, in paragraph 2—

- (a) in point (a), for “Part 3 of Annex VI” substitute “the UK mandatory classification and labelling list”;
- (b) in point (b), for “Part 3 of Annex VI” substitute “the UK mandatory classification and labelling list” and for “classification and labelling inventory” substitute “UK notification database”;
- (c) in point (c), for “Part 3 of Annex VI nor the classification and labelling inventory” substitute “the UK mandatory classification and labelling list nor the UK notification database”.

(53) [1986 c. 14](#).

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

- 22.** In Article 21, in paragraph 3, for “Part 3 of Annex VI” substitute “the UK mandatory classification and labelling list”.
- 23.** In Article 24—
- (a) in paragraph 2—
 - (i) for “referred to in Article 111 of Regulation (EC) No 1907/2006 and shall” substitute “specified by the Agency. The Agency may require the request to”;
 - (ii) omit the second subparagraph;
 - (b) for paragraph 4, substitute—

“4. If the Agency does not accept the request, the manufacturer, importer or downstream user may ask the Agency to review its decision.”;
 - (c) omit paragraph 5;
 - (d) in paragraph 6, for “practical arrangements referred to in Article 118(3) of Regulation (EC) No 1907/2006 shall apply”, substitute “manufacturer, importer or downstream user may ask the Agency to review the withdrawal or amendment.”
- 24.** In Article 25—
- (a) in paragraph 1, in the third subparagraph, for “Part 3 of Annex VI” substitute “the UK mandatory classification and labelling list”;
 - (b) in paragraph 2, in the first subparagraph, for “Directive 91/414/EEC” substitute “Regulation (EC) No 1107/2009”.
- 25.** In Article 26, in paragraph 2, in the second subparagraph, for “Part 3 of Annex VI” substitute “the UK mandatory classification and labelling list”.
- 26.** In Article 29—
- (a) in paragraph 1, omit “in the languages of the Member State in which the substance or mixture is placed on the market”;
 - (b) in paragraph 5, for “Commission” substitute “Secretary of State or a Devolved Authority”.
- 27.** In Article 30, in paragraph 3—
- (a) for “Directives 91/414/EEC or 98/8/EC” substitute “Regulation (EC) No 1107/2009 or Regulation (EC) No 528/2012”;
 - (b) for “Directives” substitute “Regulations”.
- 28.** In Article 32—
- (a) in paragraphs 2 and 3, after “language” in each place it occurs, insert “,where languages other than English are used”;
 - (b) in paragraph 6, for “Community Acts” substitute “retained EU law”.
- 29.** Omit Article 34.
- 30.** For the heading of Title V substitute “MANDATORY CLASSIFICATION AND LABELLING OF SUBSTANCES AND THE UK NOTIFICATION DATABASE”.
- 31.** For the heading of Chapter 1 in Title V substitute “Establishing mandatory classification of substances”.
- 32.** In Article 36—
- (a) in the heading, for “Harmonisation of” substitute “Mandatory”.
 - (b) in paragraph 1—
 - (i) for “harmonised” substitute “mandatory”;

- (ii) after “Article 37” insert “or Article 37A”;
 - (c) in paragraph 2—
 - (i) for “[Directive 91/414/EEC](#) or [Directive 98/8/EC](#)” substitute “[Regulation \(EC\) No 1107/2009](#) or [Regulation \(EC\) No 528/2012](#)”;
 - (ii) for “harmonised” substitute “mandatory”;
 - (iii) after “Article 37” insert “or Article 37A”;
 - (iv) omit “paragraphs 1, 4, 5 and 6”;
 - (d) in paragraph 3—
 - (i) for “harmonised” substitute “mandatory”;
 - (ii) after “classification and labelling”, insert “requirement”;
 - (iii) after “Article 37” insert “or Article 37A”;
 - (iv) for “Annex VI”, substitute “the UK mandatory classification and labelling list”;
 - (v) omit “at Community level”.
- 33.** For Article 37, substitute—

“Article 37

Procedure for mandatory classification and labelling where the EU Risk Assessment Committee publishes an opinion

1. This Article applies in relation to a substance—
 - (a) on which the Committee for Risk Assessment of the European Chemicals Agency (“the Committee”) publishes an opinion under Article 37(4) of the EU CLP Regulation on or after exit day; or
 - (b) on which the Committee has published an opinion under Article 37(4) of the EU CLP Regulation before exit day, but which has not, as at exit day, been included in Part 3 of Annex VI of the CLP Regulation.
2. Within 6 months of the publication of the Committee’s opinion, the Agency must publish its own opinion.
3. Where the Agency’s opinion recommends aligning with the Committee’s opinion that there should be a change—
 - (a) the Agency must, within 12 months of the publication of its opinion, submit a recommendation to the Secretary of State to give effect to the classification and labelling requirement set out in the Agency’s opinion, and must send a copy of that recommendation to each of the Devolved Authorities;
 - (b) the Secretary of State must decide whether to accept that recommendation and must publish that decision, together with the reasons for that decision, and specifying the date when any new or revised classification and labelling requirement is to be included in the UK mandatory classification and labelling list;
 - (c) the Secretary of State’s function under point (b) is subject to the consent requirement in Article 53B;
 - (d) the Agency must without undue delay update the UK mandatory classification and labelling list in accordance with the Secretary of State’s decision.

4. Where the Agency’s opinion does not recommend aligning with the Committee’s opinion, the Agency may produce a proposal under paragraph 2 of Article 37A for a new or revised mandatory classification and labelling requirement.”

34. After Article 37, insert—

“Article 37A

Procedure where Article 37(1) does not apply

1. This Article applies in relation to substances to which Article 37(1) does not apply.

2.—(1) The Agency may produce a proposal for a new or revised mandatory classification and labelling requirement and, where appropriate, specific concentration limits or M-factors.

(2) A Competent Authority may submit to the Agency a proposal for a new or revised mandatory classification and labelling requirement and, where appropriate, specific concentration limits or M-factors.

(3) A proposal under sub-paragraph (1) or (2) must follow the format set out in Part 2 of Annex VI and contain the relevant information provided for in Part 1 of Annex VI.

3.—(1) A manufacturer, importer or downstream user of a substance may submit to the Agency a proposal for a mandatory classification of that substance, and, where appropriate, specific concentration limits or M-factors, provided that there is no entry in the UK mandatory classification and labelling list for such substance in relation to the hazard class or differentiation covered by that proposal.

(2) A manufacturer, importer or downstream user who has new information which may lead to a change of the mandatory classification and labelling elements of a substance in the UK mandatory classification and labelling list must submit a proposal to the Agency for a revised classification.

(3) A proposal under subparagraph (1) or (2) must follow the format set out in Part 2 of Annex VI and contain the relevant information provided for in Part 1 of Annex VI.

(4) Where a proposal under subparagraph (1) concerns the mandatory classification and labelling of a substance in accordance with Article 36(3), it must be accompanied by a fee.

4. Within 12 months of a proposal being received by or produced by the Agency, the Agency must publish an opinion on the proposal, after giving the parties concerned the opportunity to comment.

5. Where the Agency considers that it is appropriate to impose or revise a mandatory classification and labelling requirement, it must within 12 months submit a recommendation to the Secretary of State to give effect to the opinion, and must send a copy to each of the Devolved Authorities.

6. The Secretary of State must decide whether to accept the recommendation and must publish that decision, together with the reasons for that decision, specifying the date when any new or revised classification is to be included on the UK mandatory classification and labelling list.

7. The Secretary of State’s function under paragraph 6 is subject to the consent requirement in Article 53B.

8. Where the Secretary of State’s decision is to accept the recommendation, the Agency must without undue delay amend the UK mandatory classification and labelling list in accordance with that decision.”

35. In Article 38—

(a) in the heading, for “harmonised” substitute “mandatory” and for “Part 3 of Annex VI” substitute “the UK mandatory classification and labelling list”;

(b) before paragraph 1, insert a new paragraph—

“A1. Any opinion of the Agency referred to in Article 37 must specify the reasons for the opinion.”;

(c) in paragraph 1, for “referred to in Article 37(4) and any decision according to Article 37(5)” substitute “of the Agency referred to in Article 37A”;

(d) for paragraph 2, substitute—

“2. When making publicly available an opinion or a decision as referred to in Article 37 or Article 37A, the Agency must not publish any information in relation to which paragraph 3 applies.”;

(e) after paragraph 2, insert—

“3. This paragraph applies to information which has been made available to the Agency in relation to which a person has submitted a justification, accepted by the Agency as valid, as to why publication of the information is potentially harmful to the commercial interests of that person or any other person.”

36. After Article 38, insert—

“Article 38A

UK mandatory classification and labelling list

The Agency must establish, maintain and publish electronically a list (to be called “the UK mandatory classification and labelling list”) of all the mandatory classifications and accompanying labelling requirements made by the Secretary of State in accordance with Article 37 and Article 37A.”

37. For the heading to Chapter 2 substitute “UK notification database”.

38. In Article 39 in point (b), omit “or [Directive 1999/45/EC](#)”.

39. In Article 40, in paragraph 1—

(a) in the first subparagraph, for “inventory” substitute “UK notification database”;

(b) in the second subparagraph, in the first sentence, after “notifier” insert “or has been notified before exit day to the European Chemicals Agency under Article 40 of Regulation [\(EC\) 1272/2008](#) of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures.”;

(c) in the third subparagraph, for “pursuant to Article 111 of Regulation [\(EC\) No 1907/2006](#), substitute “by the Agency”.

40. In Article 41, for “inventory” in both places it occurs, substitute “UK notification database”.

41. In Article 42—

(a) in the heading, for “classification and labelling inventory” substitute “UK notification database”;

- (b) in paragraph 1—
 - (i) in the first subparagraph, for “a classification and labelling inventory in the form of a database” substitute “a database, (to be called “the UK notification database”);”;
 - (ii) in the second subparagraph, for “inventory, as well as information submitted as part of registrations under Regulation (EC) No 1907/2006”, substitute “UK notification database”;
 - (iii) for the third subparagraph, substitute—
 - “Information in the UK notification database which corresponds to the information referred to in Article 38(1) is to be made publicly accessible by the Agency except where Article 38(3) applies to that information.”;
 - (c) in paragraph 2, for “inventory” substitute “UK notification database”;
 - (d) in paragraph 3, in the first subparagraph—
 - (i) for point (a), substitute—
 - “(a) whether in respect of the entry, there is mandatory classification and labelling by inclusion in the UK mandatory classification and labelling list;”;
 - (ii) omit points (b), (c) and (d);
 - (e) in paragraph 3, in the second subparagraph, for “37(5)” substitute “37(3)(b) and Article 37A(6)”.
- 42.** For the heading to Title VI, substitute “HELPDESK AND APPOINTMENT OF BODIES”.
- 43.** Omit Article 43.
- 44.** In Article 44, for “Member States shall establish national helpdesks” substitute “The Agency must establish a helpdesk”.
- 45.** In Article 45—
- (a) in paragraph 1, for “Member States” substitute “The Secretary of State in relation to England, and the Devolved Authorities in relation to their respective countries”;
 - (b) after paragraph 1, insert—
 - “**1A.** The Secretary of State may carry out the function set out in paragraph 1 in relation to Scotland, Wales or Northern Ireland, if the Devolved Authority in question has consented to the Secretary of State exercising that function.”;
 - (c) in paragraph 2, in point (b), for “Member State” substitute “Secretary of State or the relevant Devolved Authority”;
 - (d) omit paragraph 4.
- 46.** Omit Articles 46 and 47.
- 47.** In Article 48, in paragraph 2, in the second subparagraph, for “Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997” substitute “the Consumer Contracts (Information, Cancellation and Additional Charges) Regulations 2013(**54**)”.
- 48.** In Article 49, in paragraph 3—
- (a) in the first subparagraph, omit “or the enforcement authorities of a Member State in which a supplier is established”;
 - (b) in the second subparagraph, omit “and the authority shall address itself to the Agency”.

(54) S.I. 2013/3134.

- 49.** In Article 50—
- (a) omit paragraph 1;
 - (b) in paragraph 2—
 - (i) omit “Secretariat of the”;
 - (ii) in point (b), for “helpdesks” substitute “helpdesk” and omit “by Member States”.
- 50.** Omit Article 51.
- 51.** For Article 52 substitute—

“Article 52

Safeguard clause

- 1.** The Secretary of State or a Devolved Authority may take appropriate provisional measures in respect of a substance or mixture if they—
 - (a) have justifiable grounds for believing that the substance or mixture, although satisfying the requirements of this Regulation, constitutes a serious risk to human health or the environment due to reasons of classification, labelling or packaging; and
 - (b) have competence to take the provisional measures, within the meaning of paragraphs 6 to 10.
- 2.** A provisional measure taken by a Devolved Authority applies only in relation to the territory in relation to which it has competence.
- 3.** Where the Secretary of State takes a provisional measure, the Secretary of State must immediately inform the Devolved Authorities, giving the reasons for the decision. Where a Devolved Authority takes a provisional measure, it must immediately inform the other Devolved Authorities and the Secretary of State, giving the reasons for the decision.
- 4.** Within 90 days of a provisional measure being taken—
 - (a) in the case of a provisional measure relating to classification or labelling of a substance—
 - (i) where the Secretary of State took the measure, the Secretary of State must request the Agency to produce a proposal for a new or revised mandatory classification and labelling requirement under Article 37A(2),
 - (ii) where a Devolved Authority took the measure, the Competent Authority for that country must request the Agency to produce a proposal for a new or revised mandatory classification and labelling requirement under Article 37A(2);
 - (b) in the case of a provisional measure that falls within the scope of Article 53—
 - (i) where the Secretary of State took the measure, the Secretary of State must decide whether or not to make the measure permanent by making regulations under Article 53,
 - (ii) where a Devolved Authority took the measure, it must decide whether or not to request the Secretary of State to make the measure permanent by making regulations under Article 53.
- 5.** The taker of the provisional measure must revoke that measure, when—

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

- (a) in the case of a provisional measure relating to the classification or labelling of a substance, the Secretary of State makes a decision under Article 37A;
- (b) in the case of a provisional measure that falls within the scope of Article 53—
 - (i) where paragraph 4(b)(i) of this Article applies, the Secretary of State either decides not to make the measure permanent or makes regulations under Article 53 to make the measure permanent, or
 - (ii) where paragraph 4(b)(ii) of this Article applies, the Devolved Authority decides not to request the Secretary of State to make the measure permanent.

6. The Secretary of State has competence to take a provisional measure if, or to the extent that, the exercise of the function to take that measure—

- (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⁽⁵⁵⁾);
- (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⁽⁵⁶⁾);
- (d) relates to Northern Ireland and is not within devolved competence in Northern Ireland.

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

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

9. A Department in Northern Ireland has competence to take a provisional measure if, or to the extent that, the exercise of the function to take that measure is within devolved competence in Northern Ireland.

10. For the purposes of paragraph 9, the exercise of the function of taking a provisional measure 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 taking that provisional measure would be outside the legislative competence of the Assembly.

The references in this paragraph 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⁽⁵⁷⁾.

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.”

52. In Article 53—

- (a) for “Commission may” substitute “Secretary of State may by regulations”;
- (b) omit the second and third sentences.

53. After Article 53, insert—

⁽⁵⁵⁾ 1998 c. 46.

⁽⁵⁶⁾ 2006 c. 32. Section 58A was inserted by the Wales Act 2017 (c. 4).

⁽⁵⁷⁾ 1998 c. 47. Section 6 is amended by section 12 of the European Union (Withdrawal) Act 2018 and S.I. 2011/1043.

“Article 53A

Regulation making power

1. Any power to make regulations conferred on the Secretary of State by this Regulation is exercisable by statutory instrument.
2. Such regulations may—
 - (a) contain incidental, supplemental, consequential and transitional provision; and
 - (b) may make different provision for different purposes.
3. A statutory instrument containing regulations made under this Regulation is subject to annulment in pursuance of a resolution of either House of Parliament.
4. The function of making regulations under this Regulation is subject to the consent requirement in Article 53B.

Article 53B

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⁽⁵⁸⁾) 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⁽⁵⁹⁾) whether or not the exercise of the function also relates to a part of the United Kingdom other than Wales.
4. The consent of a Northern Ireland Department 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 paragraph 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.

⁽⁵⁸⁾ 1998 c. 46.

⁽⁵⁹⁾ 2006 c. 32.

7. References in paragraph 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⁽⁶⁰⁾. 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.”

54. Omit Articles 54, 60, 61 and 62.

55. In Annex I—

- (a) in point 1.1.2.2.2.(a)(i), for “Part 3 of Annex VI or in the classification and labelling inventory” substitute “UK mandatory classification and labelling list or in the UK notification database”;
- (b) in point 1.1.2.2.2.(a)(ii), for “Part 3 of Annex VI or in the classification and labelling inventory” in both places it occurs substitute “the UK mandatory classification and labelling list or in the UK notification database”;
- (c) in point 1.1.2.2.2.(a)(iii), for “Part 3 of Annex VI or in the classification and labelling inventory” substitute “the UK mandatory classification and labelling list or in the UK notification database”;
- (d) in point 1.1.2.2.2.(a)(iv), for “Part 3 of Annex VI or in the classification and labelling inventory” substitute “the UK mandatory classification and labelling list or in the UK notification database”;
- (e) in point 1.1.2.2.2.(b)(i), for “Part 3 of Annex VI or in the classification and labelling inventory” substitute “the UK mandatory classification and labelling list or in the UK notification database”;
- (f) in point 1.1.2.2.2.(b)(ii), for “Part 3 of Annex VI or in the classification and labelling inventory” substitute “the UK mandatory classification and labelling list or in the UK notification database”.

