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 [M1].

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.

Marginal Citations

M1 2018 c. 16. Treasury consent has been obtained pursuant to paragraph 3(1) of Schedule 4.

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.

Commencement Information

I1 Reg. 1 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 [M2];

[F1](b) . . . . . .

(c) the Control of Substances Hazardous to Health Regulations 2002 [M3];

(d) the Dangerous Substances and Explosive Atmospheres Regulations 2002 [M4];

[F2](e) . . . . . .

[F3](f) . . . . . .

(g) the Plant Protection Products (Fees and Charges) Regulations 2011 [M5];

(h) the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 [M6];

[F4](i) . . . . . .

(j) the Genetically Modified Organisms (Contained Use) Regulations 2014 [M7];

(k) the Control of Major Accident Hazards Regulations 2015 [M8];

[F5](l) . . . . . .

[F6](m) . . . . . .

[F7](n) . . . . . .

[F8](o) . . . . . .

(p) the Health and Safety and Nuclear (Fees) Regulations 2016 [M9].

(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;

(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 same 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.

Textual Amendments

F1 Reg. 2(1)(b) omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), regs. 1(2), **4(a)**

F2 Reg. 2(1)(e) omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), regs. 1(2), **4(b)**

F3 Reg. 2(1)(f) omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), regs. 1(2), **4(c)**

F4 Reg. 2(1)(i) omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), regs. 1(2), **4(d)**

F5 Reg. 2(1)(l) omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), regs. 1(2), **4(e)**

F6 Reg. 2(1)(m) omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), regs. 1(2), **4(f)**

F7 Reg. 2(1)(n) omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), regs. 1(2), **4(g)**

F8 Reg. 2(1)(o) omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), regs. 1(2), **4(h)**

Commencement Information

I2 Reg. 2 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M2 S.I. 1998/494, amended by S.I. 2015/21.
M3 S.I. 2002/2677, amended by S.I. 2015/21.
M4 S.I. 2002/2776, amended by S.I. 2015/21.
M5 S.I. 2011/2132, amended by S.I. 2016/254.
M6 S.I. 2013/1506.
M7 S.I. 2014/1663, amended by S.I. 2015/1637.
M8 S.I. 2015/483.
M9 S.I. 2016/253.

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.

Commencement Information

I3 Reg. 3 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

[F9Revocation of Commission Delegated Regulation (EU) No 492/2014

4. Commission Delegated Regulation (EU) No 492/2014 of 7 March 2014 supplementing Regulation (EU) 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 is revoked.**]**

Textual Amendments

F9 Reg. 4 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), regs. 1(2), **5**

Commencement Information

I4 Reg. 4 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

[F10Savings and transitional arrangements

5. Schedule 4 (Savings and transitional arrangements) has effect.**]**

Textual Amendments

F10 Reg. 5 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), regs. 1(2), **6**

Commencement Information

I5 Reg. 5 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

We consent

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

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 [M10] are amended as follows.

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

Commencement Information

I6 Sch. 1 para. 1 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M10 S.I. 1998/494, amended by S.I. 2015/21.

PROSPECTIVE

[F11] **...**

[F11] **2.** . . . . . .

Textual Amendments

F11 Sch. 1 para. 2 and heading omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 2**

Control of Substances Hazardous to Health Regulations 2002

3.—(1) The Control of Substances Hazardous to Health Regulations 2002 [M11] 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 ".

Commencement Information

I7 Sch. 1 para. 3 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M11 S.I. 2002/2677, amended by S.I. 2015/21.

Dangerous Substances and Explosive Atmospheres Regulations 2002

4.—(1) The Dangerous Substances and Explosive Atmospheres Regulations 2002 [M12] are amended as follows.

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

Commencement Information

I8 Sch. 1 para. 4 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M12 S.I. 2002/2776, amended by S.I. 2015/21.

PROSPECTIVE

[F12]...

[F12]**5.** . . . . . .

Textual Amendments

F12 Sch. 1 para. 5 and heading omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 3**

PROSPECTIVE

[F13]...

[F13]**6.** . . . . . .

Textual Amendments

F13 Sch. 1 para. 6 and heading omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 4**

Plant Protection Products (Fees and Charges) Regulations 2011

7. The Plant Protection Products (Fees and Charges) Regulations 2011 [M13] are amended in accordance with paragraphs 8 to 16.

Commencement Information

I9 Sch. 1 para. 7 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M13 S.I. 2011/2132, amended by S.I. 2016/254.

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

(2) Omit the definition of "the Directive".

[F14(2A) After the definition of "authorisation holder", insert—

""Great Britain competent authorities" means—

(a) in relation to England, the Secretary of State;

(b) in relation to Wales, the Welsh Ministers;

(c) in relation to Scotland, the Scottish Ministers;".

(2B) In the definition of "import tolerance", after "has" insert ", in relation to Great Britain,".**]**

(3) After the definition of "liability period" insert—

[F15""MRL compliance" means, in relation to products placed on the market in Great Britain, compliance with the requirements of Article 18 of the MRL Regulation;"**]**.

[F16(3A) For the definition of "the MRL Regulation" substitute—

""the MRL Regulation" means—

(a) in relation to Great Britain, Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC;

(b) in relation to Northern Ireland, Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC as it has effect in EU law".**]**

(4) After the definition of "the MRL Regulation" insert—

""MRL supplementary information requirement" means information requested **[**F17by a Great Britain competent authority**]** in accordance with Article 14(3) of the MRL Regulation;".

[F18(4A) After the definition of "nominated sales representative", insert—

""Northern Ireland competent authority" means the Department of Agriculture, Environment and Rural Affairs;".

(4B) For the definition of "Regulation 1107/2009" substitute—

""Regulation 1107/2009" means—

(a) in relation to Great Britain, Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market, as last amended by Regulation (EU) 2019/1009 of the European Parliament and of the Council;

(b) in relation to Northern Ireland, Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market, as last amended by Regulation (EU) 2019/1009 of the European Parliament and of the Council as it has effect in EU law;".**]**

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

""standalone MRL application" means an application **[**F19to a Great Britain competent authority**]** which is only for the setting, modification or deletion of a maximum residue level of an active substance;".

Textual Amendments

F14 Sch. 1 para. 8(2A)(2B) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 5(2)**

F15 Words in Sch. 1 para. 8(3) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 5(3)**

F16 Sch. 1 para. 8(3A) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 5(4)**

F17 Words in Sch. 1 para. 8(4) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 5(5)**

F18 Sch. 1 para. 8(4A)(4B) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 5(6)**

F19 Words in Sch. 1 para. 8(5) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 5(7)**

Commencement Information

I10 Sch. 1 para. 8 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

[F20**9.** Regulation 3 is amended as follows—

(a) for the heading, substitute "Functions in Article 74(1) of Regulation 1107/2009: Northern Ireland";

(b) in paragraph (1)—

(i) omit "of the Member State";

(ii) for "United Kingdom competent authorities" substitute "Northern Ireland competent authority";

(c) omit paragraph (2).**]**

Textual Amendments

F20 Sch. 1 para. 9 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 6**

Commencement Information

I11 Sch. 1 para. 9 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

[F21**10.** Regulation 4 is amended as follows—

(a) in paragraph 1—

(i) omit sub-paragraph (b);

(ii) at the end, after "in accordance with" insert "paragraphs 1 and 3 respectively of";

(b) after paragraph 1, insert—

"(1A) A Great Britain competent authority may charge fees for work carried out within the scope of Regulation 1107/2009 which relates to evaluating applications made to it for the approval of active substances, safeners, synergists or basic substances, and such fees are payable in accordance with paragraph 2 of Schedule 1.

(1B) The Northern Ireland competent authority may charge fees for work carried out within the scope of Regulation 1107/2009 which relates to evaluating parallel trade applications made to it and such fees are payable in accordance with paragraph 1A of Schedule 1.";

(c) in paragraph 2—

(i) for "United Kingdom" substitute "Great Britain";

(ii) after "applications for import tolerances" insert "and standalone MRL applications";

(d) after paragraph 2, insert—

"(2A) A Great Britain 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.";

(e) in paragraph (4), for "a United Kingdom" substitute "the relevant";

(f) in paragraph (5), for "A United Kingdom" substitute "The relevant";

(g) in paragraph (7), for "a United Kingdom" substitute "the relevant".**]**

Textual Amendments

F21 Sch. 1 para. 10 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 7**

Commencement Information

I12 Sch. 1 para. 10 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 [M14] ".

Commencement Information

I13 Sch. 1 para. 11 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M14 S.I. 2012/1657, amended by S.I. 2016/765, 2018/942.

12. In regulation 7(2)—

(a) omit "or";

[F22(aa) for "under regulation 4(1)" substitute "under regulations 4(1), 4(1A) or 4(1B)";]

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

Textual Amendments

F22 Sch. 1 para. 12(aa) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 8**

Commencement Information

I14 Sch. 1 para. 12 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

[F23**13.** In regulation 8(6), for the definition of "total costs incurred" substitute—

""total costs incurred" means the costs referred to in regulations 5 and 6, excluding any costs in respect of which a fee is payable under—

(a) regulations 4(1), 4(1A) or 4(1B) and Schedule 1,

(b) regulation 4(2) and Schedule 2, or

(c) regulation 4(2A) and Schedule 3;".]

Textual Amendments

F23 Sch. 1 para. 13 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 9**

Commencement Information

I15 Sch. 1 para. 13 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

(2) In paragraph 1—

[F24(a) in the first sentence, after "product-related applications" insert "to a United Kingdom competent authority";]

[F25(b)] in the table—

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

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

(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;

[F26(c)] 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 ".