56. In Annex II—

- (a) in point 1.2.5, in the second paragraph, for “Part 3 of Annex VI” substitute “the UK mandatory classification and labelling list”;
- (b) in point 2.10, in the second indent under the fifth indent, omit “Community”;
- (c) in part 4, for “Article 16 of [Directive 91/414/EEC](#) and Annex V of that Directive, the labelling for plant protection products subject to [Directive 91/414/EEC](#)” substitute “Article 65 of Regulation [\(EC\) No 1107/2009](#) and Regulation [\(EC\) No 547/2011](#) as regards labelling requirements for plant protection products subject to Regulation [\(EC\) No 1107/2009](#)”.

57.—(1) Annex VI is amended as follows.

(2) In the title, for “Harmonised” substitute “Mandatory”.

(3) In the introduction—

- (a) in the first paragraph, for “harmonised” substitute “mandatory” and for “Table 3” substitute “the UK mandatory classification and labelling list”;
- (b) in the second paragraph, for “harmonised” substitute “mandatory” and omit “at Union level”;
- (c) omit the third paragraph.

(4) In Part 1—

⁽⁶⁰⁾ 1998 c. 47.

- (a) in the title, for “harmonised” substitute “mandatory”;
 - (b) in point 1.1.1.1, for “Part 3” substitute “the UK mandatory classification and labelling list”;
 - (c) in point 1.1.1.4, in the fifth paragraph, for “Part 3” substitute “the UK mandatory classification and labelling list”;
 - (d) in point 1.1.1.5, in the first, second and fourth paragraphs, for “Part 3” substitute “the UK mandatory classification and labelling list”, and in the second paragraph for “this Annex” substitute “the list”;
 - (e) in point 1.1.2, for “Table 3” substitute “the UK mandatory classification and labelling list”;
 - (f) in point 1.1.2.3, for “in this Annex” substitute “in the list”, and for “table 3” and “Table 3” in each place they occur substitute “the UK mandatory classification and labelling list”;
 - (g) in point 1.1.3.1—
 - (i) in Note A in the first and second paragraph, Note B in the second paragraph, Note D in the first paragraph, Note F, and Note J, for “Part 3” substitute “the UK mandatory classification and labelling list”;
 - (ii) in Note K, omit “(Table 3.1) or the S-phrases (2-) 9-16 (Table 3.2)” and for “Part 3” substitute “the UK mandatory classification and labelling list”;
 - (iii) in Note L, Note M, and Note N, for “Part 3” substitute “the UK mandatory classification and labelling list”;
 - (iv) in Note P in the second paragraph, omit “(Table 3.1) or the S-phrases (2-) 23-24-62 (Table 3.2)” and in the third paragraph for “Part 3” substitute “the UK mandatory classification and labelling list”;
 - (v) in Note S, in the first paragraph omit “(Table 3.1)” and omit the second paragraph;
 - (h) in point 1.2.1, for “this Annex” in both places it occurs substitute “the UK mandatory classification and labelling list”, and for “Table 3” substitute “the UK mandatory classification and labelling list”;
 - (i) in point 1.2.2, for “in Table 3” substitute “in the UK mandatory classification and labelling list”;
 - (j) in point 1.2.3 for “in Table 3” substitute “in the UK mandatory classification and labelling list”;
 - (k) in point 1.2.4, for “in Table 3” substitute “in the UK mandatory classification and labelling list”.
- (5) Omit Part 3.

Commission Regulation (EU) No 544/2011

58.—(1) [Commission Regulation \(EU\) No 544/2011](#) of 10 June 2011 implementing Regulation [\(EC\) No 1107/2009](#) of the European Parliament and of the Council as regards the data requirements for active substances is amended as follows.

- (2) In the Annex, in Part A—
 - (a) in point 1.4—
 - (i) for the words from “Annex VI” to “Council” substitute “the UK mandatory classification and labelling list”;
 - (ii) for “Regulation” in the second place it occurs substitute “list”;
 - (b) after point 1.4 insert—

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

“1.4.1. In point 1.4, “the UK mandatory classification and labelling list” means the list of mandatory classification and labelling requirements of substances and groups of substances established and maintained in accordance with Article 38A of Regulation (EC) No 1272/2008.”

Commission Regulation (EU) No 545/2011

59.—(1) Commission Regulation (EU) No 545/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products is amended as follows.

(2) In the Annex—

(a) in the Introduction, after point 4 insert—

“5. In this Annex, “the UK mandatory classification and labelling list” means the list of mandatory classification and labelling requirements of substances and groups of substances established and maintained in accordance with Article 38A of Regulation (EC) No 1272/2008.”;

(b) in Part A, in point 1.4.3, in the first sentence—

(i) for “Annex VI to Regulation (EC) No 1272/2008” substitute “the UK mandatory classification and labelling list”;

(ii) for “Regulation” in the second place it occurs substitute “list”;

(c) in Part B, in point 1.4(iii), in the first sentence—

(i) for “Annex VI to Regulation (EC) No 1272/2008” substitute “the UK mandatory classification and labelling list”;

(ii) for “Regulation” in the second place it occurs substitute “list”.

Commission Regulation (EU) No 547/2011

60.—(1) Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products is amended as follows.

(2) In Annex I—

(a) in point (1)(c), in the second sentence, for “the list contained in Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council” substitute “the UK mandatory classification and labelling list”;

(b) after point (1) insert—

“(1A) In point (1)(c), the “UK mandatory classification and labelling list” means the list of mandatory classification and labelling requirements of substances and groups of substances established and maintained in accordance with Article 38A of Regulation (EC) No 1272/2008.”

Regulation (EU) No 528/2012

61. Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products is amended in accordance with paragraphs 62 to 143.

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

(2) In paragraph 1—

- (a) omit “internal”;
- (b) omit “the harmonisation of the”.
- (3) In paragraph 2—
 - (a) for “Union” substitute “United Kingdom”;
 - (b) omit point (c);
 - (c) for “one or more Member States or the Union” substitute “ the United Kingdom”.

63.—(1) Article 2 is amended as follows.

- (2) In paragraph 2, in the first subparagraph—
 - (a) omit “Union”;
 - (b) after “instruments” insert “(as they had effect immediately before exit day)”.
- (3) In paragraph 6, for “Chapter VIII” substitute “Chapter VI”.
- (4) In paragraph 7, for “Member States” substitute “the competent authority or any other relevant authority from”.
- (5) In paragraph 8, for “Member States” substitute “The Secretary of State”.
- (6) In paragraph 9, omit “the Union and”.

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

- (2) In paragraph 1—
 - (a) in point (d), after the words “on 14 May 2000” insert “, in a country which was a Member State of the EU on that date,”;
 - (b) in point (e), after the words “on 14 May 2000” insert “in a country which was a Member State of the EU on that date”;
 - (c) in point (f), omit the first indent;
 - (d) in point (k), for “Union” substitute “United Kingdom”;
 - (e) in point (m)—
 - (i) omit “of a Member State”;
 - (ii) omit “in its territory or part thereof”;
 - (f) for point (n), substitute—
 - “(n) ‘Union authorisation’ means the administrative act by which the Commission authorised the making available on the market and use of a biocidal product or a product family in the territory of the Union or part thereof before exit day;”;
 - (g) in point (o), omit “, Union authorisation”;
 - (h) in point (p)—
 - (i) for “within the Union” substitute “in the United Kingdom”;
 - (ii) for “a particular Member State or in the Union” substitute “the United Kingdom”;
 - (i) in point (t), for “competent authorities, the Agency, or the Commission” insert “the competent authority”;
 - (j) omit point (x);
 - (k) after point (ae) insert—
 - “(af) ‘the consent requirement’ means the requirement for consent in accordance with Article 83B;

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- (ag) ‘the UK List’ means the list of approved substances established and maintained in accordance with Article 8A;
- (ah) ‘the Simplified Active Substance List’ means the list of active substances which can be used in biocidal products that qualify for the simplified authorisation procedure, established and maintained in accordance with Article 24A.
- (ai) ‘appropriate fee’ means the fee payable for the activity concerned in—
 - (i) regulations made under section 43 of the Health and Safety at Work etc. Act 1974⁽⁶¹⁾ where the competent authority is appointed in accordance with regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013⁽⁶²⁾; or
 - (ii) regulations made under Article 40 of the Health and Safety at Work (Northern Ireland) Order 1978⁽⁶³⁾ where the competent authority is appointed in accordance with regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013⁽⁶⁴⁾.
- (ah) ‘Devolved Authority’ means:
 - (i) the Scottish Ministers,
 - (ii) the Welsh Ministers, or
 - (iii) a Northern Ireland department.”

(3) For paragraphs 3 and 4, substitute—

“3. The Secretary of State may issue a decision which is to be published, as to whether a substance is a nanomaterial, having regard in particular to Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial and whether a specific product or group of products is a biocidal product or a treated article or neither.

4. A decision issued under paragraph 3 above is subject to the consent requirement.

5. The Secretary of State may by regulations adapt the definition of nanomaterial set out in point (z) of paragraph 1 of this Article in view of technical and scientific progress, taking into account the Recommendation referred to in paragraph 3 above.

6. Regulations made under paragraph 5 above are subject to the consent requirement.

7. Where any of the Devolved Authorities makes proposals in relation to adaptations under paragraph 5 above, the Secretary of State must have regard to such proposals in deciding whether to exercise functions in that paragraph.”

65. In Article 5—

- (a) in paragraph 1, in point (d), for the words from “, on the basis” to “subparagraphs of paragraph 3,” substitute “meet the criteria in Regulation (EU) No 2100/2017”;
- (b) in paragraph 2, omit the final sentence;
- (c) omit paragraph 3.

66.—(1) Article 6 is amended as follows.

- (2) In paragraph 2, omit “evaluating”.

⁽⁶¹⁾ 1974 c. 37.

⁽⁶²⁾ S.I. 2013/1506.

⁽⁶³⁾ S.I. 1978/1039 (N.I. 9).

⁽⁶⁴⁾ S.R. 2013 No. 206.

(3) In paragraph 4, for “Commission shall be empowered to adopt delegated acts in accordance with Article 83 specifying criteria” substitute “Secretary of State may by regulations amend the criteria”.

(4) After paragraph 4, insert—

“5. Regulations made under paragraph 4 above are subject to the consent requirement.

6. Where any of the Devolved Authorities makes proposals in relation to regulations under paragraph 4 above, the Secretary of State must have regard to such proposals when deciding whether to exercise functions under that paragraph.”

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

(2) For paragraph 1 substitute—

“1. The applicant shall submit an application for approval of an active substance, or for making subsequent amendments to the conditions of approval of an active substance, to the competent authority.”

(3) Omit paragraph 2.

(4) In paragraph 3—

(a) in the first subparagraph—

(i) for “Agency accepting” substitute “competent authority receiving”;

(ii) for “the evaluating competent authority” substitute “it”;

(b) in the second subparagraph omit “evaluating”;

(c) in the third subparagraph—

(i) omit “evaluating”;

(ii) for “the Agency has accepted” substitute “it has received”;

(iii) omit “under Article 80(2)”.

(5) In paragraph 4—

(a) omit “evaluating” in each place it occurs;

(b) in the third subparagraph—

(i) omit “and the Agency accordingly”;

(ii) omit “in accordance with Article 80(1) and (2)”.

(6) In paragraph 5—

(a) omit “evaluating”;

(b) omit “, the Agency and other competent authorities”.

(7) Omit paragraph 6.

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

(2) In the first subparagraph of paragraph 1—

(a) omit “evaluating”;

(b) for “send” substitute “produce”;

(c) for “the conclusions of its evaluation to the Agency” substitute “evaluation conclusions”.

(3) For the second subparagraph of paragraph 1 substitute—

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

“The competent authority shall give the applicant the opportunity to provide written comments on the assessment report and on the conclusions of the evaluation within 30 days. The competent authority shall take due account of those comments.”

(4) In paragraph 2—

- (a) omit “evaluating” in both places it occurs;
- (b) omit “, and shall inform the Agency accordingly”.

(5) After paragraph 2, insert—

“**2A.** The competent authority may request from the applicant available information on, and take into account, evaluations undertaken by third countries in order to complete its evaluation. The weight given to those third country evaluations shall take into account the equivalence of the evaluation process.”

(6) In paragraph 3, omit “evaluating”.

(7) For paragraph 4 substitute—

“**4.** Within 270 days of producing its assessment reports and evaluation conclusions the competent authority shall prepare and submit an opinion on the approval of the active substance to the Secretary of State and the Devolved Authorities.”

69. After Article 8 insert—

“Article 8A

The UK List

The competent authority shall establish, maintain and make electronically available to the public a list of approved active substances (“the UK List”).”

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

(2) In paragraph 1—

- (a) for “Commission” substitute “Secretary of State”;
- (b) for “Agency” substitute “competent authority”;
- (c) in point (a), for “adopt an implementing Regulation” substitute “issue a decision”;
- (d) in point (b), for “adopt an implementing” substitute “issue a”;
- (e) omit the subparagraph after point (b).

(3) After paragraph 1, insert—

“**1A.** A decision issued under paragraph 1 is subject to the consent requirement.”

(4) For paragraph 2, substitute—

“**2.** Approved active substances shall be included in the UK List established under Article 8A of this Regulation.”

71.—(1) Article 10 is amended as follows.

(2) In paragraph 2, for “Agency” substitute “competent authority”.

(3) In paragraph 3—

- (a) for “Commission” substitute “Secretary of State and the Devolved Authorities”;
- (b) for “Agency” in both places it occurs substitute “competent authority”.

(4) In paragraph 5, for “Regulation adopted” substitute “decision issued”.

72. Omit Article 11.

73. In Article 12—

- (a) in paragraph 1, for “Commission” substitute “Secretary of State”;
- (b) in paragraph 2, for “Commission” substitute “Secretary of State”;
- (c) in paragraph 3, for “implementing regulation adopted” substitute “decision issued”;
- (d) after paragraph 3, insert—

“4. The renewal of an approval under paragraph 1 or amendment of the conditions in paragraph 2 is subject to the consent requirement.”

74. In Article 13—

- (a) in paragraph 1, for “Agency” substitute “competent authority”;
- (b) omit paragraph 3;
- (c) omit paragraph 4.

75.—(1) Article 14 is amended as follows.

(2) In paragraph 1—

- (a) omit “evaluating”;
- (b) for “the Agency accepting” substitute “receiving”;
- (c) for “13(3)” substitute “13”.

(3) In paragraph 2—

- (a) omit “evaluating” in each place it occurs;
- (b) in the second subparagraph—
 - (i) for “the Agency accepting” substitute “receiving”;
 - (ii) for “13(3)” substitute “13”;
 - (iii) for “Agency” substitute “Secretary of State and the Devolved Authorities”;
- (c) in the third subparagraph—
 - (i) for “the Agency has accepted” substitute “it has received”;
 - (ii) for “fees payable under Article 80(2)” substitute “appropriate fees”.

(4) In paragraph 3—

- (a) for “receipt of a recommendation from the evaluating competent authority” substitute “the completion of the evaluation conclusions”;
- (b) for “Agency” substitute “competent authority”;
- (c) for “Commission” substitute “Secretary of State and the Devolved Authorities”.

(5) In paragraph 4—

- (a) for “Commission” substitute “Secretary of State”;
- (b) for “Agency” substitute “competent authority”;
- (c) for “adopt” substitute “issue”;
- (d) in point (a), for “an implementing regulation” substitute “a decision”;
- (e) in point (b), omit “an implementing” substitute “a”;
- (f) omit the penultimate subparagraph.

(6) After paragraph 4 insert—

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

“**4A.** The competent authority shall update the UK List with details of the renewal of the approval of the active substance”

(7) For paragraph 5, insert—

“**5.** Where, for reasons beyond the control of the applicant, the approval of the active substance is likely to expire before a decision has been taken on its renewal, the Secretary of State shall issue a decision postponing the expiry date of approval for a period sufficient to enable the competent authority to examine the application.”

(8) After paragraph 5, insert—

“**5A.** A decision issued under paragraph 4 or 5 above is subject to the consent requirement.”

(9) In paragraph 6—

- (a) for “Commission” substitute “Secretary of State”;
- (b) for “Member States or, in the case of a Union authorisation, the Commission” substitute “competent authority”.

76. For Article 15, substitute—

“Article 15

Review of approval of an active substance

1. The Secretary of State may review the approval of an active substance for one or more product-types at any time where there are significant indications that the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2) are no longer met. The Secretary of State may also review the approval of an active substance for one or more product-types at the request of the competent authority if there are indications that the use of the active substance in biocidal products or treated articles raises significant concerns about the safety of such biocidal products or treated articles. The Secretary of State shall make publically available the information that it is carrying out a review and shall provide an opportunity for the applicant to submit comments. The Secretary of State shall take due account of those comments in the review.

2. Where any of the Devolved Authorities proposes that an active substance should be reviewed the Secretary of State shall have regard to such proposals in deciding whether to review the approval of an active substance.

3. Where those indications are confirmed, the Secretary of State shall issue a decision amending the conditions of approval of an active substance or cancelling its approval. Article 9(2) shall apply. The competent authority shall inform the initial applicants for the approval accordingly.

4. On duly justified imperative grounds of urgency the Secretary of State may issue immediately applicable decisions.

5. Paragraphs 1, 3 and 4 are subject to the consent requirement.

6. Where the Secretary of State decides to cancel or amend the approval of an active substance for one or more product-types the competent authority shall cancel or, where appropriate, amend the authorisations of biocidal products of the product-type(s) concerned containing that active substance. Articles 48 and 52 shall apply accordingly.”

77. Omit Article 16.

78.—(1) Article 17 is amended as follows.

- (2) In paragraph 2—
 - (a) in the first subparagraph after “prospective authorisation holder” insert “to the competent authority”;
 - (b) omit the second subparagraph;
 - (c) omit the third subparagraph.
- (3) In paragraph 5, for “Member States” substitute “The competent authority”.
- (4) In paragraph 6—
 - (a) for “authorisation holder shall notify each competent authority that has granted a national authorisation for a biocidal product family” substitute “biocidal product family authorisation holder shall notify the competent authority”;
 - (b) omit the final sentence.
- (5) Omit paragraph 7.
- 79.** Omit Article 18.
- 80.** In Article 19—
 - (a) in paragraph 1, in point (a), for “Annex I” substitute “the Simplified Active Substance List”;
 - (b) in paragraph 4, omit point (a);
 - (c) in paragraph 5, omit the final sentence;
 - (d) omit paragraph 8.
- 81.** In Article 20—
 - (a) in paragraph 1, after point (a)(iii) insert—

“the competent authority may refuse to accept a letter of access for the purposes of this Article if it does not hold the relevant data.”;
 - (b) for paragraph 2 substitute—

“2. Applications must be submitted in English.”;
 - (c) omit paragraph 3.
- 82.** In Article 21, omit paragraph 3.
- 83.**—(1) Article 23 is amended as follows.
 - (2) In paragraph 1, for “receiving competent authority, or in the case of an evaluation of an application for a Union authorisation, the evaluating competent authority,” substitute “competent authority”.
 - (3) Omit paragraph 2.
 - (4) In paragraph 3—
 - (a) for “receiving competent authority or, in the case of a decision on the application for a Union authorisation, the Commission” substitute “competent authority”;
 - (b) omit “, performed in accordance with the technical guidance notes referred to in Article 24,”.
 - (5) Omit paragraph 5.
- 84.** Omit Article 24.
- 85.** Before Article 25, insert—

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

“Article 24A

The Simplified Active Substance List

The competent authority must establish, maintain and make electronically available “the Simplified Active Substance List” of active substances that can be used in products that qualify for the simplified authorisation procedure under Article 25 of this Regulation.”

86. In Article 25, paragraph 1, in point (a)—

- (a) for “Annex I” substitute “the Simplified Active Substance List”;
- (b) for “that Annex” substitute “that list”.

87.—(1) Article 26 is amended as follows.

(2) Omit “evaluating” in each place it occurs.

(3) In paragraph 1—

- (a) for “Agency” substitute “competent authority”;
- (b) omit the words from “informing” to the end of that paragraph.

(4) In paragraph 2, for “fees payable under Article 80(2)” in both places it occurs substitute “appropriate fees”.

(5) In paragraph 4, omit “paid in accordance with Article 80(2)”.

88. Omit Article 27.

89. In Article 28—

- (a) in the heading, for “Annex I” substitute “the Simplified Active Substance List”;
- (b) for paragraph 1, substitute—

“**1.** The competent authority must, after receiving the decision of the Secretary of State, update the Simplified Active Substance List in order to include active substances provided that there is evidence that they do not give rise to concern according to paragraph 2 of this Article.”;

- (c) for paragraphs 3, 4 and 5, substitute—

“**3.** The Secretary of State may agree to the restriction or removal of an entry of an active substance to the Simplified Active Substance List on the recommendation of the competent authority if there is evidence that biocidal products containing that substance do not, in certain circumstances, satisfy the conditions set out in paragraph 1 of this Article or in Article 25.

4. Paragraph 1 or 3 shall apply at the initiative of the Secretary of State or at the request of an economic operator or at the request of a Devolved Authority providing the necessary evidence as referred to in those paragraphs.

5. The Secretary of State may make regulations to further specify the procedures to be followed with respect to the amendment of the Simplified Active Substance List.

6. A decision issued or a function carried out under paragraph 1, 3 or 5 is subject to the consent requirement.

7. Where any of the Devolved Authorities makes proposals in relation to regulations under paragraph 5 above, the Secretary of State must have regard to such proposals when deciding whether to exercise functions under that paragraph.”

90.—(1) Article 29 is amended as follows.

- (2) Omit “receiving” in each place it occurs.
- (3) In paragraph 1, for “fees payable under Article 80(2)” in both places it occurs substitute “appropriate fees”.
- (4) In paragraph 2—
 - (a) for “it complies with the following requirements:” substitute “the relevant information referred to in Article 20 has been submitted”;
 - (b) omit points (a) and (b).
- (5) Omit paragraph 4.
- 91.** In Article 30, omit “receiving” in each place it occurs.
- 92.** In Article 31—
 - (a) omit “receiving” in each place it occurs;
 - (b) in paragraph 4, for “fees payable under Article 80(2)” in both places it occurs substitute “appropriate fees”.
- 93.** Omit Articles 32 to 46.
- 94.** In Article 47—
 - (a) in paragraph 1, omit “that granted the national authorisation and the Agency or, in the case of a Union authorisation, the Commission and the Agency”;
 - (b) in paragraph 2, omit “that granted the national authorisation or, in the case of a Union authorisation, the Agency”;
 - (c) omit paragraph 3.
- 95.**—(1) Article 48 is amended as follows.
 - (2) In paragraph 1, omit “of a Member State or, in the case of a Union authorisation, the Commission”.
 - (3) In paragraph 2—
 - (a) omit “or, in the case of a Union authorisation, the Commission,”;
 - (b) for “evaluating competent authority or, in the case of a Union authorisation, the Commission,” substitute “competent authority”.
 - (4) In paragraph 3—
 - (a) omit “or, in the case of a Union authorisation, the Commission,”;
 - (b) omit “, the competent authorities of other Member States and, where relevant, the Commission”;
 - (c) omit the second subparagraph;
 - (d) omit the final subparagraph.
- 96.** In Article 49—
 - (a) omit “that granted the national authorisation or, in the case of a Union authorisation, the Commission,”;
 - (b) omit the final sentence.
- 97.**—(1) Article 50 is amended as follows.
 - (2) Omit paragraph 1.
 - (3) In paragraph 2—

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

- (a) for “authorities of relevant Member States having authorised the biocidal product concerned, or in the case of a Union authorisation, the Agency” substitute “authority”;
- (b) for “Those competent authorities shall decide, or, in the case of a Union authorisation, the Agency shall examine and the Commission” substitute “The competent authority shall”;
- (c) in the second subparagraph, for “fees payable under Article 80(1) and (2)” substitute “appropriate fees”.

98. Omit Article 51.

99. In Article 52, omit “or, in the case of a biocidal product authorised at Union level, the Commission,”.

100. Omit Article 53.

101. In Article 54—

- (a) for “Agency” in each place it occurs substitute “competent authority”;
- (b) in paragraph 3, for “fees payable under Article 80(1)” substitute “appropriate fees”;
- (c) in paragraph 4, omit “to Member States and”;
- (d) omit paragraph 6;
- (e) omit paragraph 8.

102. For Article 55, substitute—

“Article 55

Derogation from the requirements

1. By way of derogation from Articles 17 and 19, the competent authority may permit, for a period not exceeding 180 days, the making available on the market or use of a biocidal product which does not fulfil the conditions for authorisation laid down in this Regulation, for a limited and controlled use under the supervision of the competent authority, if such a measure is necessary because of a danger to public health, animal health or the environment which cannot be contained by other means.

On receipt of a reasoned request from the competent authority, the Secretary of State or a Devolved Authority shall issue a decision, with or without conditions, on whether the action taken may be extended for a period not exceeding 550 days if they have competence to exercise the derogation within the meaning in paragraphs 4 to 8.

2. By way of derogation from point (a) of Article 19(1) and until an active substance is approved, the competent authority may authorise, for a period not exceeding three years, a biocidal product containing a new active substance.

Such a provisional authorisation may be issued only if, after dossiers have been evaluated in accordance with Article 8, the competent authority has produced an assessment report and evaluation conclusions on the new active substance and consider that the biocidal product is expected to comply with points (b), (c) and (d) of Article 19(1) taking into account the factors set out in Article 19(2).

If the Secretary of State decides not to approve the new active substance, the competent authority shall cancel that authorisation.

Where a decision on the approval of the new active substance has not yet been made by the Secretary of State when the period of three years expires, the competent authority may extend the provisional authorisation for a period not exceeding one year, provided that there

are good reasons to believe that the active substance will satisfy the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2).

3. By way of derogation from point (a) of Article 19(1), the Secretary of State or a Devolved Authority shall issue a decision allowing the competent authority to authorise a biocidal product containing a non-approved active substance if the Secretary of State or a Devolved Authority is satisfied that that active substance is essential for the protection of cultural heritage and that no appropriate alternatives are available. To obtain such a derogation, the competent authority shall apply to the Secretary of State or a Devolved Authority providing due justification.

4. The Secretary of State has competence to grant a derogation under paragraph 1 or 3 if, or to the extent that, the exercise of the function to take that measure—

- (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⁽⁶⁵⁾);
- (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⁽⁶⁶⁾);
- (d) relates to Northern Ireland and is not within devolved competence in Northern Ireland as set out in paragraphs 7 and 8.

5. The Scottish Ministers have competence to grant a derogation under paragraph 1 or 3 if, or to the extent that, the exercise of the function to take that measure is within devolved competence (within the meaning of section 54 of the Scotland Act 1998).

6. The Welsh Ministers have competence to exercise a derogation under paragraph 1 or 3 if, or to the extent that, the exercise of the function to take that measure is within devolved competence (within the meaning of section 58A(7) and (8) of the Government of Wales Act 2006).

7. A Department in Northern Ireland has competence to exercise a derogation under paragraph 1 or 3 if, or to the extent that, the function to take that measure is within devolved competence in Northern Ireland.

8. For the purposes of paragraph 7, the exercise of the function of exercising a derogation 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 taking that provisional measure would be outside the legislative competence of the Assembly.

The references in this paragraph 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.

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.

9. Where the Secretary of State grants a derogation, the Secretary of State must immediately inform the Devolved Authorities giving reasons for the decision. Where a Devolved Authority exercises a derogation, it must immediately inform the other Devolved Authorities and the Secretary of State giving reasons for the decision.”

103.—(1) Article 56 is amended as follows.

⁽⁶⁵⁾ 1998 c.46

⁽⁶⁶⁾ 2006 c.32; section 58A was inserted by the Wales Act 2017 (c.4).

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

(2) In paragraph 2—

- (a) omit “of the Member State where the experiment or test will occur”;
- (b) for “authorities” substitute “authority”.

(3) In paragraph 3—

- (a) for “relevant competent authority of the Member State concerned” substitute “competent authority”;
- (b) omit the final sentence.

(4) Omit paragraph 4.

104. In Article 57, omit “ 27.”.

105.—(1) Article 58 is amended as follows.

(2) In paragraph 2, for “Annex I” substitute “the Simplified Active Substance List”.

(3) In paragraph 6, for “the official language or languages of the Member State of introduction, unless that Member State provides otherwise” substitute “English”.

(4) Omit paragraph 7.

(5) In paragraph 8—

- (a) for “the Commission” substitute “the Secretary of State”;
- (b) for “Annex I” substitute “the Simplified Active Substance List”.

(6) After paragraph 8 insert—

“**9.** Where any of the Devolved Authorities proposes that an active substance should be reviewed in accordance with paragraph 8 above, the Secretary of State shall have regard to such proposals in deciding whether to review the active substance.”

106.—(1) Article 59 is amended as follows.

(2) For the heading, substitute “Protection of data held by the competent authority”.

(3) In paragraph 1, for “competent authorities or the Agency” substitute “the competent authority”.

(4) In paragraph 2—

- (a) for “a”, in the first place it occurs, substitute “the”;
- (b) omit “or to the Agency”.

(5) In paragraph 3, omit “or the Agency”.

(6) Omit paragraph 4.

107.—(1) Article 60 is amended as follows.

(2) In paragraph 3, for “, 30(1), 33(3), 33(4), 34(6), 34(7), 36(4), 37(2), 37(3) or 44(5)”, in both places it occurs, substitute “or 30(1)”.

(3) After paragraph 3 insert—

“**4.** The protection period for data submitted for biocidal products containing only existing active substances which were authorised in the United Kingdom prior to exit day shall end 10 years from the first day of the month following the first decision concerning the authorisation of the product taken in accordance with Article 26(3), 30(1), 33(3), 33(4), 34(6), 34(7), 36(4), 37(2), 37(3) or 44(5) of this Regulation as it had effect immediately before exit day.

5. The protection period for data submitted for biocidal products containing a new active substance which were authorised in the United Kingdom prior to exit day shall end 15 years from the first day of the month following the first decision concerning the authorisation of the product taken in accordance with Article 26(3), 30(1), 33(3), 33(4), 34(6), 34(7), 36(4), 37(2), 37(3) or 44(5) of this Regulation as it had effect immediately before exit day.”

108. In Article 62(2)—

- (a) for “Agency” substitute “competent authority” in each place it occurs;
- (b) in the second and third subparagraphs, omit “or to a competent authority” in both places it occurs.

109. In Article 63—

- (a) in paragraph 3, for “Agency” in each place it occurs substitute “competent authority”;
- (b) in paragraph 4, for “established by the Agency” substitute “either specified or referred to by the competent authority”;
- (c) in paragraph 5, for “Agency” substitute “competent authority”.

110.—(1) Article 64 is amended as follows.

(2) In paragraph 1—

- (a) for “the receiving competent authority or the Agency” in each place it occurs substitute “the competent authority”;
- (b) in the first and second sub paragraphs, after “the first applicant” in both places it occurs insert “, where the data was provided to the competent authority,”;
- (c) in the third subparagraph for “Agency,” substitute “competent authority”.

(3) In paragraph 2, for “receiving competent authority or the Agency” substitute “competent authority”.

111.—(1) Article 65 is amended as follows.

(2) In paragraph 1, for “Member States” substitute “The competent authority”.

(3) In paragraph 2—

- (a) in the first subparagraph for “Member States” substitute “The competent authority”;
- (b) in the second subparagraph for “Union” substitute “United Kingdom”;
- (c) omit the third subparagraph;
- (d) in the final subparagraph for “Member States” substitute “the competent authority”.

(4) Omit paragraph 3.

(5) Omit paragraph 4.

112.—(1) Article 66 is amended as follows.

(2) Omit paragraph 1.

(3) In paragraph 2—

- (a) for “Agency and the competent authorities” substitute “competent authority”;
- (b) for “Agency or the competent authorities” substitute “competent authority”.

(4) In paragraph 4, omit “Agency or a”.

113.—(1) Article 67 is amended as follows.

(2) In paragraph 1—

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

- (a) for “Commission adopts an implementing Regulation” substitute “Secretary of State issues a decision”;
 - (b) after the words “up-to-date information” insert “, where”;
 - (c) for “Agency or the Commission” substitute “competent authority”.
- (3) In paragraph 2, for the first sentence substitute “From the date on which a biocidal product is authorised, the following up-to-date information, where held by the competent authority, shall be made publicly and easily available free of charge—”.
- (4) In paragraph 3—
- (a) for “Commission adopts an implementing Regulation” substitute “Secretary of State issues a decision”;
 - (b) for “Agency” substitute “competent authority”;
 - (c) omit “or the Agency”;
 - (d) after the words “up-to-date information” insert “where held by the competent authority”.
- (5) In paragraph 4—
- (a) for “Agency” substitute “competent authority”;
 - (b) omit “or the Agency”;
 - (c) after the words “up-to-date information” insert “where held by the competent authority”.

114. In Article 68, omit paragraph 2.

115.—(1) Article 69 is amended as follows.

- (2) In paragraph 1, omit “, and with [Directive 1999/45/EC](#)”.
- (3) In paragraph 2—
 - (a) in point (c), omit “or the Commission”;
 - (b) in point (o), for “[Directive 2000/54/EC](#)” substitute “the Control of Substances Hazardous to Health Regulations 2002(**67**), in relation to Great Britain, and the Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003(**68**), in relation to Northern Ireland”.
- (4) In paragraph 3—
 - (a) for “Member States” substitute “The competent authority”;
 - (b) for “in their territories be labelled in their official language or languages” substitute “be labelled in English”.

116. Omit Article 70.

117.—(1) Article 71 is amended as follows.

- (2) For the heading substitute “Exchange of information”.
- (3) For paragraph 1, substitute—

“**1.** The competent authority shall establish and maintain a system for the exchange of information between the competent authority and applicants.”.
- (4) Omit paragraph 2.
- (5) In paragraph 3, for “Register for Biocidal Products” substitute “system referred to in paragraph 1”.

(67) [S.I. 2002/2677](#), amended by [S.I. 2004/3386](#), [2015/21](#). There other amendments which are not relevant.

(68) [S.R. 2003 No. 34](#).

- (6) In paragraph 4—
- (a) for “Agency” in both places it occurs substitute “competent authority”;
 - (b) omit “and notify the relevant competent authority accordingly without delay”.
- (7) Omit paragraphs 5 to 9.
- 118.** Omit Articles 74 to 76.
- 119.** For Article 77, substitute—

“Article 77

Appeals

- 1.** Appeals against decisions of the competent authority taken pursuant to this Regulation shall be available:
 - (a) in Great Britain as provided for in regulation 14 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013⁽⁶⁹⁾;
 - (b) in Northern Ireland as provided for in regulation 13 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013⁽⁷⁰⁾.
 - 2.** Fees may be payable as appropriate by the person bringing an appeal.
 - 3.** An appeal lodged pursuant to paragraph 1 shall have suspensive effect.”
- 120.** Omit Article 78.
- 121.** For Article 79, substitute—

“Article 79

Formats for submission of information to the competent authority

The competent authority shall specify formats for submission of information. Applicants shall use these formats in their submissions to the competent authority pursuant to this Regulation.”

- 122.** Omit Article 80.
- 123.**—(1) Article 81 is amended as follows.
- (2) For the heading, substitute “The competent authority”.
 - (3) For paragraph 1, substitute—
 - 1.** The competent authority responsible for the application of this Regulation shall be that as appointed in:
 - (a) regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013, in respect of Great Britain; and
 - (b) regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013, in respect of Northern Ireland.
- The competent authority shall have a sufficient number of suitably qualified and experienced staff so that the obligations laid down in this Regulation can be carried out efficiently and effectively.”

⁽⁶⁹⁾ S.I. 2013/1506.

⁽⁷⁰⁾ S.R. 2013 No. 206.