[F27(2A) After paragraph 1, insert—

"**1A.** Fees for parallel trade applications to the Northern Ireland competent authority are in accordance with the following table, and each item is charged cumulatively.

Item	*Chargeable item*	*Fee(£)*
1	Preliminary consideration of an application to determine whether the application can proceed further	229
2	Parallel trade applications—	
	(a) co-ordination of application for a new product or change to an existing product involving parallel trade(1)	728
	(b) parallel trade verification(2)	208
	(c) parallel trade permit for personal use	156".**]**

(1) Application for a parallel trade permit for other than personal use.

(2) Verification that the product to be traded is identical to a product authorised in accordance with Regulation 1107/2009.

(3) In paragraph 2—

(a) in the heading, for "or synergist" substitute " , synergist or basic substance ";

[F28(b) in the first sentence—

(i) after "The fees" insert "chargeable by a Great Britain competent authority";

(ii) 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 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."

[[F29](3A) In paragraph 3, after "organisation" insert "by a United Kingdom competent authority".**]**

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

Textual Amendments

F24 Sch. 1 para. 14(2)(a) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 10(2)(b)**

F25 Sch. 1 para. 14(2)(a) renumbered as Sch. 1 para. 14(2)(b) (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 10(2)(a)**

F26 Sch. 1 para. 14(2)(b) renumbered as Sch. 1 para. 14(2)(c) (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 10(2)(a)**

F27 Sch. 1 para. 14(2A) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 10(3)**

F28 Sch. 1 para. 14(3)(b) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 10(4)**

F29 Sch. 1 para. 14(3A) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 10(5)**

Commencement Information

I16 Sch. 1 para. 14 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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—

[[F30](a) in the first sentence, for the words from the start to "product-related applications" substitute "Fees chargeable by a Great Britain competent authority for 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 **[**[F31]Great Britain**]** 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 **[**[F31]Great Britain**]**.";

(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 **[**[F32]Great Britain**]** 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 **[**[F33]Great Britain**]** 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 **[**[F34]chargeable by a Great Britain competent authority**]** for standalone MRL applications are in accordance with the following table.

Item	***Category***	***Fee (£)***
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 **[**F35Great Britain**]** 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 **[**F35Great Britain**]**.

(2) This category is for active substances where toxicological endpoints have already been agreed and accepted in respect of the part of **[**F35Great Britain**]** 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 **[**F35Great Britain**]** 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.”

Textual Amendments

F30 Sch. 1 para. 15(5)(a) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 11(2)(a)**

F31 Words in Sch. 1 para. 15(5)(c)(i) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 11(2)(b)(i)**

F32 Words in Sch. 1 para. 15(5)(c)(ii)(bb) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 11(2)(b)(ii)**

F33 Words in Sch. 1 para. 15(5)(c)(iii)(bb) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 11(2)(b)(ii)**

F34 Words in Sch. 1 para. 15(6) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 11(3)(a)**

F35 Words in Sch. 1 para. 15(6) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 11(3)(b)**

Commencement Information

I17 Sch. 1 para. 15 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

16. After Schedule 2 insert—

"SCHEDULE 3 Regulation 4(2A)

Maximum residue level supplementary information fees
[[F36]chargeable by a Great Britain competent authority**]**

Fees **[**[F36]chargeable by a Great Britain competent authority**]** for the evaluation of supplementary information provided in accordance with Article 14(3) of the MRL Regulation are in accordance with the following table.

Item	***Category***	***Fee (£)***
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

(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."

Textual Amendments

F36 Words in Sch. 1 para. 16 inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 12**

Commencement Information

I18 Sch. 1 para. 16 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

17. The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 [M15] are amended in accordance with paragraphs 18 to 29.

Commencement Information

I19 Sch. 1 para. 17 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M15 S.I. 2013/1506.

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 " **[**[F37]Great Britain**]** ";

(d) after the definition of "devolved administration" insert—

""Devolved Authority" means—

(a) the Scottish Ministers, **[**[F38]or**]**

(b) the Welsh Ministers[F39]...

[F40](c) . . . . . .;";

[[F41](e) for the definition of "the PIC Regulation", substitute—

""the PIC Regulation" means—

(a) in relation to Great Britain, 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, of which Annexes II, IV and VI are to be read as amended from time to time;

(b) in relation to Northern Ireland, 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 as it has effect in EU law;";**]**

[[F42](f) after the definition of "the PIC Regulation" insert—

""the Review Regulation" 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;".**]**

Textual Amendments

F37 Words in Sch. 1 para. 18(c) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 13(a)**

F38 Word in Sch. 1 para. 18(d) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 13(b)(i)**

F39 Word in Sch. 1 para. 18(d) omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 13(b)(ii)**

F40 Words in Sch. 1 para. 18(d) omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 13(b)(iii)**

F41 Sch. 1 para. 18(e) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 13(c)**

F42 Sch. 1 para. 18(f) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 13(d)**

Commencement Information

I20 Sch. 1 para. 18 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

Commencement Information

I21 Sch. 1 para. 19 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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.