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- (4) In paragraph 2—
- (a) in the first subparagraph—
 - (i) for “Competent authorities” substitute “The competent authority”;
 - (ii) omit the final sentence;
 - (b) in the second subparagraph—
 - (i) for “Competent authorities” substitute “The competent authority”;
 - (ii) for “helpdesks”, in the first place it occurs, substitute “a helpdesk”;
 - (c) omit paragraph 3.
- 124.** Omit Articles 82, 83 and 84.
- 125.** Before Article 85 insert—

“Article 83A

Regulation procedure

1. Regulations made by the Secretary of State under this Regulation are to be made by statutory instrument.
2. Such regulations may—
 - (a) contain consequential, incidental, supplementary, transitional or saving provision (including provision amending, repealing or revoking enactments);
 - (b) make different provision for different purposes.
3. A statutory instrument containing regulations under this Regulation is subject to annulment in pursuance of a resolution of either House of Parliament.

Article 83B

The consent requirement

1. Where any provision of this Regulation states that a function is subject to the consent requirement, 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⁽⁷¹⁾) 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⁽⁷²⁾) whether or not the exercise of the function also relates to a part of the United Kingdom other than Wales.
4. The consent of a Northern Ireland Department 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 paragraph 5 or 6.

⁽⁷¹⁾ 1998 c. 46.

⁽⁷²⁾ 2006 c. 32.

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.

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(73). 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.”

126. For Article 85, substitute—

“Article 85

Adaptation to scientific and technical progress

1. The Secretary of State may by regulations amend Annexes II, III and IV to this Regulation to take account of current scientific and technical knowledge.

2. Regulations made under paragraph 1 above shall be subject to the consent requirement.”

127. In Article 86, for “for which the Commission has adopted directives including them” substitute “included”.

128. Omit Article 87.

129. For Article 88, substitute—

“Article 88

Safeguard clause

1. Where on the basis of new evidence the competent authority has justifiable grounds to consider that a biocidal product, although authorised in accordance with this Regulation, constitutes a serious immediate or long-term risk to the health of humans, particularly of vulnerable groups, or animals, or to the environment, it may take appropriate provisional measures.

2. The Secretary of State or a Devolved Authority shall issue a decision to either permit the provisional measure for a time period defined in the decision or require the competent authority to revoke the provisional measure if they have competence to issue the decision within the meaning in paragraphs 3 to 7.

3. The Secretary of State has competence to issue a decision if, or to the extent that, the exercise of the function to take that measure—

- (a) relates to England;

(73) 1998 c. 47. Section 6 is amended by section 12 of the European Union (Withdrawal) Act 2018 and S.I. 2011/1043.

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- (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 as set out in paragraphs 6 and 7.

4. The Scottish Ministers have competence to issue the decision if, or to the extent that, the exercise of the function to take that measure is within devolved competence (within the meaning of section 54 of the Scotland Act 1998).

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

6. A Department in Northern Ireland has competence to issue a decision if, or to the extent that, the exercise of the function to take that measure is within devolved competence in Northern Ireland.

7. For the purposes of paragraph 6, the exercise of the function of issuing a decision 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 taking that measure would be outside the legislative competence of the Assembly.

The references in this paragraph 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.

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.

8. Where the Secretary of State issues the decision under paragraph 2 the Secretary of State must immediately inform the Devolved Authorities giving reasons for the decision. Where a Devolved Authority issues the decision under paragraph 2, it must immediately inform the other Devolved Authorities and the Secretary of State giving reasons for the decision.”

130. For Article 89, substitute—

“Article 89

Existing transitional measures

1. The competent authority shall carry on with the work programme for the systematic examination of all existing active substances commenced in accordance with Article 16(2) of [Directive 98/8/EC](#) with the aim of achieving it by 31 December 2024.

2. The Secretary of State may by regulations—

- (a) extend the date for the systematic examination of all existing active substances referred to in this Article;
- (b) specify matters in relation to the carrying out of the work programme and the related rights and obligations of the competent authority and the participants in the programme.

3. Where any of the Devolved Authorities makes proposals in relation to regulations under paragraph 2, the Secretary of State must have regard to such proposals in deciding whether to exercise functions under that paragraph.

4. Regulations made under paragraph 2 above are subject to the consent requirement.

5. In order to facilitate a smooth transition from [Directive 98/8/EC](#) to this Regulation, during the work programme the Secretary of State shall either issue decisions providing that an active substance is approved, and under which conditions, or, in cases where the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2), are not satisfied or where the requisite information and data have not been submitted within the prescribed period, issue decisions stating that an active substance is not approved. Decisions approving an active substance shall specify the date of approval. Article 9(2) shall apply.

6. A decision made under paragraph 5 is subject to the consent requirement.

7. By way of derogation from Articles 17(1), 19(1) and 20(1) of this Regulation, and without prejudice to paragraphs 1, 2 and 9 of this Article, the current system or practice of making available on the market or using a given biocidal product continues to apply for up to three years after the date of approval of the last of the active substances to be approved in that biocidal product. The competent authority may, in accordance with the current system or practice, authorise the making available on the market or use of a biocidal product containing only—

- (a) existing active substances which—
 - (i) have been evaluated under [Commission Regulation \(EC\) No 1062/2014](#) but which have not yet been approved of that product-type;
 - (ii) are being evaluated under that Regulation but have not yet been approved for that product-type; or
- (b) a combination of active substances referred to in point (a) and active substances approved in accordance with this Regulation.

8. By way of derogation from paragraph 7, in the case of a decision not to approve an active substance, the competent authority may continue to apply its current system or practice of making biocidal products available on the market for up to 12 months after the date of the decision not to approve an active substance in accordance with paragraph 5, and may continue to apply the current system or practice of using biocidal products for up to 18 months after that decision.

9. Following a decision to approve a particular active substance for a specific product-type, the competent authority shall ensure that authorisations for biocidal products of that product-type and containing that active substance are granted, modified or cancelled, as appropriate, in accordance with this Regulation within three years of the date of approval.

To that effect, those wishing to apply for the authorisation of biocidal products of that product-type containing no active substances other than existing active substances shall submit applications for authorisation no later than the date of approval of the active substance or substances. In the case of biocidal products containing more than one active substance, applications shall be submitted no later than the date of approval of the last active substance for that product-type.

10. Where no application for authorisation has been submitted in accordance with paragraph 9 above—

- (a) the biocidal product shall no longer be made available on the market with effect from 180 days after the date of approval of the active substance or substances; and

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- (b) use of existing stocks of the biocidal product may continue for up to 365 days after the date of approval of the active substance or substances.

11. Where the competent authority decides to reject an application submitted in accordance with paragraph 9 for authorisation of a biocidal product already made available on the market, or decides not to grant an authorisation or to impose conditions for the authorisation making it necessary to change such a product, the following shall apply—

- (a) a biocidal product which has not been authorised or, where relevant, which does not comply with the conditions of the authorisation, shall no longer be made available on the market with effect from 180 days after the date of the decision of the competent authority; and
- (b) use of existing stocks of the biocidal product may continue for up to 365 days after the date of the decision of the competent authority.”

131.—(1) Article 90 is amended as follows.

(2) Omit paragraph 1.

(3) In paragraph 2—

- (a) omit “Member States”;
- (b) for “has” substitute “had”;
- (c) for “authorities” substitute “authority”;
- (d) for “1451/2007” in both places it occurs substitute “1062/2014”;
- (e) omit the final subparagraph.

132. In Article 91, in the first subparagraph—

- (a) for “has” substitute “had”;
- (b) for “authorities” substitute “authority”.

133. In Article 92, after paragraph 1 insert—

“1A. The competent authority may request further data relating to the original authorisation as necessary.

1B. It is the duty of the authorisation holder to provide the necessary data within 60 days of such a request.

1C. The competent authority may cancel the authorisation if this Article is not complied with and the period of grace set out in the second paragraph of Article 52 shall apply.”

134.—(1) Article 93 is amended as follows.

(2) In the first subparagraph—

- (a) for “a Member State may continue to apply its” substitute “the”;
- (b) after the words “on 1 September 2013” insert “, shall continue to apply—”;
- (c) omit “The derogation shall apply until one of the following dates:”.

(3) In point (a)—

- (a) for “are” substitute “were”;
- (b) for “of Article 89(2)” to the end, substitute “Article 89(7), in Article 89(8) to (10) and in Article 89(11); or”.

(4) In point (b), for “is” substitute “was”.

135.—(1) Article 94 is amended as follows.

(2) In paragraph 1—

- (a) for “Annex I” substitute “the Simplified Active Substance List”;
- (b) in point (a), for the words “after 1 September 2016” substitute “by the Commission after 1 September 2016 but before exit day or issued by the Secretary of State after exit day”.

(3) Omit paragraph 2.

136.—(1) Article 95 is amended as follows.

(2) In paragraph 1—

(a) in the first subparagraph—

- (i) for “As of 1 September 2013, the Agency” substitute “The competent authority”;
- (ii) for “has been” substitute “is”;
- (iii) for “a Member State” substitute “the competent authority”;
- (iv) in the final sentence, for “Agency” substitute “competent authority”;

(b) in the second subparagraph—

- (i) for “Union” substitute “United Kingdom”;
- (ii) for “Agency” in both places it occurs substitute “competent authority”;
- (iii) for “letter of access to a complete substance dossier” substitute “letter of access which provides the competent authority with access to a complete substance dossier”;
- (iv) in the last sentence omit “evaluating”;

(c) in the third subparagraph—

- (i) for “Agency” substitute “competent authority”;
- (ii) for “fees payable under Article 80(1)” substitute “appropriate fees”;

(d) in the fourth subparagraph—

- (i) for “fees payable under Article 80(1)” substitute “appropriate fees”;
- (ii) for “Agency” substitute “competent authority”.

(3) In paragraph 4, after the words “Article 20(1)” insert “, where that letter of access gives the competent authority direct access to the information, and where the competent authority holds the relevant data”.

(4) In paragraph 6, for “Annex I” substitute “the Simplified Active Substance List”.

(5) In paragraph 7, for “Agency” in both places it occurs substitute “competent authority”.

(6) After paragraph 7, insert—

“**8.** The competent authority may refuse to accept a letter of access for the purposes of this Article if they do not hold the relevant data.”

137. After Article 95 insert—

“Article 95A

Transitional measures for simplified notification procedure

1. Where a product was authorised in a country which was a Member State of the EU other than the United Kingdom prior to exit day in accordance with Article 26 of Regulation

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(EU) No 528/2012 and placed on the market in the United Kingdom in accordance with Article 27 of Regulation (EU) No 528/2012—

- (a) it is to be treated as if it were authorised by the competent authority under Article 26 of this Regulation; and
- (b) the competent authority shall grant an authorisation under Article 26 of this Regulation.

2. The authorisation shall be cancelled and Article 52 of this Regulation shall apply where—

- (a) the authorisation holder is not established in the United Kingdom within 12 months after exit day; or
- (b) the authorisation holder does not supply the competent authority with relevant scientific and authorisation data—
 - (i) by the date of any application for an amendment to the authorisation under Article 50 of this Regulation; or
 - (ii) within 60 days of any request made by the competent authority to the authorisation holder

whichever is earlier.

Article 95B

Transitional measures for mutual recognition applications

1. This Article applies where an application for mutual recognition of a national authorisation of a biocidal product has been made before exit day in accordance with Article 33, 34 or 39 of this Regulation and where a decision on authorisation had not been made before exit day.

2. Paragraphs 3, 4, 7 and 8 apply where the United Kingdom was the reference Member State, before exit day, for an application for mutual recognition under Article 34 of Regulation (EU) No 528/2012.

3. The application for mutual recognition shall be treated as having been made under Article 29 of this Regulation and the time limits under Articles 29 and 30 shall be suspended until—

- (a) the date on which the applicant resubmits the application and any supporting data to the competent authority; or
- (b) where the applicant relies on a letter of access, whichever is the later of the date on which—
 - (i) the applicant resubmits the application; and
 - (ii) the data owner resubmits the data

in accordance with Article 71 of this Regulation, provided this date is within 90 days from exit day.

4. On receipt of the resubmitted application and data to the competent authority, the time limits under Articles 29 and 30 of this Regulation shall apply less any time which expired between the date of acceptance of the application and data under Article 34 of Regulation (EU) No 528/2012 and exit day.

5. Paragraphs 6, 7 and 8 apply where the United Kingdom was, before exit day, the Member State concerned in relation to an application for mutual recognition under Articles 33, 34 or 39 of Regulation (EU) No 528/2012.

6. The application shall be treated as having been made under Article 29 of this Regulation and shall be subject to the time limits under Articles 29 and 30 from—

- (a) the date on which the applicant resubmits the application and any supporting data to the competent authority; or
- (b) where the applicant relies on a letter of access, whichever is the later of the date on which—
 - (i) the applicant resubmits the application; and
 - (ii) the data owner resubmits the data

in accordance with Article 71 of this Regulation, provided this date is within 180 days from exit day.

7. Where the applicant does not meet the requirements of this Article, the application shall be rejected by the competent authority and Article 89(11) shall apply as if the application had been submitted in accordance with Article 89(9).

8. Anything done before exit day by the United Kingdom, either as the Member State concerned or as the reference Member State is taken to have been done by the competent authority under this Regulation.

Article 95C

Renewal of authorisations subject to mutual recognition under Regulation 492/2014

1. This Article applies where an application for the renewal of a biocidal product authorisation subject to mutual recognition was made before exit day in accordance with Article 3 of Commission Delegated Regulation (EU) No 492/2014 of 7 March 2014 supplementing Regulation No 528/2012 of the European Parliament and of the Council as regards the rules for the renewal of authorisations of biocidal products subject to mutual recognition, where a decision on the renewal of the authorisation had not been made before exit day.

2. Paragraph 3 applies where the United Kingdom was the reference Member State, before exit day, for an application for renewal.

3. The application shall be treated as having been made under Article 31 of this Regulation and the time limits under Article 31 shall be suspended until—

- (a) the date on which the applicant resubmits the application and any supporting data to the competent authority; or
- (b) where the applicant relies on a letter of access, whichever is the later of the date on which—
 - (i) the applicant resubmits the application; and
 - (ii) the data owner resubmits the data

in accordance with Article 71 of this Regulation, provided this date is within 90 days from exit day.

4. On receipt of the resubmitted application and data to the competent authority, the time limits under Articles 30 and 31 (where applicable) of this Regulation shall apply less

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any time which expired between the date of acceptance of the application and data under Articles 3 and 4 of Regulation (EU) No 492/2014(74) and exit day.

5. Paragraph 6 applies where the United Kingdom was a Member State concerned, before exit day, for an application for renewal.

6. The application shall be treated as having been made under Article 31 of this Regulation and shall be subject to the time limits under Articles 30 and 31 (where applicable) from—

- (a) the date on which the applicant resubmits the application and any supporting data to the competent authority; or
- (b) where the applicant relies on a letter of access, whichever is the later of the date on which—
 - (i) the applicant resubmits the application; and
 - (ii) the data owner resubmits the data

in accordance with Article 71 of this Regulation, provided this date is within 180 days from exit day.

7. Anything done before exit day by the United Kingdom, either as the Member State concerned or as the reference Member State, is taken to have been done by the competent authority under this Regulation.

Article 95D

Transitional measures for national authorisation applications

1. This Article shall apply to an application made, before exit day, under Article 29 or Article 31 of Regulation (EU) No 528/2012 and where a decision on authorisation or renewal has not been made before exit day.

2. The application shall be treated as having been made under this Regulation and the time limits under Articles 29, 30 and 31 as appropriate shall be suspended until—

- (a) the date on which the applicant resubmits the application and any supporting data to the competent authority; or
- (b) where the applicant relies on a letter of access, whichever is the later of the date on which—
 - (i) the applicant resubmits the application; and
 - (ii) the data owner resubmits the data

in accordance with Article 71 of this Regulation, provided this date is within 90 days from exit day.

3. Where the applicant does not meet the requirements of this Article, the application shall be—

- (a) cancelled by the competent authority and Article 52 shall apply; or
- (b) rejected by the competent authority and Article 89(11) shall apply as if the application had been submitted in accordance with Article 89(9).

4. Anything done before exit day by the United Kingdom, as the receiving competent authority, is taken to have been done by the competent authority under this Regulation.

(74) OJ L 139, 14.5.2014, p. 1–6

Article 95E

Transitional Measures Simplified Authorisation Applications

1. This Article shall apply to an application made before exit day under Article 25 or 26 of Regulation (EU) No 528/2012 and where a decision on authorisation has not been made before exit day.

2. Where the application was made to the United Kingdom as the receiving competent authority, the application shall be treated as having been made under this Regulation and the time limits under Article 26 shall be suspended until—

- (a) the date on which the applicant resubmits the application and any supporting data to the competent authority; or
- (b) where the applicant relies on a letter of access, whichever is the later of the date on which—
 - (i) the applicant resubmits the application; and
 - (ii) the data owner resubmits the data

in accordance with Article 71 of this Regulation, provided this date is within 90 days from exit day.

3. Where the application was made and the United Kingdom was not the receiving competent authority, the application shall be treated as having been made under this Regulation and the time limits under Article 26 shall be suspended until the date on which—

- (a) the applicant resubmits the application and any supporting data to the competent authority; or
- (b) where the applicant relies on a letter of access—
 - (i) the applicant resubmits the application; and
 - (ii) the data owner resubmits the data

in accordance with Article 71 of this Regulation, provided this date is within 180 days from exit day.

4. Where the applicant does not meet the requirements of this Article, the application shall be rejected by the competent authority and Article 89(11) shall apply as if the application had been submitted in accordance with Article 89(9).

5. Anything done before exit day by the United Kingdom, as the receiving competent authority, is taken to have been done by the competent authority under this Regulation.

Article 95F

Transitional measures for applications for same biocidal product authorisations

1. This Article applies to an application under Article 3 or 4a of Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council⁽⁷⁵⁾, and where a decision on authorisation has not been made before exit day.

2. The application shall be treated as having been made under Article 3 or 4a (as appropriate) of Regulation 414/2013 and the time limits under those Articles shall be suspended until—

(75) OJ L 125, 7.5.2013, p.4-6.

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- (a) the date on which the applicant either resubmits the application and any supporting data to the competent authority; or
- (b) where the applicant relies on a letter of access, whichever is the later of the date on which—
 - (i) the applicant resubmits the application; and
 - (ii) the data owner resubmits the data

in accordance with Article 71 of this Regulation, provided this date is within 90 days from exit day.

3. Where the applicant does not meet the requirements of this Article, the application shall be rejected by the competent authority and Article 89(11) shall apply as if the application had been submitted in accordance with Article 89(9).

4. For the purposes of this Article, data submitted by the applicant or the data owner shall include relevant data on the reference product.

Article 95G

Transitional measures for Regulation (EU) No 528/2012 authorisations

1. This Article applies to authorisations granted before exit day under Articles 19, 26, 30, 31, 33, 34, 36, 39 or 44 of Regulation (EU) No 528/2012.

2. The authorisation is to be treated as if it were authorised by the competent authority under the relevant Article of this Regulation.

3. The authorisation shall be cancelled and Article 52 of this Regulation shall apply where—

- (a) the authorisation holder is not established in the United Kingdom within 365 days after exit day; or
- (b) the authorisation holder does not supply the competent authority with relevant scientific and authorisation data—
 - (i) by the date of any application for renewal or the date of any application for amendment to the authorisation under Article 50; or
 - (ii) within 60 days of any request made by the competent authority to the authorisation holder

whichever is earlier.

Article 95H

Transitional measures for ongoing applications for Union authorisations

1. This Article applies to an application for Union authorisation made in accordance with Article 42, 43 or 45 and evaluated under either Article 44 or Article 46 of Regulation (EU) No 528/2012, and where a decision on authorisation has not been made before exit day.

2. Paragraph 3 applies where, prior to exit day, the United Kingdom was the evaluating competent authority for applications for Union authorisation made under Regulation (EU) No 528/2012.

3. The application shall be taken as being made under Article 29 or 31 of this Regulation and the time limits under Article 29, 30 or 31 shall be suspended until—

- (a) the date on which the applicant resubmits the application and any supporting data to the competent authority; or
- (b) where the applicant relies on a letter of access, whichever is the later of the date on which—
 - (i) the applicant resubmits the application; and
 - (ii) the data owner resubmits the data

in accordance with Article 71 of this Regulation, provided this date is within 90 days from exit day.

4. On receipt of the resubmitted application and data to the competent authority, the time limits under Article 29, 30 or 31 of this Regulation shall apply less any time which expired between the date of acceptance of the application and data under Article 43, 44, 45 or 46 of Regulation (EU) No 528/2012 and exit day.

5. Paragraph 6 applies where, prior to exit day, the United Kingdom was not the evaluating competent authority for applications for Union authorisation made under Regulation (EU) No 528/2012.

6. The application shall be treated as having been made under Article 29, 30 or 31 of this Regulation and shall be subject to the time limits under those Articles from—

- (a) the date on which the applicant resubmits the application and any supporting data to the competent authority; or
- (b) where the applicant relies on a letter of access, whichever is the later of the date on which:
 - (i) the applicant resubmits the application; and
 - (ii) the data owner resubmits the data

in accordance with Article 71 of this Regulation, provided the date is within 180 days from exit day.

7. Where the applicant or authorisation holder does not meet the requirements of this Article, the application shall be—

- (a) cancelled by the competent authority and Article 52 shall apply; or
- (b) rejected by the competent authority and Article 89(11) shall apply as if the application had been submitted in accordance with Article 89(9).

8. Anything done before exit day by the United Kingdom, as the evaluating competent authority, is taken to have been done by the competent authority under this Regulation.

Article 95I

Transitional measures Article 95 List

1. This Article applies to the list prepared pursuant to Article 95 of Regulation (EU) No 528/2012 (“the Article 95 pre-exit day List”).

2. The entries included on the Article 95 pre-exit day List shall be included in the list prepared pursuant to Article 95 of this regulation (“the Article 95 List”) subject to paragraph 3 below.

3. An entry on the Article 95 List shall be removed if the following conditions are not met within 2 years from exit day—

- (a) the person is established in the United Kingdom; and

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- (b) the person provides to the competent authority—
 - (i) a complete substance dossier for the relevant substance;
 - (ii) a reference to a complete substance dossier for which all data protection periods have expired and the competent authority is able to obtain all the data;
 - (iii) a letter of access to the complete substance dossier and the data owner has submitted the data to the competent authority and the competent authority holds the data after exit day.

4. Where an entry is removed from the Article 95 List for reasons beyond the control of the supplier of a biocidal product containing the relevant active substance, the competent authority may grant a period of grace for the making available on the market of that biocidal product except in cases where the continued making available on the market of the biocidal product would constitute an unacceptable risk to human health, animal health or the environment.

A period of grace in excess of 180 days may only be granted in exceptional circumstances.

5. Where a period of grace is granted and the supplier of a biocidal product does not comply with Article 95 (2) in that period the prohibition in Article 95 (2) shall apply.

Article 95J

Transitional measures active substance applications

1. This Article applies to applications made before exit day under Article 7 of Regulation (EU) No 528/2012.

2. Where the United Kingdom was the evaluating competent authority and has not concluded its evaluation of an application before exit day, the application is to be treated as if it were made under Article 7 of this Regulation and the time limits under Articles 7 and 8 shall be suspended until—

- (a) the date on which the applicant resubmits the application and any supporting data to the competent authority; or
- (b) where the applicant relies on a letter of access, whichever is the later of the date on which—
 - (i) the applicant resubmits the application; and
 - (ii) the data owner resubmits the data

in accordance with Article 71 of this Regulation, provided this date is within 90 days from exit day.

3. On receipt of the resubmitted application and data to the competent authority, the time limits under Articles 7 and 8 shall apply less any time which expired between the date of acceptance of the application and data under Article 7 of Regulation (EU) No 528/2012 and exit day.

4. Where the applicant does not meet the requirements of this Article, the application shall be rejected by the competent authority.

5. Anything done before exit day by the United Kingdom as the evaluating competent authority under Regulation (EU) No 528/2012 is to be taken to have been done by the competent authority under this Regulation.

Article 95K

Transitional measures application for renewal of an approval of an active substance

1. This Article shall apply where an application for renewal of an approval of an active substance was made in accordance with Article 13 of Regulation (EU) No 528/2012.

2. Where the United Kingdom was the evaluating competent authority and has not concluded its evaluation of an application before exit day, the application is to be treated as if it were made under Article 13 of this Regulation and the time limits under Articles 13 and 14 shall be suspended until—

- (a) the date on which the applicant resubmits the application and any supporting data to the competent authority; or
- (b) where the applicant relies on a letter of access, whichever is the later of the date on which—
 - (i) the applicant resubmits the application; and
 - (ii) the data owner resubmits the data

in accordance with Article 71 of this Regulation, provided this date is within 90 days from exit day.

3. On receipt of the resubmitted application and data by the competent authority, the time limits under Articles 13 and 14 of this Regulation shall apply less any time which expired between the date of acceptance of the application and data under Article 13 Regulation (EU) No 528/2012 and exit day.

4. Where the United Kingdom was not the evaluating competent authority and the evaluation of the application has not been concluded before exit day, the application is to be treated as if it were made under Article 13 of this Regulation and the time limits under Articles 13 and 14 shall be suspended until—

- (a) the date on which the applicant resubmits the application and any supporting data to the competent authority; or
- (b) where the applicant relies on a letter of access, whichever is the later of the date on which—
 - (i) the applicant resubmits the application; and
 - (ii) the data owner resubmits the data

in accordance with Article 71 of this Regulation, provided this date is within 180 days from exit day.

5. Where the applicant does not meet the requirements of this Article, the approval shall not be renewed by the competent authority and Article 52 shall apply to any biocidal product containing the active substance.

6. Anything done before exit day by the United Kingdom as the evaluating competent authority under Regulation (EU) No 528/2012 is to be taken to have been done by the competent authority under this Regulation.

Article 95L

Transitional measures for ongoing applications to change or amend authorisations

1. This Article applies to an application under Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in

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accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council.

2. The application shall be treated as having been made under Regulation 354/2013 and the time limits under that Regulation shall be suspended until—

- (a) the date on which the applicant resubmits the application and any supporting data to the competent authority; or
- (a) where the applicant relies on a letter of access, whichever is the later of the date on which—
 - (i) the applicant resubmits the application; and
 - (ii) the data owner resubmits the data

in accordance with Article 71 of this Regulation, provided this date is within 180 days from exit day.

3. Where the applicant does not meet the requirements of this Article, the application shall be rejected by the competent authority.

4. For the purposes of this Article, data submitted by the applicant or the data owner shall include relevant data on the reference product.”

138. Omit Article 97.

139. Omit Annex I.

140.—(1) Annex II is amended as follows.

(2) In paragraph 2—

- (a) in the fourth subparagraph, for “available on the website of the Agency” substitute “to be made available online by the competent authority”;
- (b) in the fifth subparagraph, omit “that will evaluate the dossier”.

(3) For paragraph 4, substitute—

“**4.** Dossiers must be formatted, prepared and submitted in accordance with the data requirements and guidance as specified by the competent authority.”

(4) In paragraph 6, for “Commission or the Agency” substitute “competent authority”.

(5) In paragraph 8, omit “of the Member State concerned”.

141.—(1) Annex III is amended as follows.

(2) In paragraph 2—

- (a) in the fourth subparagraph, for “Agency” substitute “competent authority”;
- (b) in the sixth subparagraph, for “available on the website of the Agency” substitute “to be made available online by the competent authority”;
- (c) in the seventh subparagraph, omit “that will evaluate the dossier”;
- (d) in the eighth subparagraph, omit “or Article 44(2)”.

(3) For paragraph 4, substitute

“**4.** Dossiers must be formatted, prepared and submitted in accordance with the data requirements and guidance as specified by the competent authority.”

(4) In paragraph 6, for “Commission or the Agency” substitute “competent authority”.

(5) In paragraph 8, omit “of the Member State”.

142. In Annex IV—

- (a) in paragraph 1.2. for “Commission” in both places it occurs substitute “competent authority”;
- (b) in paragraph 1.3., omit the final subparagraph;
- (c) in paragraph 1.5., omit the final subparagraph;
- (d) in paragraph 3.1., omit the final subparagraph.

143.—(1) Annex VI is amended as follows.

(2) In paragraph 1—

- (a) for “a Member State or the Commission” substitute “the competent authority”;
- (b) for “available on the website of the Agency” substitute “to be made available online by the competent authority”.

(3) In paragraph 6, for “evaluating body” substitute “competent authority”.

(4) In paragraph 8, for “evaluating body” substitute “competent authority”.

(5) In paragraph 9—

- (a) for “competent authorities or the Commission” substitute “competent authority or the Secretary of State”;
- (b) for “competent authorities” substitute “competent authority”.

(6) In paragraph 10, for “authorities or the Commission” substitute “authority”.

(7) In paragraph 11, for “evaluating bodies” substitute “competent authority”.

(8) In paragraph 12, for “evaluating body” substitute “competent authority”.

(9) In paragraph 13—

- (a) omit “evaluating or receiving”;
- (b) for “competent authorities” substitute “competent authority”.

(10) In paragraph 15, omit the final sentence.

(11) In paragraphs 20, 26, 36, 48, 50, 51, 52, 53, 55, 56, 57, 58, 59, 60, 62, 64, 66, 67, 68, 69, 71, 72, 73, 74, 75, 77, 78 and the paragraph following paragraph 78, for “evaluating body”, in each place it occurs, substitute “competent authority”.

(12) In paragraph 52, for “Union” substitute “United Kingdom”.

(13) In paragraph 75, for “evaluating authority” substitute “competent authority”.

(14) In paragraph 77, for “Member State or, where appropriate, in the Union” substitute “United Kingdom”.

Regulation (EU) No 649/2012

144. Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals is amended in accordance with paragraphs 145 to 175.

145. In Article 1—

- (a) in paragraph 1, in the second subparagraph, for “Union” substitute “United Kingdom”;
- (b) in paragraph 2, for “Member States” substitute “United Kingdom”.

146.—(1) Article 2 is amended as follows.

(2) In paragraph 1, in point (b), for “Union or a Member State” substitute “United Kingdom”.

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- (3) In paragraph 2—
- (a) in point (b), for the words from “Council” to the end substitute “the Ionising Radiations Regulations 2017(76) and the Ionising Radiations Regulations (Northern Ireland) 2017(77)”;
 - (b) in point (c), for the words from “Directive” to the end substitute “the Waste (England and Wales) Regulations 2011(78), the Waste (Scotland) Regulations 2011(79), and the Waste Regulations (Northern Ireland) 2011(80)”;
 - (c) in point (g), for the words from “Directive” to the end substitute “the Genetically Modified Organisms (Deliberate Release) Regulations 2002(81), the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002(82), the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002(83), and the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003(84)”;
 - (d) in point (h)—
 - (i) for the words from “Directive 2001/83/EC” to “use” substitute “the Human Medicines Regulations 2012(85)”;
 - (ii) for the words from “Directive 2001/82/EC” to “products” substitute “the Veterinary Medicines Regulations 2013(86)”.
- (4) In paragraph 3, in the second subparagraph, for “using the Database referred to in Article 6(1)(a)” substitute “from the exporter’s Designated National Authority”.

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

- (2) In point (4), for “Union legislation” substitute “retained EU law”.
- (3) In point (5)(b)—
- (a) for the words “Directive” to “market” substitute “Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products”;
 - (b) for “Directives 2001/82/EC and 2001/83/EC” substitute “the Veterinary Medicines Regulations 2013 and the Human Medicines Regulations 2012”.
- (4) In point (7)—
- (a) for “within the Union” substitute “by retained EU law”;
 - (b) for “Annex I” substitute “the UK PIC list”.
- (5) In point (8)—
- (a) in the first sentence, for “within the Union or a Member State” substitute “by retained EU law”;
 - (b) in the second sentence, for “Union” substitute “United Kingdom”;
 - (c) for “Annex I” substitute “the UK PIC list”.

(76) S.I. 2017/1075.

(77) S.R. 2017 No. 229.

(78) S.I. 2011/988.

(79) S.S.I. 2011/226.

(80) S.R. 2011 No. 127.

(81) S.I. 2002/2443.

(82) S.S.I. 2002/541.

(83) S.I. 2002/3188 (W.304).

(84) S.R. 2003 No. 167.

(85) S.I. 2012/1916.

(86) S.I. 2013/2033.

- (6) In point (9)—
- (a) before “Annex III” insert “both”;
 - (b) for “Annex I to this Regulation” substitute “the UK PIC list”.
- (7) In point (10)—
- (a) in point (a), for “the Union” substitute “retained EU law”;
 - (b) in point (b), for “Union” substitute “United Kingdom”.
- (8) In point (11)—
- (a) in point (a), for “the Union” substitute “retained EU law”;
 - (b) in point (b), for “Union” substitute “United Kingdom”.
- (9) Omit point (12).
- (10) Omit point (15).
- (11) For point (16) substitute—
- “(16) ‘export’ means the export of chemicals from the United Kingdom:
 - (a) made in accordance with section 35 or 36 of the Taxation (Cross-border Trade) Act 2018⁽⁸⁷⁾; or
 - (b) where the chemicals were, immediately prior to export, in a temporary storage facility or subject to the control of any HMRC officer as described in paragraph 1(2) of Schedule 1 to the Taxation (Cross-border Trade) Act 2018,but does not include chemicals which are under a transit procedure by which chargeable goods may be moved between places in the United Kingdom.”
- (12) In point (17) for the words from “physical” to the end substitute “importation into the United Kingdom and release to a customs procedure, other than a transit procedure by which chargeable goods may be moved between places in the United Kingdom, of any chemical”.
- (13) In point (18)—
- (a) in points (a) and (b) for “customs territory of the Union” substitute “United Kingdom”;
 - (b) in point (c) for “Union”, in both places it occurs, substitute “United Kingdom”.
- (14) In point (19), for “customs territory of the Union” substitute “United Kingdom”.
- (15) Omit point (22).
- (16) In point (23), omit “, unless otherwise specified in this Regulation”.
- (17) After point (23), insert—
- “(24) ‘Designated National Authority’ means the authority or authorities designated by the Secretary of State under the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013⁽⁸⁸⁾ to carry out the administrative functions required by this Regulation;
 - (25) ‘exporter’s Designated National Authority’ means the Designated National Authority of the country in which the exporter is established;
 - (26) ‘UK PIC list’ means the list established and maintained in accordance with Articles 7 and 23.”

148. Omit Article 4.

149.—(1) Article 5 is amended as follows.

⁽⁸⁷⁾ 2018 c. 22.

⁽⁸⁸⁾ S.I. 2013/1506.