[F43(2) In accordance with Article 18 of the PIC Regulation, the Designated National Authority is responsible for controlling the export and import of the following chemicals—

(a) in relation to Great Britain, the chemicals listed in Parts 1, 2 and 3 of the GB PIC list;

(b) in relation to Northern Ireland, the chemicals listed in Annex I to the PIC Regulation.**]**

[F44(3) In paragraph (2), "the GB PIC list" means the list established and maintained in accordance with Articles 7 and 23 of the PIC Regulation."**]**

Textual Amendments

F43 Words in Sch. 1 para. 20 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 14(a)**

F44 Words in Sch. 1 para. 20 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 14(b)**

Commencement Information

I22 Sch. 1 para. 20 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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), **[**F45**]**79**]**, 93 and 95(1) of the Biocides Regulation."

Textual Amendments

F45 Word in Sch. 1 para. 21(b) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 15**

Commencement Information

I23 Sch. 1 para. 21 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**F46**]**Article 22 of the Review Regulation**]**.";

(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 ".

Textual Amendments

F46 Words in Sch. 1 para. 22(a) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 16**

Commencement Information

I24 Sch. 1 para. 22 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

[F47 23.—(1) Regulation 14 is amended as follows.

(2) In paragraph (1)—

(a) for "paragraphs (3) and (4)" substitute "paragraph (4)";

(b) at the end insert "or the Review Regulation listed in paragraph (2A)".

(3) In paragraph (2)—

(a) at the start, for "The decisions" substitute "In relation to the Biocides Regulation, the decisions";

(b) above paragraph (a) insert—

"(za) to prohibit or amend the terms and conditions under which a biocidal product may be made available on the market under Article 17A(2);";

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

(d) before sub-paragraph (m) insert—

"(la) to reject an application due to 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);";

(e) after paragraph (n) insert—

"(na) to give a prospective applicant data under Article 63(3);

(nb) to refuse a request under Article 63(3) where every effort has not been made to reach an agreement;";

(f) after paragraph (o) insert—

"(oa) to allow a subsequent applicant to refer to data previously provided by P under Article 64(1);".

(4) After paragraph (2) insert—

"(2A) In relation to the Review Regulation, the decision referred to in paragraph 9(1) is a decision to reject a notification made under Articles 14(2) or 16(5).".

(5) Omit paragraph (3).

(6) 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)";

(d) after sub-paragraph (d) insert—

"(e) in relation to paragraph (2)(za), the decision relates to a notification by P, or someone on behalf of P";

(f) in relation to paragraph (2A), the decision relates to a notification by P, or by someone on behalf of P.".

(7) In paragraph (7), for "Commission or another competent authority" substitute "Secretary of State or a Devolved Authority".**]**

Textual Amendments

F47 Sch. 1 para. 23 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 17**

Commencement Information

I25 Sch. 1 para. 23 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

Commencement Information

I26 Sch. 1 para. 24 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

25. In regulation 21—

(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 ".

Commencement Information

I27 Sch. 1 para. 25 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

26. In regulation 30(1)—

(a) in sub-paragraph (a), omit "or";

(b) omit sub-paragraph (b).

Commencement Information

I28 Sch. 1 para. 26 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

27. In regulation 38 omit paragraph (2).

Commencement Information

I29 Sch. 1 para. 27 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(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."

Commencement Information

I30 Sch. 1 para. 28 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

29. In Schedule 3, in paragraph 7, omit sub-paragraphs (c) and (d).

Commencement Information

I31 Sch. 1 para. 29 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

PROSPECTIVE

F48 **...**

F49 **30.** . . . . . .

Textual Amendments

F48 Sch. 1 para. 30 heading omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 18**

F49 Sch. 1 paras. 30-39 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 18**

PROSPECTIVE

F49 **31.** . . . . . .

Textual Amendments

F49 Sch. 1 paras. 30-39 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 18**

PROSPECTIVE

F49 32. . . . . . .

Textual Amendments

F49 Sch. 1 paras. 30-39 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 18**

PROSPECTIVE

F49 33. . . . . . .

Textual Amendments

F49 Sch. 1 paras. 30-39 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 18**

PROSPECTIVE

F49 34. . . . . . .

Textual Amendments

F49 Sch. 1 paras. 30-39 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 18**

PROSPECTIVE

F49 35. . . . . . .

Textual Amendments

F49 Sch. 1 paras. 30-39 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 18**

PROSPECTIVE

F49 36. . . . . . .

Textual Amendments

F49 Sch. 1 paras. 30-39 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 18**

PROSPECTIVE

F49 37. . . . . . .

Textual Amendments

F49 Sch. 1 paras. 30-39 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 18**

PROSPECTIVE

F49 38. . . . . . .