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- (2) In the heading, for “Union” substitute “United Kingdom”.
 - (3) In paragraph 1—
 - (a) for “a joint” substitute “the”;
 - (b) for “Commission and the Member States” substitute “Secretary of State”.
 - (4) For paragraph 2 substitute—
 - “(1) The Designated National Authority must:
 - (a) transmit United Kingdom export notifications to other Parties and countries pursuant to Article 8; and
 - (b) receive information from the Secretariat more generally.
 - (2) The Secretary of State must provide to the Secretariat:
 - (a) notifications of each relevant final regulatory action concerning chemicals qualifying for PIC notification pursuant to Article 11;
 - (b) information concerning other final regulatory actions involving chemicals not qualifying for PIC notification pursuant to Article 12; and
 - (c) United Kingdom import responses for chemicals subject to the PIC procedure pursuant to Article 13.
 - (3) The Secretary of State must also coordinate the United Kingdom input on all technical issues relating to the following:
 - (a) the Convention;
 - (b) the preparation of the Conference of the Parties established by Article 18(1) of the Convention;
 - (c) the Chemical Review Committee established in accordance with Article 18(6) of the Convention;
 - (d) other subsidiary bodies of the Conference of the Parties.”
 - (5) Omit paragraph 3.
- 150.** For Article 6 substitute—

“Article 6

Tasks of the Designated National Authority

The Designated National Authority must, in addition to the tasks allocated to it under Articles 5, 7, 8, 9, 10, 11, 13, 14, 16, 18, 19 and 20, carry out the following tasks:

- (a) where appropriate, provide assistance and guidance for industry in order to ensure the effective application of this Regulation;
- (b) at the request of the Secretary of State, and within the available resources, provide input in drafting of decision guidance documents referred to in Article 7 of the Convention and other technical documents related to the implementation of the Convention;
- (c) upon request, provide the Secretary of State with technical and scientific input and assist the Secretary of State in order to ensure the effective implementation of this Regulation.”

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

- (2) In the heading—
 - (a) after “PIC notification,” omit “and”;

- (b) after “PIC procedure” insert “, chemicals subject to Regulation (EC) No 850/2004, and chemicals already subject to an export ban”.
 - (3) For paragraph 1 substitute—
 - “1. The Secretary of State must include the following chemicals in the UK PIC list:
 - (a) the chemicals subject to the export notification procedure under Article 8;
 - (b) the chemicals qualifying for the PIC notification procedure under Article 11;
 - (c) the chemicals subject to the PIC procedure as listed in Annex III to the Convention;
 - (d) the chemicals subject to Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants; and
 - (e) the chemicals other than persistent organic pollutants as listed in Annexes A and B to the Stockholm Convention on Persistent Organic Pollutants that are already subject to an export ban.”
 - (4) For paragraph 2 substitute—
 - “2. The Secretary of State must assign chemicals listed in the UK PIC list to one or more of the following groups:
 - (a) Part 1 of the UK PIC list, which lists chemicals that are subject to the export notification procedure laid down in Article 8, with detailed information being given on the identity of the substance, on the use category and/or subcategory subject to restriction, the type of restriction and, where appropriate, additional information, in particular on exemptions to requirements for export notification;
 - (b) Part 2 of the UK PIC list, which lists chemicals that, in addition to being subject to the export notification procedure laid down in Article 8, qualify for the PIC notification procedure set out in Article 11, with detailed information being given on the identity of the substance and on the use category;
 - (c) Part 3 of the UK PIC list, which lists chemicals that are subject to the PIC procedure with the use category being given and, where appropriate, additional information, in particular on any requirements for export notification;
 - (d) Part 4 of the UK PIC list, which lists chemicals that are subject to Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants;
 - (e) Part 5 of the UK PIC list, which lists chemicals other than persistent organic pollutants as listed in Annexes A and B to the Stockholm Convention on Persistent Organic Pollutants and are already subject to an export ban.”
 - (5) In paragraph 3—
 - (a) for the words from the beginning to “made” substitute “The Designated National Authority must make the UK PIC list”;
 - (b) for the words “by means of the Database” substitute “via its website”.
- 152.**—(1) Article 8 is amended as follows.
- (2) In paragraph 1, for “Annex I” substitute “the UK PIC list”.
 - (3) In paragraph 2—
 - (a) in the first subparagraph—
 - (i) for “Union” substitute “United Kingdom”;

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- (ii) for “designated national authority of the Member State in which he is established (the ‘exporter’s Member State’)” substitute “exporter’s Designated National Authority”;
 - (iii) for “that designated national authority” substitute “the Designated National Authority”;
 - (iv) in the final sentence, omit the words from “and” to the end;
 - (b) in the second subparagraph—
 - (i) for “designated national authority of the exporter’s Member State” substitute “exporter’s Designated National Authority”;
 - (ii) omit the words from “and” to the end;
 - (c) in the third subparagraph, for “The Agency shall, on behalf of the Commission,” substitute “The Designated National Authority must”;
 - (d) in the fourth subparagraph—
 - (i) for “Agency”, in both places it occurs, substitute “Designated National Authority”;
 - (ii) for “shall register each export notification and assign it” substitute “must maintain a list of export notifications and assign each export notification”;
 - (iii) omit “in the Database”;
 - (iv) omit “and the designated national authorities of the Member States, as appropriate,”;
 - (v) for “by means of the Database” substitute “via its website”.
 - (4) In paragraph 3—
 - (a) for “Agency”, in both places it occurs, substitute “Designated National Authority”;
 - (b) for “Annex I” substitute “the UK PIC list”;
 - (c) omit “, on behalf of the Commission,” in both places it occurs.
 - (5) In paragraph 4, for “Union legislation” substitute “retained EU law”.
 - (6) In paragraph 5, for the words from “designated” to the end substitute “exporter’s Designated National Authority”.
 - (7) In paragraph 6—
 - (a) in the first subparagraph, in point (c)—
 - (i) for “Commission” substitute “Designated National Authority”;
 - (ii) omit the words from “and has forwarded” to the end;
 - (b) in the third subparagraph, in point (b)—
 - (i) for “Commission” substitute “Designated National Authority”;
 - (ii) for the words from “and has forwarded” to the end substitute “and has made it publicly available via its website”.
 - (8) In paragraph 7, for the words from “The Commission” to “Agency” substitute “The Designated National Authority”.
 - (9) Omit paragraph 8.
- 153.**—(1) Article 9 is amended as follows.
- (2) In paragraph 1—
 - (a) omit the first subparagraph;
 - (b) in the second subparagraph—

- (i) for “The Agency shall, on behalf of the Commission,” substitute “The Designated National Authority must”;
 - (ii) after “received” insert “concerning the export to the United Kingdom of a chemical the manufacture, use, handling, consumption, transport or sale of which is subject to prohibition or severe restriction under a Party’s or other country’s legislation,”;
 - (c) omit the third subparagraph.
- (3) Omit paragraph 2.

154.—(1) Article 10 is amended as follows.

- (2) In paragraph 1—
- (a) in point (a), for “Annex I” substitute “Part 1, 2 or 3 of the UK PIC list”;
 - (b) in point (c), for “Annex I” substitute “the UK PIC list”;
 - (c) in the second subparagraph, for “designated national authority of the exporter’s Member State” substitute “exporter’s Designated National Authority”;
 - (d) in the third subparagraph, in both places it occurs, for “Union” substitute “United Kingdom”.
- (3) In paragraph 2, for the words from “Commission” to “Member State,” substitute “Designated National Authority”.
- (4) In paragraph 3—
- (a) omit the first sentence;
 - (b) for “Agency shall summarise that information at Union level and” substitute “Designated National Authority”;
 - (c) for “by means of the Database” substitute “via its website”.

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

- (2) In paragraph 1—
- (a) for “Commission” substitute “Secretary of State”;
 - (b) for “Annex I,” substitute “the UK PIC list”.
- (3) In paragraph 2—
- (a) for “Annex I” substitute “the UK PIC list”;
 - (b) for “Commission” substitute “Secretary of State”;
 - (c) omit “at Union level”.
- (4) In paragraph 4—
- (a) in the first subparagraph—
 - (i) for “Commission” substitute “Secretary of State”;
 - (ii) for “Annex I” substitute “the UK PIC list”;
 - (b) in the second subparagraph, for “Commission” substitute “Designated National Authority”.
- (5) In paragraph 5 for “Commission”, in both places it occurs, substitute “Secretary of State”.
- (6) In paragraph 6—
- (a) in the first subparagraph, for “Commission” substitute “Secretary of State”;
 - (b) omit the second subparagraph.

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- (7) In paragraph 7—
- (a) omit the first subparagraph;
 - (b) in the second subparagraph—
 - (i) for “Where” substitute “On the basis of the information that the Secretary of State receives from the Secretariat regarding chemicals notified as banned or severely restricted by other Parties, where”;
 - (ii) for “Commission” substitute “Secretary of State”;
 - (iii) for “Member States and the Agency” substitute “Designated National Authority, the Scottish Ministers, the Welsh Ministers, and a Northern Ireland Department”;
 - (iv) for “propose” substitute “take”;
 - (v) omit “at Union level”;
 - (vi) omit “within the Union”.
- (8) Omit paragraph 8.

156. In Article 12, for the words from “Annex” to “the Commission” substitute “the UK PIC list, the Secretary of State”.

157.—(1) Article 13 is amended as follows.

- (2) In paragraph 1—
- (a) omit the first subparagraph;
 - (b) in the second subparagraph—
 - (i) at the beginning, for “The Commission shall, by means of an implementing act” substitute “Where the Secretary of State receives a decision guidance document from the Secretariat, the Secretary of State must, taking into account the information in the decision guidance document”;
 - (ii) omit “on behalf of the Union”;
 - (iii) omit the second sentence;
 - (iv) for “Commission” substitute “Secretary of State”;
 - (c) in the third subparagraph—
 - (i) omit “under Union legislation”;
 - (ii) for “Commission”, in both places it occurs, substitute “Secretary of State”;
 - (iii) omit “, by means of an implementing act,”;
 - (iv) omit the second sentence.
- (3) Omit paragraph 2.
- (4) In paragraph 4, for “Commission” substitute “Secretary of State”.
- (5) In paragraph 5—
- (a) for “Each designated national authority of the Member States” substitute “The Designated National Authority”;
 - (b) for the words from “available to those concerned” to the end substitute “publicly available via its website”.
- (6) In paragraph 6—
- (a) for “Commission” substitute “Secretary of State”;
 - (b) for “Member States and the Agency” substitute “Designated National Authority, the Scottish Ministers, the Welsh Ministers, and a Northern Ireland Department”;

- (c) for “propose” substitute “take”;
 - (d) omit “at Union level”;
 - (e) omit “within the Union”.
- (7) After paragraph 6, insert—
- “7. The functions of the Secretary of State under paragraph 1 to adopt an import decision and to adopt a revised import decision are subject to the consent requirement in Article 23B.”

158.—(1) Article 14 is amended as follows.

- (2) In paragraph 1—
- (a) for the words from the beginning to “receives” substitute “The Designated National Authority must make available via its website the information which it receives”;
 - (b) omit the second sentence;
 - (c) for “Agency” substitute “Designated National Authority”;
 - (d) for the words “by means of the Database” to the end substitute “via its website”.
- (3) Omit paragraphs 2 and 3.
- (4) In paragraph 4, for “Commission” substitute “Designated National Authority”.
- (5) In paragraph 5, for the words from the beginning to “Member States” substitute “The Designated National Authority”.
- (6) In paragraph 6—
- (a) in the first subparagraph—
 - (i) for “Annex I” substitute “the UK PIC list”;
 - (ii) in point (a), for the words from “designated national authority of the exporter’s” to “Agency” substitute “exporter’s Designated National Authority”;
 - (iii) in point (b), for “Annex I” substitute “the UK PIC list”;
 - (b) in the second subparagraph—
 - (i) for “Annex I” substitute “the UK PIC list”;
 - (ii) for “designated national authority of the exporter’s Member State” substitute “exporter’s Designated National Authority”;
 - (iii) omit “in consultation with the Commission and on a case-by-case basis”;
 - (c) in the third subparagraph—
 - (i) for “Agency”, in each place it occurs, substitute “Designated National Authority”;
 - (ii) omit “, on behalf of the Commission,”;
 - (iii) for the words from “unless” to “forwarded it to the Agency” substitute “to the designated national authority of the importing Party or an appropriate authority in the importing other country”.
- (7) In paragraph 7—
- (a) in the first subparagraph—
 - (i) for “Annex I” substitute “the UK PIC list”;
 - (ii) for “designated national authority of the exporter’s Member State” substitute “exporter’s Designated National Authority”;
 - (iii) omit the words from “in consultation” to “case-by-case basis and”;
 - (iv) in point (b), for “Annex I” substitute “the UK PIC list”;

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- (b) in the second subparagraph, for “Annex I” substitute “the UK PIC list”;
- (c) in the third subparagraph—
 - (i) for “Annex I” substitute “the UK PIC list”;
 - (ii) for “designated national authority of the exporter’s Member State” substitute “exporter’s Designated National Authority”;
 - (iii) omit “, in consultation with the Commission assisted by the Agency,”;
 - (iv) omit the words from “, and submit” to the end.
- (8) In paragraph 8, for “Commission in consultation with the Member States concerned” substitute “Designated National Authority”.
- (9) Omit paragraph 9.
- (10) In paragraph 11, for “Union legislation” substitute “retained EU law”.
- 159.** In Article 15—
 - (a) in paragraph 1, in point (a), for “Annex I” substitute “the UK PIC list”;
 - (b) in paragraph 2—
 - (i) for “Union” substitute “United Kingdom”;
 - (ii) for “Annex V” substitute “Part 4 or 5 of the UK PIC list”.
- 160.** In Article 16—
 - (a) in paragraph 2—
 - (i) for “Annex I” substitute “the UK PIC list”;
 - (ii) for “designated national authority of the exporter’s Member State” substitute “exporter’s Designated National Authority”;
 - (b) omit paragraph 3;
 - (c) in paragraph 4—
 - (i) for “Commission” substitute “Designated National Authority”;
 - (ii) for “paragraph 3” substitute “paragraph 2”.
- 161.** In Article 17—
 - (a) in paragraph 1—
 - (i) for “[Directive 98/8/EC](#)” substitute “Regulation (EU) No 528/2012”;
 - (ii) for “Union legislation” substitute “retained EU law”;
 - (b) in paragraph 2, for “Annex I” substitute “Part 1, 2 or 3 of the UK PIC list”.
- 162.**—(1) Article 18 is amended as follows.
 - (2) In the heading, for “authorities of the Member States” substitute “Designated National Authority”.
 - (3) In paragraph 1—
 - (a) in the first subparagraph—
 - (i) for the words from the beginning to “authorities that” substitute “The Designated National Authority”;
 - (ii) for the words from “Annex I” to the end substitute “Parts 1, 2 and 3 of the UK PIC list”;
 - (b) in the second subparagraph, for the words from the beginning to “Member States” substitute “The Designated National Authority”.

(4) Omit paragraphs 2 and 3.

163. In Article 19—

- (a) in paragraph 1, omit the words from “(box 44” to the end;
- (b) in paragraph 2, for “using the Database” substitute “from the exporter’s Designated National Authority”;
- (c) omit paragraph 3.

164. In Article 20—

- (a) in paragraph 1—
 - (i) in the first subparagraph, for the words from the beginning to “Member States” substitute “The Secretary of State”;
 - (ii) in the second subparagraph, for the words from the beginning to “Agency” substitute “The Secretary of State”;
- (b) in paragraph 2, for the words from the beginning to “Agency” substitute “The Secretary of State and the Designated National Authority”;
- (c) in paragraph 3, for the words from “Directive” to “environmental information” substitute “the Environmental Information Regulations 2004(89) and the Environmental Information (Scotland) Regulations 2004(90)”;
- (d) in paragraph 4, for “Agency” substitute “Designated National Authority”.

165. In Article 21—

- (a) in the first paragraph—
 - (i) for the words from the beginning to “Agency” substitute “The Secretary of State”;
 - (ii) for “cooperate in promoting” substitute “promote”;
- (b) in the third paragraph—
 - (i) for “The Commission and the Member States”, in both places it occurs, substitute “The Secretary of State”;
 - (ii) for “they are” substitute “the Secretary of State is”.

166. Omit Article 22.

167. In Article 23—

- (a) in the heading, for “annexes” substitute “the UK PIC list”;
- (b) in paragraph 1—
 - (i) before “list” insert “Secretary of State must review the”;
 - (ii) for “Annex I shall be reviewed by the Commission” substitute “the UK PIC list”;
 - (iii) for “Union” substitute “retained EU”;
- (c) in paragraph 2—
 - (i) omit “at Union level” in both places it occurs;
 - (ii) for “Annex I”, in both places it occurs, substitute “the UK PIC list”;
- (d) in paragraph 3—
 - (i) after “The” insert “Secretary of State must take the”;
 - (ii) for “Annex I” substitute “the UK PIC list”;

(89) S.I. 2004/3391.

(90) S.S.I. 2004/520.

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

- (iii) omit “shall be taken”;
- (e) in paragraph 4, from “Commission” to the end substitute “Secretary of State may by regulations amend Annexes II, IV and VI”;
- (f) after paragraph 4, insert—
 - “5. The function of the Secretary of State under paragraph 3 is subject to the consent requirement in Article 23B.”

168. After Article 23, insert—

“Article 23A

Regulation making power

1. Any power to make regulations conferred on the Secretary of State by this Regulation is exercisable by statutory instrument.
2. Such regulations may—
 - (a) contain incidental, supplemental, consequential and transitional provision, and
 - (b) may make different provision for different purposes.
3. A statutory instrument containing regulations made under this Regulation is subject to annulment in pursuance of a resolution of either House of Parliament.

Article 23B

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⁽⁹¹⁾) 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⁽⁹²⁾) whether or not the exercise of the function also relates to a part of the United Kingdom other than Wales.
4. The consent of a Northern Ireland Department 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 paragraph 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

⁽⁹¹⁾ 1998 c. 46.

⁽⁹²⁾ 2006 c. 32.

(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.

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⁽⁹³⁾. 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.”

169. Omit Articles 24 to 31.

170. Omit Annex I.

171.—(1) Annex II is amended as follows.

(2) In paragraph 1(d), for “CUS number (European Customs Inventory of Chemical Substances) and Combined Nomenclature code” substitute “a classification code in accordance with section 8 of the Taxation (Cross-border Trade) Act 2018”.

(3) In paragraph 2—

- (a) in point (b), for “Annex I” substitute “Part 1, 2 or 3 of the UK PIC list”;
- (b) in point (c), for “CUS number (European Customs Inventory of Chemical Substances) and Combined Nomenclature code” substitute “a classification code in accordance with section 8 of the Taxation (Cross-border Trade) Act 2018”.

(4) In paragraph 3(b), for “Annex I” substitute “Part 1, 2 or 3 of the UK PIC list”.

(5) In paragraph 5—

- (a) for “Designated national authorities” substitute “Designated National Authority”;
- (b) in point (a), for “designated authority in the Union” substitute “Designated National Authority”.

(6) In paragraph 8—

- (a) for “Union”, in both places it occurs, substitute “United Kingdom”;
- (b) in paragraph (b), for “Annex I of the Regulation” substitute “Parts 1, 2 and 3 of the UK PIC list”.

172. Omit Annex III.

173. In Annex IV, in paragraph 1, in point (f), for “Union” substitute “United Kingdom”.

174. Omit Annex V.

175. Omit Annex VII.

Commission Regulation (EU) No 283/2013

176.—(1) **Commission Regulation (EU) No 283/2013** of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market is amended as follows.

(93) 1998 c. 47.

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

(2) In the Annex, in Part A, in Section 1—

(a) in point 1.4—

(i) for “Part III of Annex VI to Regulation (EC) No 1272/2008” substitute “the UK mandatory classification and labelling list”;

(ii) for “Regulation” in the second place it occurs, substitute “list”;

(b) after point 1.4 insert—

“1.4.1. In point 1.4, “the UK mandatory classification and labelling list” means the list of mandatory classification and labelling requirements of substances and groups of substances established and maintained in accordance with Article 38A of Regulation (EC) No 1272/2008.”

Commission Regulation (EU) No 284/2013

177.—(1) Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market is amended as follows.

(2) In the Annex—

(a) in Part A—

(i) in point 1.4.3—

(aa) for “Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council” substitute “the UK mandatory classification and labelling list”;

(bb) for “Regulation” in the second place it occurs, substitute “list”;

(ii) after point 1.4.3 insert—

“1.4.3.1. In point 1.4.3, “the UK mandatory classification and labelling list” means the list of mandatory classification and labelling requirements of substances and groups of substances established and maintained in accordance with Article 38A of Regulation (EC) No 1272/2008.”;

(b) in Part B—

(i) in point 1.4(iii)—

(aa) for “Annex VI to Regulation (EC) No 1272/2008” substitute “the UK mandatory classification and labelling list”;

(bb) for “Regulation” in the second place it occurs, substitute “list”;

(ii) after point 1.4 insert—

“1.4.1. In point 1.4(iii), “the UK mandatory classification and labelling list” has the same meaning as in point 1.4.3.1 of Part A.”

Regulation (EU) No 354/2013

178. Commission Delegated Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council is amended in accordance with paragraphs 179 to 193.

179. In Article 2, in paragraph 2—

(a) for “Agency” in both places it occurs substitute “competent authority”;

(b) for the second subparagraph substitute—

“The opinion shall be delivered within 45 days following receipt of the request and payment of the appropriate fee. In this Regulation ‘appropriate fee’ means the fee payable for the activity concerned in—

(a) regulations made under section 43 of the Health and Safety at Work etc. Act 1974⁽⁹⁴⁾ where the competent authority is appointed in accordance with regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013⁽⁹⁵⁾; or

(b) regulations made under Article 40 of the Health and Safety at Work (Northern Ireland) Order 1978⁽⁹⁶⁾ where the competent authority is appointed in accordance with regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013⁽⁹⁷⁾.”

180. Omit Article 3.

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

(2) In paragraph 2, in point (d), for “Member State evaluating the application in accordance with Article 7(4) or 8(4), or in the case of a change of Union authorisation, the Agency,” substitute “competent authority”.

(3) In the subparagraph after point (d)—

(a) omit “or 12”;

(b) omit “or 13”.

182.—(1) Article 5 is amended as follows.

(2) In point (1)—

(a) omit “as available from the Register for Biocidal Products”;

(b) omit points (b) to (d);

(c) in point (e)—

(i) omit “in, as appropriate”;

(ii) omit points (1) and (2).

(3) In point (4), after the words “Article 19 or 25 of Regulation (EU) No 528/2012;” insert “, including any further information requested by the competent authority.”

(4) Omit point (5).

183. In the heading of Chapter II, for “products authorised by member states” substitute “authorised products”.

184.—(1) Article 6 is amended as follows.

(2) In paragraph 1—

(a) omit “simultaneously to all Member States concerned”;

(b) after “a notification” insert “to the competent authority”;

(c) omit “, in each of those Member States,”;

⁽⁹⁴⁾ 1974 c. 37.

⁽⁹⁵⁾ S.I. 2013/1506

⁽⁹⁶⁾ S.I. 1978/1039 (N.I. 9).

⁽⁹⁷⁾ S.R. 2013 No. 206.

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

- (d) for “fee payable in accordance with Article 80(2) of Regulation (EU) No 528/2012” substitute “appropriate fee”.
- (3) In paragraph 3—
 - (a) in the first subparagraph—
 - (i) for “one of the Member States concerned” substitute “the competent authority”;
 - (ii) for “that Member State” substitute “the competent authority”;
 - (iii) omit “and the other Member States concerned”;
 - (b) in the second subparagraph—
 - (i) for “a Member State concerned” substitute “the competent authority”;
 - (ii) for “that Member State” substitute “it”.
- (4) In paragraph 4—
 - (a) for “Each of the Member States concerned which” substitute “Where the competent authority”;
 - (b) after “with paragraph 3” insert “it”.

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

- (2) For “reference Member State” in each place it occurs substitute “competent authority”.
- (3) In paragraph 1, omit “simultaneously to all Member States concerned”.
- (4) In paragraph 2—
 - (a) for “Each Member State concerned” substitute “The competent authority”;
 - (b) for “the fee payable in accordance with Article 80(2) of Regulation (EU) No 528/2012” substitute “the appropriate fee”;
 - (c) omit “and the other Member States concerned”;
 - (d) for “Member State concerned” in both places it occurs substitute “competent authority”.
- (5) In paragraph 3, omit “and the Member States concerned” in both places it occurs.
- (6) In paragraph 4, omit “to the Member States concerned and”.
- (7) In paragraph 5, omit “and the Member States concerned”.
- (8) Omit paragraph 6.
- (9) For paragraph 7 substitute—

“7. Where authorisation of the change is granted, the competent authority shall, within 30 days, amend the authorisation of the biocidal product in conformity with the change.”

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

- (2) For “reference Member State” in each place it occurs substitute “competent authority”.
- (3) In paragraph 1, for “simultaneously to all Member States concerned” substitute “to the competent authority”.
- (4) In paragraph 2—
 - (a) for “Each Member State concerned” substitute “The competent authority”;
 - (b) for “fee payable in accordance with Article 80(2) of Regulation (EU) No 528/2012” substitute “appropriate fee”;
 - (c) for “the Member State concerned” in both places it occurs substitute “the competent authority”;

- (d) omit “and the other Member States concerned”.
- (5) In paragraph 3 omit “and the Member States concerned” in both places it occurs.
- (6) In paragraph 4 omit “to the Member States concerned and”.
- (7) In paragraph 5 omit “and the Member States concerned”.
- (8) Omit paragraph 6.
- (9) For paragraph 7 substitute—
 - “7. Where authorisation of the change is granted, the competent authority shall, within 30 days, amend the authorisation of the biocidal product in conformity with the change.”

187. Omit Articles 9 to 13.

188.—(1) Article 14 is amended as follows.

- (2) In paragraph 1—
 - (a) for “Articles 6 and 11” in both places it occurs substitute “Article 6”;
 - (b) for “Member State or, in the case of changes of a product authorised by Union authorisation, the Commission” substitute “competent authority”.
- (3) In paragraph 2, for “relevant Member States or, in the case of changes of a product authorised by Union authorisation, the Commission” substitute “competent authority”.

189.—(1) Article 15 is amended as follows.

- (2) Omit paragraphs 1 and 2.
- (3) In paragraph 3—
 - (a) for “Member States” substitute “the competent authority”;
 - (b) for “reference Member State” substitute “competent authority”;
 - (c) for “made the agreement available in the Register for Biocidal Products” insert “informed the applicant that it has agreed to the change”.

190. In Article 16, for “concerned Member States have or, in the case of changes of a product authorised by Union authorisation, the Commission” substitute “competent authority”.

191. In Article 17—

- (a) for “a Member State, the Agency or the Commission” substitute “the competent authority”;
- (b) for “requesting” substitute “competent”.

192. Omit Article 18.

193.—(1) Section 1 of Title 1 of the Annex is amended as follows.

- (2) In point 3, for “European Economic Area (EEA)” substitute “United Kingdom”.
- (3) In point 4, for “EEA” substitute “United Kingdom”.
- (4) In point 5, for “Agency” substitute “competent authority”.

Commission Implementing Regulation (EU) No 414/2013

194. Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council is amended in accordance with paragraphs 195 to 205.

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

195. In Article 1, in the first paragraph, after “authorised or registered in” insert “the United Kingdom in”.

196. In Article 2—

- (a) in the first sentence omit “and the information requirements in Article 43(1) thereof”;
- (b) in point (a) for the words “the application number” to the end substitute “the application number of the related reference product provided by the competent authority on submission of that application”.

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

(2) In the heading omit “national”.

(3) In paragraph 1—

- (a) after the words “by national authorisation” insert “in the United Kingdom”;
- (b) omit “that has granted or is requested to grant the national authorisation of the related reference product”;
- (c) omit paragraph 1a.

(4) In paragraph 2, for “paragraphs 2 and 4” substitute “paragraph 2”.

198. Omit Article 4.

199. In Article 4a, in paragraph 1, omit “that has granted or is requested to grant the authorisation of the related reference product”.

200. Omit Article 4b.

201. In Article 5—

- (a) in the heading omit “national”;
- (b) for “receiving competent authority” substitute “competent authority”.

202. Omit Article 6.

203. In Article 6a—

- (a) in paragraph 1, for “receiving competent authority” substitute “competent authority”;
- (b) omit paragraph 3.

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

(2) In paragraph 1, for “Register for Biocidal Products shall show a” substitute “competent authority shall record the”.

(3) In paragraph 2 —

- (a) for “receiving competent authority” substitute “competent authority”;
- (b) omit “or, where relevant, the Agency”;
- (c) omit “in the Register for Biocidal Products”.

205. Omit Article 8.

Commission Implementing Regulation (EU) No 88/2014

206. Commission Implementing Regulation (EU) No 88/2014 of 31 January 2014 specifying a procedure for the amendment of Annex I to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products is amended in accordance with paragraphs 207 to 212.

207. In Article 1—

- (a) in the first paragraph, for “Annex I to” substitute “the Simplified Active Substance List under”;
- (b) in point (a), for “that Annex” substitute “the Simplified Active Substance List”.

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

(2) In paragraph 1—

- (a) omit “(2),”;
 - (b) omit “, and Article 7(6)”.
- (3) In paragraph 2, for “Annex I to” substitute “the Simplified Active Substance List under”.

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

(2) In paragraph 1—

- (a) omit “evaluating”;
- (b) for “assessment report and the conclusions of its evaluation” substitute “opinion”;
- (c) for “European Chemicals Agency set up under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (‘the Agency’)” substitute “Secretary of State, the Scottish Ministers, the Welsh Ministers and a Northern Ireland department”;
- (d) for “Annex I to” in both places it occurs substitute “the Simplified Active Substance List under”;
- (e) for “assessment report and the conclusions” in both places it occurs substitute “opinion”;
- (f) in the second subparagraph—
 - (i) for “conclusions” substitute “opinion”;
 - (ii) for “Agency” substitute “Secretary of State, the Scottish Ministers, the Welsh Ministers and a Northern Ireland department”;
 - (iii) omit “evaluating” in both places it occurs;
 - (iv) for “assessment report and on the conclusions of the evaluation” substitute “opinion”;
 - (v) for “evaluation” substitute “opinion”.

(3) In paragraph 2—

- (a) for “carry out the evaluation” substitute “provide the opinion”;
- (b) omit “evaluating”;
- (c) omit “, and shall inform the Agency accordingly”.

(4) In paragraph 3, for “Annex I to” in both places it occurs substitute “the Simplified Active Substance List under”.

(5) Omit paragraph 4.

210.—(1) Article 5 is amended as follows.

(2) For the heading substitute “Decision on inclusion of an active substance in the Simplified Active Substance List”.

(3) For “Commission may adopt” substitute “Secretary of State may with the consent of the Scottish Ministers, the Welsh Ministers and a Northern Ireland department, issue”.

(4) For “Annex I to” substitute “the Simplified Active Substance List under”.

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

- (5) For “Agency” substitute “competent authority”.
- (6) In point (a)—
 - (a) for “(4)” substitute “(1)”;
 - (b) after “this Regulation;” insert “or”.
- (7) In point (b) omit “; or”.
- (8) Omit point (c).
- 211.** Omit Article 6.
- 212.** In the Annex—
 - (a) in the heading, for “Annex I to” substitute “the Simplified Active Substance List under”;
 - (b) for “Annex I to” in both places it occurs substitute “the Simplified Active Substance List under”.

Commission Delegated Regulation (EU) No 1062/2014

213. Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council is amended in accordance with paragraphs 214 to 241.

- 214.—**(1) Article 2 is amended as follows.
- (2) For point (a), substitute—
 - “(a) ‘non-approval decision’ means a decision—
 - (i) pursuant to Article 9(1)(b) of Regulation (EU) No 528/2012 not to approve a substance/product-type combination;
 - (ii) made before exit day, pursuant to the third subparagraph of Article 89(1) of that Regulation as it had effect immediately before exit day, not to approve a substance/product-type combination;
 - (iii) made after exit day, pursuant to Article 89(5) of that Regulation, not to approve a substance/product-type combination; or
 - (iv) not to include it in Annex I or IA to [Directive 98/8/EC](#).”
- (3) In point (b)(i)—
 - (a) in the second indent after the words “a Regulation” insert “, made before exit day,”;
 - (b) after the second indent, insert—
 - “a decision issued by the Secretary of State pursuant to Article 89(5) of Regulation (EU) No 528/2012 after exit day;”.
- (4) For point (d), substitute—
 - “(d) ‘competent authority’ means the authority appointed in accordance with—
 - (i) regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013(**98**);
 - (ii) regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013(**99**);”.
- (5) After point (d), insert—

(98) S.I. 2013/1506.

(99) S.R. 2013 No. 206.

- “(e) ‘the consent requirement’ means the requirement for consent in accordance with Article 83B of Regulation (EU) No 528/2012.
- (f) ‘appropriate fee’ means the fee payable for the activity concerned in—
- (i) regulations made under section 43 of the Health and Safety at Work etc. Act 1974⁽¹⁰⁰⁾ where the competent authority is appointed in accordance with regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013; or
 - (ii) regulations made under Article 40 of the Health and Safety at Work (Northern Ireland) Order 1978⁽¹⁰¹⁾ where the competent authority is appointed in accordance with regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013
- (g) ‘Devolved Authority’ means—
- (i) the Scottish Ministers,
 - (ii) the Welsh Ministers, or
 - (iii) a Northern Ireland department.”

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

(2) In the heading, for “Annex I to Regulation (EU) No 528/2012” substitute “the Simplified Active Substance List”.

(3) For “Agency” in both places it occurs substitute “competent authority”.

(4) In paragraph 1—

- (a) for “Annex I to Regulation (EU) No 528/2012” in both places it occurs substitute “the Simplified Active Substance List”;
- (b) in the second subparagraph, for “Annex” substitute “list”.

216. For Article 4 substitute—

“The competent authority shall inform the participant of the appropriate fee within 30 days after the competent authority has accepted the application. If the participant fails to pay the fee within 30 days of notification of the fee, the competent authority shall reject the application and inform the participant accordingly.”

217.—(1) Article 5 is amended as follows.

(2) In the heading, for the words “Annex I to Regulation (EU) No 528/2012” substitute “the Simplified Active Substance List”.

(3) For paragraph 1 substitute—

“**1.** Where an application for approval or inclusion in category 6 of the Simplified Active Substance List containing the data required in accordance with Article 6(1) and (2) of Regulation (EU) No 528/2012 has been accepted by the competent authority and the appropriate fee has been paid pursuant to Article 4 the competent authority shall validate the application within 30 days of that payment.”

(4) Omit paragraph 2.

(5) In paragraph 3—

- (i) for “paragraphs 1 and 2” substitute “paragraph 1”;
- (ii) omit “evaluating”.

⁽¹⁰⁰⁾1974 c. 37.

⁽¹⁰¹⁾S.I. 1978/1039 (N.I. 9).

- (6) In paragraph 4—
 - (a) omit “evaluating” in each place it occurs;
 - (b) in the second subparagraph, for “2” substitute “1”;
 - (c) in the third subparagraph—
 - (i) in the first sentence omit “and the Agency”;
 - (ii) in the final sentence, for “fees paid in accordance with Article 80(1) and (2) of Regulation (EU) No 528/2012” substitute “appropriate fees paid”;
 - (d) in the fourth subparagraph, omit “the Agency and other competent authorities accordingly.”.

218.—(1) Article 6 is amended as follows.