Textual Amendments

F49 Sch. 1 paras. 30-39 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 18**

PROSPECTIVE

F49 39. . . . . . .

Textual Amendments

F49 Sch. 1 paras. 30-39 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 18**

Genetically Modified Organisms (Contained Use) Regulations 2014

40.—(1) The Genetically Modified Organisms (Contained Use) Regulations 2014 [M16] 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 [M17];".

(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 [M18].

(2) The written consent referred to in paragraph (1) must be valid immediately before **[**[F50]IP completion 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 **[**[F50]IP completion 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;".

Textual Amendments

F50 Words in Sch. 1 para. 40(3) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 19**

Commencement Information

I32 Sch. 1 para. 40 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M16 S.I. 2014/1663, amended by S.I. 2015/1637.
M17 S.I. 2013/2033, amended by S.I. 2014/599, 2018/761.
M18 OJ No. L 106, 17.04.2001, p.1.

Control of Major Accident Hazards Regulations 2015

41.—(1) The Control of Major Accident Hazards Regulations 2015 [M19] 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 **[**[F51]GB**]** 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) ".

Textual Amendments

F51 Word in Sch. 1 para. 41(2) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 20**

Commencement Information

I33 Sch. 1 para. 41 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M19 S.I. 2015/483.

PROSPECTIVE

[F52]...

[F52]**42.** . . . . . .

Textual Amendments

F52 Sch. 1 para. 42 and heading omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 21**

PROSPECTIVE

F53 ...

F53 **43.** . . . . . .

Textual Amendments

F53 Sch. 1 para. 43 and heading omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 22**

PROSPECTIVE

F54 ...

F54 **44.** . . . . . .

Textual Amendments

F54 Sch. 1 para. 44 and heading omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 23**

PROSPECTIVE

F55 ...

F55 **45.** . . . . . .

Textual Amendments

F55 Sch. 1 para. 45 and heading omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 24**

Health and Safety and Nuclear (Fees) Regulations 2016

46.—(1) The Health and Safety and Nuclear (Fees) Regulations 2016 [M20] 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

"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 [M21] 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—

"1 Activity	*2 Fee per person per day worked*
(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

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

Commencement Information

I34 Sch. 1 para. 46 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M20 S.I. 2016/253.

M21 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.

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.

Commencement Information

I35 Sch. 2 para. 1 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

2. In Article 3, after paragraph 41 insert—

"**42.** **[**[F56]GB**]** 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. **[**[F56]GB**]** notification database: the database established in accordance with Article 42 of Regulation (EC) No 1272/2008."

Textual Amendments

F56 Word in Sch. 2 para. 2 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 2(a)**

Commencement Information

I36 Sch. 2 para. 2 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**[F57]GB**]** 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."

Textual Amendments

F57 Word in Sch. 2 para. 3 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 2(b)**

Commencement Information

I37 Sch. 2 para. 3 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

4. In Article 59, in paragraphs 2 and 3, for "Part 3 of Annex VI to Regulation (EC) No 1272/2008" substitute " the **[**[F58]GB**]** mandatory classification and labelling list ".

Textual Amendments

F58 Word in Sch. 2 para. 4 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 2(c)**

Commencement Information

I38 Sch. 2 para. 4 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

5. In Annex I—

(a) in point 1.3.1, for "Part 3 of Annex VI to Regulation (EC) No 1272/2008" substitute " the **[**F59GB**]** 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 **[**F59GB**]** mandatory classification and labelling list ".

Textual Amendments

F59 Word in Sch. 2 para. 5 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 2(d)**

Commencement Information

I39 Sch. 2 para. 5 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**F60GB**]** mandatory classification and labelling list ";

(b) in point 3.2.1(a)(iv) and (vi), for "classification and labelling inventory" substitute " **[**F60GB**]** notification database ".

Textual Amendments

F60 Word in Sch. 2 para. 6 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 2(e)**

Commencement Information

I40 Sch. 2 para. 6 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**F61GB**]** 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 **[**F61GB**]** mandatory classification and labelling list ".

Textual Amendments

F61 Word in Sch. 2 para. 7 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 2(f)**

Commencement Information

I41 Sch. 2 para. 7 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**F62GB**]** 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 **[**F62GB**]** 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 **[**F62GB**]** 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 **[**F62GB**]** mandatory classification and labelling list ".

(5) In Note A, for "Part 3 of Annex VI to that Regulation" substitute " the **[**F62GB**]** mandatory classification and labelling list ".

(6) In Note D, for "Part 3 of Annex VI to Regulation (EC) No 1272/2008" substitute " the **[**F62GB**]** mandatory classification and labelling list ".

Textual Amendments

F62 Word in Sch. 2 para. 8 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 2(g)**

Commencement Information

I42 Sch. 2 para. 8 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

9. In the heading of Appendix 1 omit "(Table 3.1)" and "(Table 3.2)".

Commencement Information

I43 Sch. 2 para. 9 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(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 **[**F63GB**]** 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 **[**F63GB**]** 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 **[**F63GB**]** 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 **[**F63GB**]** mandatory classification and labelling list ".

Textual Amendments

F63 Word in Sch. 2 para. 10 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 2(h)**

Commencement Information

I44 Sch. 2 para. 10 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

Commencement Information

I45 Sch. 2 para. 11 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(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.

Commencement Information

I46 Sch. 2 para. 12 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**F64GB**]** 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 " **[**F65GB**]** notification database of substances notified to the Agency after **[**F66IP completion 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 [M22F67]... ";

(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 [M23] ";

(b) in point (b), for "Directive 2001/82/EC" substitute " the Veterinary Medicines Regulations 2013 [M24] ";

(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 [M25] 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)—

(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 ".

Textual Amendments

F64 Word in Sch. 2 para. 13(2)(c) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 3(a)**

F65 Word in Sch. 2 para. 13(2)(d) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 3(b)(i)**

F66 Words in Sch. 2 para. 13(2)(d) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 3(b)(ii)**

F67 Words in Sch. 2 para. 13(3)(a) omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 3(c)**

Commencement Information

I47 Sch. 2 para. 13 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M22 S.1. 2017/1075.
M23 S.I. 2012/1916.
M24 S.I. 2013/2033.
M25 S.I. 2002/618.

[F68 14. In Article 2—

(a) for point 10 (definition of "producer of an article"), substitute—

"**10.** "producer of an article" means any natural or legal person—

(a) who makes or assembles an article within Great Britain;

(b) who makes or assembles an article within Northern Ireland which is a qualifying Northern Ireland good and which is placed directly on the market in Great Britain;";

(b) for point 15 (definition of "manufacturer") substitute—

"**15.** "manufacturer" means any natural or legal person—

(a) established in Great Britain, who manufactures a substance within Great Britain";

(b) established in Northern Ireland, who manufactures a substance which is a qualifying Northern Ireland good and which is placed directly on the market in Great Britain;";

(c) for point 16 (definition of "import") substitute—

"**16.** "import" means the physical introduction into Great Britain, except where the goods are qualifying Northern Ireland goods;";

(d) for point 17 (definition of "importer") substitute—

"**17.** "importer" means any natural or legal person established within Great Britain who is responsible for import;";

(e) in point 19 (definition of "downstream user"), for "within the Community" substitute "within Great Britain, or within Northern Ireland in the case of qualifying Northern Ireland goods which are placed directly on the market in Great Britain";

(f) in point 20 (definition of "distributor"), for "within the Community" substitute "within Great Britain, or within Northern Ireland in the case of qualifying Northern Ireland goods which are placed directly on the market in Great Britain";

(g) in point 23 (definition of "the Agency"), for the words from "European Chemicals Agency" to the end substitute "Health and Safety Executive";

(h) in point 24 (definition of "competent authority"), 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";

(i) after point 37 (definition of "intermediate packaging") insert—

"**38.** "GB 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. "GB 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 as it has effect in EU law;

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, as it has effect in EU law;

42. "Devolved Authority" means—

(a) the Scottish Ministers, or

(b) the Welsh Ministers;

43. "qualifying Northern Ireland goods" has the meaning given by regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018.".**]**

Textual Amendments

F68 Sch. 2 para. 14 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 4**

Commencement Information

I48 Sch. 2 para. 14 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

[[F69]**15.** In Article 4—

(a) in paragraph 3—

(i) in the first subparagraph—

(aa) for "harmonised" substitute "mandatory";

(bb) for "Part 3 of Annex VI" substitute "the GB mandatory classification and labelling list";

(ii) in the second subparagraph, for "Part 3 of Annex VI" substitute "the GB mandatory classification and labelling list";

(b) in paragraph 5, after "distributors" insert "who are established within Great Britain";

(c) in paragraph 6, after "downstream users" insert "who are established within Great Britain".**]**

Textual Amendments

F69 Sch. 2 para. 15 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 5**

Commencement Information

I49 Sch. 2 para. 15 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 [M26] applies ".

Commencement Information

I50 Sch. 2 para. 16 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M26 1986 c. 14.

17. In Article 10—

(a) in paragraph 3, for "harmonised" substitute " mandatory " and for "Part 3 of Annex VI" substitute " the **[**[F70]GB**]** 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 **[**[F70]GB**]** mandatory classification and labelling list ";

(ii) in the second subparagraph, for "Part 3 of Annex VI" substitute " the **[**[F70]GB**]** mandatory classification and labelling list ";

(c) in paragraph 5, for "classification and labelling inventory" substitute " **[**[F70]GB**]** notification database ".

Textual Amendments

F70 Word in Sch. 2 para. 17 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 6(a)**

Commencement Information

I51 Sch. 2 para. 17 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

18. In Article 15—

(a) in paragraph 4, for "harmonised" substitute " mandatory " and for "Part 3 of Annex VI" substitute " the **[**[F71]GB**]** 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 ".