- (2) In paragraph 1—
 - (a) for point (b) substitute—
 - “(b) where, before exit day, the evaluating competent authority in a Member State has accepted the dossier as complete pursuant to Article 13 of Regulation (EC) No 1451/2007 but not yet submitted the competent authority report to the Commission pursuant to Article 14(4) of that Regulation;”;
 - (b) in point (c)—
 - (i) for “Annex I of Regulation (EU) No 528/2012” substitute “the Simplified Active Substance List”;
 - (ii) omit “by the Agency pursuant to Article 4(2)”;
 - (iii) for “fee” substitute “appropriate fee”.
- (3) In paragraph 2—
 - (a) omit “evaluating”;
 - (b) for “send an assessment report and the conclusions of its evaluation to the Agency” substitute “produce an assessment report and conclusions of its evaluation”.
- (4) In paragraph 3—
 - (a) omit “evaluating”;
 - (b) for “sent” substitute “produced”;
 - (c) in subparagraph (b), for “provided for by Annex III” substitute “specified by the Secretary of State and Devolved Authorities”.
- (5) In paragraph 4—
 - (a) for “submitting” substitute “producing”;
 - (b) omit “to the Agency,”;
 - (c) omit “evaluating” in each place it occurs.
- (6) In paragraph 5, in the first subparagraph—
 - (a) omit “evaluating”;
 - (b) omit the words from “, and shall” to the end.
- (7) In paragraph 6 omit “evaluating”.
- (8) In paragraph 7—
 - (a) omit “evaluating”;

- (b) for “of submission of the assessment report” substitute “the assessment report is produced”;
- (c) in point (a)—
 - (i) for “Agency” substitute “relevant authority”;
 - (ii) for “Article 37(1)” substitute “Article 37A(2)”;
 - (iii) for “part 3 of Annex VI to that Regulation” substitute “the UK mandatory classification and labelling list defined in Article 2 of that Regulation”;
- (d) in point (b) for “Agency” substitute “relevant authority appointed under Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC”.

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

(2) In the heading, for “the Agency” substitute “the competent authority”.

(3) For paragraphs 1 and 2 substitute—

“1. This Article shall apply where the competent authority has produced an assessment report pursuant to Article 6(2) and, where relevant, a proposal or a consultation pursuant to Article 6(7).

2. The competent authority shall within 270 days of completion of the assessment report, prepare and submit an opinion to the Secretary of State and the Devolved Authorities on the approval of the substance/product-type combination or its inclusion in category 1, 2, 3, 4, 5 or 6 of the Simplified Active Substance list or both.

The competent authority shall start the preparation of the opinion within 90 days of the completion of the assessment report and evaluation conclusions.”

220. In Article 8—

- (a) for “the Agency” in each place it occurs substitute “the competent authority”;
- (b) in paragraph 2, for “the Commission” substitute “the Secretary of State”;
- (c) in paragraph 3, for “Regulation adopted pursuant” to the end substitute “decision made pursuant to Article 89(5) of that Regulation”.

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

(2) For the heading, substitute “Decision”.

(3) In the first paragraph—

- (a) for “the Agency” substitute “the competent authority”;
- (b) for “the Commission” substitute “the Secretary of State”;
- (c) for “prepare a draft decision for adoption pursuant to Article 89(1)” substitute “issue a decision pursuant to Article 89(5)”.

(4) After the first paragraph, insert—

“The Secretary of State’s decision is subject to the consent requirement.”

222.—(1) Article 10 is amended as follows.

(2) For “Agency” in each place it occurs substitute “competent authority”.

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- (3) In paragraph 2—
 - (a) for “the Register for Biocidal Products” substitute “the system for the exchange of information between the competent authority and applicants”;
 - (b) omit “(hereinafter ‘the Register’)”.
- (4) In paragraph 3, for “the information in the Register” substitute “its records”.
- (5) In paragraph 4, for “Union” substitute “United Kingdom”.

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

- (2) In paragraph 1—
 - (a) in point (a)—
 - (i) omit “Agency or the evaluating”;
 - (ii) omit “through the Register”;
 - (b) in point (c), omit “Article 4(1)”;
 - (c) in point (e), for “evaluating competent authority or the Agency” substitute “competent authority”.
- (3) In paragraph 2 omit “evaluating”.

224.—(1) Article 12 is amended as follows.

- (2) For “the Agency” in each place it occurs substitute “the competent authority”.
- (3) Omit paragraph 1.
- (4) In paragraph 2, for “the information in the Register” substitute “its records”.
- (5) In paragraph 3—
 - (a) for “Commission” substitute “Secretary of State and the Devolved Authorities”;
 - (b) omit the words from “thereof” to the end of the sentence.

225.—(1) Article 13 is amended as follows.

- (2) In paragraph 1—
 - (a) omit “evaluating”;
 - (b) omit the final sentence.
- (3) In paragraph 2—
 - (a) for “Agency” substitute “competent authority”;
 - (b) for “the information in the Register” substitute “its records”.

226. In Article 14, in paragraph 1, for “Agency” substitute “competent authority”.

227.—(1) Article 15 is amended as follows.

- (2) For “Annex I to that Regulation” substitute “the Simplified Active Substance List”.
- (3) In point (a)—
 - (a) for “the person placing the product on the market” insert “the product was placed on the market before exit day and the person placing the product on the market”;
 - (b) after the words “by the Commission” insert “before exit day or the competent authority after exit day”.
- (4) After point (a) insert—

“(aa) the product was placed on the market after exit day and the person placing the product on the market has relied on guidance published by, or written advice received from, the competent authority after exit day, where that guidance or advice gave objectively justified reasons to believe that the product was excluded from the scope of Regulation (EU) No 528/2012, or that the relevant product-type was one for which the active substance had been notified and where that guidance or advice is subsequently reviewed in a decision issued pursuant to Article 3(3) of Regulation (EU) No 528/2012;”.

(5) In point (b), at the end insert “and the person placing the product on the market has complied with the time limits provided for by Regulation (EU) No 528/2012”.

(6) Omit point (c).

228.—(1) Article 16 is amended as follows.

(2) For paragraph 1, substitute—

“**1.** A declaration of interest to notify a substance which is eligible for inclusion in the review programme pursuant to Article 15 shall be submitted through the system for the exchange of information between the competent authority and applicants referred to in Article 71 of Regulation (EU) No 528/2012 by any person with an interest to notify a substance/product-type combination to the competent authority at the latest 12 months after the publication of the decision or guidance referred to in point (a) or (aa) of Article 15.”

(3) In paragraph 2, after “referred to in point (a)” insert “or (aa)”.

(4) In paragraph 3—

(a) for “or (c)” substitute “or (aa)”;

(b) for “Commission finds, in consultation with Member States” substitute “competent authority finds”;

(c) after “listed in point (a)” insert “or (aa)”;

(d) for “it shall inform the Agency thereof” substitute “it shall update its records accordingly”.

(5) In paragraph 4, for “a declaration has been made in the case referred to in point (b) of Article 15, or where the Commission has informed the Agency pursuant to paragraph 3, the Agency” substitute “the competent authority determines that a declaration made under paragraph 3 is valid, the competent authority”.

(6) In paragraph 6—

(a) for “points (a) and (c)” substitute “points (a) and (aa)”;

(b) in point (b), for “the evaluating Member State” substitute “the competent authority”.

229.—(1) Article 17 is amended as follows.

(2) For “Agency” in each place it occurs substitute “competent authority”.

(3) For paragraph 1, substitute—

“**1.** Notifications pursuant to Article 14(2) or Article 16(5) shall be made to the competent authority.”

(4) In paragraph 2, for “in IUCLID format” substitute “in accordance with the format specified under Article 79 of Regulation 528/2012”.

(5) Omit paragraph 3.

(6) For paragraph 4 substitute—

“**4.** Upon receipt of a notification, the competent authority shall inform the notifier of the fee payable. If the notifier fails to pay the appropriate fee within 30 days from the

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receipt of that information, the competent authority shall reject the notification and inform the notifier.”

- (7) In paragraph 5, omit the words from “, and” to the end of the sentence.
- (8) In paragraph 6, omit “paragraph 4 or”.
- (9) In paragraph 7—
 - (a) in point (a), for “update the information in the Register” substitute “update its records”;
 - (b) in point (b) for “inform the Commission of the compliance” substitute “update its records”.

230. For Article 18 (except the heading), substitute—

“Where a substance/product-type combination is considered notified in accordance with Article 16(6) or 17(7)(b) the Secretary of State shall include the substance/product-type combination in the review programme.

The paragraph above is subject to the consent requirement.”

231. In Article 19—

- (a) for “the Agency” in each place it occurs substitute “the competent authority”;
- (b) omit “inform the Member States thereof through the Register and”.

232.—(1) Article 20 is amended as follows.

- (2) In the heading omit “Commission”.
- (3) For the first subparagraph substitute—

“The competent authority shall make a recommendation to the Secretary of State to issue a non-approval decision pursuant to the third subparagraph of Article 89(5) of Regulation (EU) No 528/2012 in the following cases:”.

- (4) In point (a)—
 - (i) for “Agency” substitute “competent authority”;
 - (ii) for “Commission” substitute “Secretary of State and the Devolved Authorities”.

233.—(1) Article 21 is amended as follows.

- (2) For “(a)” in each place it occurs substitute “(a) or (aa)”.
- (3) Omit paragraph 1.
- (4) In paragraph 2—
 - (a) for “A Member State may continue to apply its” substitute “The”;
 - (b) for the words “point (a) of Article 15” substitute “point (a) or (aa) of Article 15 shall continue to apply”;
 - (c) for points (a) and (b) substitute—
 - “(a) The biocidal product shall no longer be made available on the market with effect from 24 months after the notification or publication of the decision or guidance referred to in point (a) or (aa) of Article 15.
 - (b) Use of existing stocks of the biocidal product may continue until 30 months after the notification or publication of the decision or guidance referred to in point (a) or (aa) of Article 15.”
- (5) In paragraph 3—
 - (a) for “A Member State may continue to apply its” substitute “The”;
 - (b) for “the Agency” in both places it occurs substitute “the competent authority”;

(c) after “relevant product-type” insert “shall continue to apply”.

234. For Article 22 (except the heading), substitute—

1. Without prejudice to Article 55(1) of Regulation No 528/2012, within 18 months of the date of a decision not to approve an existing active substance, where the competent authority considers this existing active substance to be essential for one of the reasons referred to in points (b) or (c) of the first subparagraph of Article 5(2) of Regulation (EU) No 528/2012, the competent authority may submit a reasoned application to the Secretary of State or a Devolved Authority for a derogation from point (a) (ii) of Article 89(8) of that Regulation.

2. The competent authority shall make the application, or where relevant, the non-confidential version, publicly available by electronic means. Any person may submit comments within 60 days of publication.

3. Taking account of the comments received, the Secretary of State or a Devolved Authority may exercise a derogation from point (a) (ii) of Article 89(8) of Regulation (EU) No 528/2012 allowing biocidal products consisting of, containing or generating the substance to be made available on the market and used in the United Kingdom subject to the conditions in paragraph 10 and any further conditions imposed by the Secretary of State or a Devolved Authority if they have competence to exercise the derogation within the meaning of paragraphs 4 to 8.

4. The Secretary of State has competence to exercise the derogation if, or to the extent that, the exercise of the function to take that measure—

- (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⁽¹⁰²⁾);
- (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⁽¹⁰³⁾);
- (d) relates to Northern Ireland and is not within devolved competence in Northern Ireland as set out in paragraphs 7 and 8.

5. The Scottish Ministers have competence to exercise the derogation if, or to the extent that, the exercise of the function to take that measure is within devolved competence (within the meaning of section 54 of the Scotland Act 1998).

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

7. A Department in Northern Ireland has competence to exercise the derogation if, or to the extent that the function to take that measure is within devolved competence in Northern Ireland.

8. For the purposes of paragraph 7, the exercise of the function of exercising the derogation 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 taking that provisional measure would be outside the legislative competence of the Assembly.

⁽¹⁰²⁾1998 c. 46.

⁽¹⁰³⁾2006 c. 32; section 58A was inserted by the Wales Act 2017 (c.4).

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The references in this paragraph 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(104).

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.

9. Where the Secretary of State grants the derogation under paragraph 3, the Secretary of State must immediately inform the Devolved Authorities giving reasons for the decision. Where a Devolved Authority exercises the derogation under paragraph 3, it must immediately inform the other Devolved Authorities and the Secretary of State giving reasons for the decision.

10. The competent authority shall:

- (a) ensure that continued use is limited to such cases where and such time during which the conditions of paragraph 1 are fulfilled;
- (b) impose appropriate risk mitigation measures to ensure the exposure of humans, animals and the environment is minimised;
- (c) ensure that alternatives are being sought, or that an application for approval of the active substance is being prepared for submission in accordance with Article 7 of Regulation (EU) No 528/2012 in due time before the expiry of the derogation.”

235. After Article 22 insert—

“Article 22A

Transitional measures for ongoing applications submitted before exit day

1. This Article applies where an application was made before exit day to a Member State in accordance with Article 3 and accepted under Article 4 of Regulation (EU) No 1062/2014 or Article 9 of Regulation (EC) No 1451/2007 as they had effect immediately before exit day and where a decision on approval has not been made before exit day.

2. The application will be treated as having been received under Article 4 of this Regulation as it has effect in retained EU law if the participant resubmits their application and supporting dossier to the competent authority within:

- (a) 90 days after exit day where the United Kingdom was the evaluating Member State prior to exit day; or
- (b) 180 days after exit day where the United Kingdom was not the evaluating Member State prior to exit day.

Article 22B

Declaration of interest to notify

1. This Article applies where a declaration of interest to notify was submitted before exit day under Article 16 of Regulation (EU) No 1062/2014 as it had effect immediately before exit day.

2. Where a declaration of interest to notify made pursuant to Article 16(1) was declared compliant under Article 16(3) or (4) it will be treated as being compliant under this Regulation as it has effect in retained EU law.

(104)1998 c. 47; section 6 is amended by section 12 of the European Union Withdrawal Act 2018 and S.I. 2011/1043.

3. If a declaration of interest to notify was made pursuant to Article 16(1) but no decision on whether the declaration is compliant has been made before exit day, the person with an interest to notify may submit their declaration of interest under Article 16 of this Regulation to the competent authority within 180 days of exit day.

4. In circumstances where the time period for declarations of interest to notify as specified in Article 16(1)(a) of Regulation (EU) 1062/2014 has not expired before exit day, applications for declarations of interest to notify may be made to the competent authority under this Regulation at the latest 365 days after the publication of the decision or guidance referred to in point (a) of Article 15 of Regulation (EU) 1062/2014.

Where a declaration of interest is made in compliance with paragraph 3 or 4 the declaration shall be treated as having been made under Article 16 of this Regulation.

Article 22C

Notification procedure pursuant to Articles 14(2) and 16(5)

1. This Article applies in relation to notifications made under Article 14(2) or 16(5) of Regulation (EU) 1062/2014.

2. Where a notification made under Article 14(2) or Article 16(5) was declared compliant under Article 17(5) before exit day, the notification will be treated as if it were compliant under this Regulation. The Secretary of State must update Annex II to this Regulation in accordance with Article 89(2) of Regulation 528/2012 if:

- (a) a declaration of interest to notify is resubmitted to the competent authority; and
- (b) the information as detailed within Annex I to this Regulation is resubmitted to the competent authority within a period of 180 days of exit day.

3. The applications referred to in Article 3(1) must be submitted to the competent authority within two years of the notification of the declaration of compliance made under Article 17(5) of this Regulation.

4. Where a notification made pursuant to either Article 14(2) or Article 16(5) was made in accordance with Regulation (EU) 1062/2014 before exit day but for which no declaration of compliance pursuant to Article 17(5) was made before exit day, the person may within 180 days of exit day resubmit their notification to the competent authority under Article 16 of this Regulation.

5. Where the relevant notification deadline as specified within Article 14(2) or Article 16(5) of Regulation (EU) 1062/2014 has not passed before exit day, a person may submit their notification to the competent authority under Article 16 of this Regulation, provided the notification is submitted before that notification deadline has passed.

6. A declaration of compliance made in accordance with paragraph 3 or 4 shall be considered as having been made under Article 17(5) of this Regulation.

Article 22D

Dossiers submitted to Rapporteur Member States before exit day

1. This Article applies where a dossier was submitted before exit day for evaluation by a Member State in accordance with Article 14 of [Commission Regulation \(EC\) No 1451/2007](#).

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2. The application will be treated as having being made under this Regulation if the applicant resubmits their application and supporting dossier to the competent authority within:

- (a) 90 days of exit day where the United Kingdom was the Reference Member State, prior to exit day; or
- (b) 180 days where the United Kingdom was a Concerned Member State, prior to exit day.”

236. Omit Article 23.

237. Omit Article 24.

238. In the text following Article 24, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”

239. In Annex I, in point (3), for “Annex 1 to regulation (EU) 528/2012” substitute “the Simplified Active Substance list”.

240. In Annex II omit the column entitled “Rapporteur Member State”.

241. Omit Annex III.

SCHEDULE 3

Regulation 2(3)

AMENDMENTS TO ANNEX II TO THE EEA AGREEMENT

1. In Annex II to the EEA agreement, in Part 2—
 - (a) omit points 12n{257} to {260};
 - (b) omit points 12o{317} and {318};
 - (c) in point 12zze—
 - (i) omit “32017 R 0542: Commission Regulation (EU) 2017/542 of 22 March 2017 (OJ L.78, 23.3.2017, p.1)”;
 - (ii) after “The Provisions of Regulation (EC) No 1272/2008 shall, for the purpose of this Agreement, be read with the following adaptations:” omit points (a) and (b);
 - (d) omit point 12zzf.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by section 8(1) of the European Union (Withdrawal) Act 2018 and the powers conferred by paragraphs 1 and 7 of Schedule 4 and paragraph 21(b) of Schedule 7 to that Act. They make provision under section 8(1) of that Act in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under section 8(2)(a), (b), (c), (d), (f) and (g) and section 8(3)(a)) arising from the withdrawal of the United Kingdom from the European Union. The Regulations make provision under paragraph

1 of Schedule 4 to that Act for the charging of fees by public bodies in the United Kingdom in connection with functions conferred on them as a result of amendments made by these Regulations under section 8(1) of that Act; and they make provision under paragraph 7 of Schedule 4 revoking provision for the charging of fees for the exercise of functions which are removed by amendments made under section 8(1).

These Regulations make amendments to legislation in the field of chemical regulation and the regulation of genetically modified organisms.

A full impact assessment has not been produced for this instrument because no, or no significant, impact on the private, voluntary or public sector is foreseen.