Textual Amendments

F71 Word in Sch. 2 para. 18 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 6(b)**

Commencement Information

I52 Sch. 2 para. 18 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

19. Omit Article 16.

Commencement Information

I53 Sch. 2 para. 19 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 ".

Commencement Information

I54 Sch. 2 para. 20 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

21. In Article 18, in paragraph 2—

(a) in point (a), for "Part 3 of Annex VI" substitute " the **[**F72GB**]** mandatory classification and labelling list ";

(b) in point (b), for "Part 3 of Annex VI" substitute " the **[**F72GB**]** mandatory classification and labelling list " and for "classification and labelling inventory" substitute " **[**F72GB**]** notification database ";

(c) in point (c), for "Part 3 of Annex VI nor the classification and labelling inventory" substitute " the **[**F72GB**]** mandatory classification and labelling list nor the **[**F72GB**]** notification database ".

Textual Amendments

F72 Word in Sch. 2 para. 21 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 6(c)**

Commencement Information

I55 Sch. 2 para. 21 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

22. In Article 21, in paragraph 3, for "Part 3 of Annex VI" substitute " the **[**F73GB**]** mandatory classification and labelling list ".

Textual Amendments

F73 Word in Sch. 2 para. 22 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 6(d)**

Commencement Information

I56 Sch. 2 para. 22 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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. "

Commencement Information

I57 Sch. 2 para. 23 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

24. In Article 25—

(a) in paragraph 1, in the third subparagraph, for "Part 3 of Annex VI" substitute " the **[**[F74]GB**]** mandatory classification and labelling list ";

(b) in paragraph 2, in the first subparagraph, for "Directive 91/414/EEC" substitute " Regulation (EC) No 1107/2009 ".

Textual Amendments

F74 Word in Sch. 2 para. 24 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 6(e)**

Commencement Information

I58 Sch. 2 para. 24 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

25. In Article 26, in paragraph 2, in the second subparagraph, for "Part 3 of Annex VI" substitute " the **[**[F75]GB**]** mandatory classification and labelling list ".

Textual Amendments

F75 Word in Sch. 2 para. 25 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 6(f)**

Commencement Information

I59 Sch. 2 para. 25 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 ".

Commencement Information

I60 Sch. 2 para. 26 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 ".

Commencement Information

I61 Sch. 2 para. 27 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 ".

Commencement Information

I62 Sch. 2 para. 28 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

29. Omit Article 34.

Commencement Information

I63 Sch. 2 para. 29 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

30. For the heading of Title V substitute " MANDATORY CLASSIFICATION AND LABELLING OF SUBSTANCES AND THE **[**F76GB**]** NOTIFICATION DATABASE ".

Textual Amendments

F76 Word in Sch. 2 para. 30 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 6(g)**

Commencement Information

I64 Sch. 2 para. 30 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

31. For the heading of Chapter 1 in Title V substitute " Establishing mandatory classification of substances ".

Commencement Information

I65 Sch. 2 para. 31 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**F77GB**]** mandatory classification and labelling list ";

(v) omit "at Community level".

Textual Amendments

F77 Word in Sch. 2 para. 32 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 6(h)**

Commencement Information

I66 Sch. 2 para. 32 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

[[F78]**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 IP completion day, or

(b) on which the Committee has published an opinion under Article 37(4) of the EU CLP Regulation before IP completion day, but which has not, as at IP completion day, been included in Part 3 of Annex VI of the EU CLP Regulation.

2. Within 6 months of the publication of the Committee's opinion, the Agency must publish a technical report on the Committee's opinion.

3. Within 12 months of the publication by the Agency of the technical report, the Agency must publish its own opinion.

4. Where the Agency's opinion recommends aligning with the Committee's opinion that there should be a change—

(a) within 12 months of the publication of its opinion, the Agency must—

(i) 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

(ii) send a copy of that recommendation to the Devolved Authorities;

(b) within 3 months of the recommendation being submitted by the Agency, the Secretary of State must—

(i) decide whether to accept the recommendation;

(ii) publish that decision, together with reasons for the decision;

(iii) where the decision referred to in paragraph (i) is to accept the recommendation, specify (alongside the decision and the reasons for the decision) the date from when any new or revised classification and labelling requirement must be complied with;

(iv) notify the Agency of the decision and details referred to in paragraphs (ii) and (iii);

(c) the Secretary of State's functions under paragraph (b)(i) and (iii) are subject to the consent requirement in Article 53B;

(d) within one month of the Secretary of State notifying the Agency of a decision in accordance with paragraph (b)(iv), the Agency must update the GB mandatory classification and labelling list accordingly, making clear the date from when the new or revised classification and labelling requirement must be complied with.

5. 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.".**]**

Textual Amendments

F78 Sch. 2 para. 33 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 7**

Commencement Information

I67 Sch. 2 para. 33 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

[F79 34. After Article 37 insert—

"**Article 37A Procedure for mandatory classification and labelling of substances where Article 37(1) does not apply**

1. This Article—

(a) applies in relation to substances to which Article 37(1) does not apply;

(b) does not apply to manufacturers, importers or downstream users established in Northern Ireland who supply qualifying Northern Ireland goods directly to Great Britain.

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 subparagraphs (1) or (2) must follow the format set out in Part 2 of Annex VI and must 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 and labelling of that substance and, where appropriate, specific concentration limits or M-factors, where there is no entry in the GB 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 GB mandatory classification and labelling list must submit a proposal to the Agency for a revised classification.

(3) A proposal under subparagraph (1) must follow the format set out in Part 2 of Annex VI and must 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, during which time the parties concerned must be given an opportunity to comment, the Agency must publish a technical report on the proposal.

5. Within 6 months of publishing the technical report, the Agency must publish an opinion on the proposal.

6. In exceptional circumstances, the 6 month time limit referred to in paragraph 5 may be extended to 12 months.

7. Where the Agency considers that it is appropriate to recommend that a new or revised mandatory classification and labelling requirement is imposed, within 12 months of the opinion being published, the Agency must—

(a) submit a recommendation to the Secretary of State to give effect to the opinion, and

(b) send a copy of that recommendation to each of the Devolved Authorities.

8.—(1) Within 3 months of the recommendation being submitted by the Agency, the Secretary of State must—

(a) decide whether to accept the recommendation;

(b) publish that decision, together with reasons for the decision;

(c) where the decision referred to in paragraph (b) is to accept the recommendation, specify (alongside the decision and the reasons for the decision) the date from when any new or revised classification and labelling requirement must be complied with;

(d) notify the Agency of the decision and details referred to in paragraphs (b) and (c).

(2) The Secretary of State's functions under subparagraphs (1)(a) and (c) are subject to the consent requirement in Article 53B.

9. Within one month of the Secretary of State notifying the Agency of a decision in accordance with paragraph 8(d), the Agency must update the GB mandatory classification and labelling list accordingly, making clear the date from when any new or revised classification and labelling requirement must be complied with.".**]**

Textual Amendments

F79 Sch. 2 para. 34 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 8**

Commencement Information

I68 Sch. 2 para. 34 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

35. In Article 38—

(a) in the heading, for "harmonised" substitute " mandatory " and for "Part 3 of Annex VI" substitute " the **[**[F80]GB**]** 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."

Textual Amendments

F80 Word in Sch. 2 para. 35 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 9(a)**

Commencement Information

I69 Sch. 2 para. 35 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

36. After Article 38, insert—

"Article 38A

[F81GB] mandatory classification and labelling list

The Agency must establish, maintain and publish electronically a list (to be called "the [F81GB] 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."

Textual Amendments

F81 Word in Sch. 2 para. 36 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 9(b)**

Commencement Information

I70 Sch. 2 para. 36 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

37. For the heading to Chapter 2 substitute " [F82GB] notification database ".

Textual Amendments

F82 Word in Sch. 2 para. 37 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 9(c)**

Commencement Information

I71 Sch. 2 para. 37 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

38. In Article 39 in point (b), omit "or Directive 1999/45/EC".

Commencement Information

I72 Sch. 2 para. 38 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

39. In Article 40, in paragraph 1—

(a) in the first subparagraph, for "inventory" substitute " **[**F83GB**]** notification database ";

(b) in the second subparagraph, in the first sentence, after "notifier" insert " or has been notified before **[**F84IP completion 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 ".

Textual Amendments

F83 Word in Sch. 2 para. 39(a) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 10(a)**

F84 Words in Sch. 2 para. 39(b) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 10(b)**

Commencement Information

I73 Sch. 2 para. 39 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

40. In Article 41, for "inventory" in both places it occurs, substitute " **[**F85GB**]** notification database ".

Textual Amendments

F85 Word in Sch. 2 para. 40 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 11**

Commencement Information

I74 Sch. 2 para. 40 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

41. In Article 42—

(a) in the heading, for "classification and labelling inventory" substitute " **[**F86GB**]** 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 **[**F86GB**]** 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 " **[**F86GB**]** notification database ";

(iii) for the third subparagraph, substitute—

"Information in the **[**F86GB**]** 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 " **[**F86GB**]** 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 **[**F86GB**]** mandatory classification and labelling list;";

(ii) omit points (b), (c) and (d);

(e) in paragraph 3, in the second subparagraph, for "37(5)" substitute " **[**F87**37(4)(b) and Article 37A(8)]** ".

Textual Amendments

F86 Word in Sch. 2 para. 41 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 12(a)**

F87 Words in Sch. 2 para. 41(e) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 12(b)**

Commencement Information

I75 Sch. 2 para. 41 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

42. For the heading to Title VI, substitute " HELPDESK AND APPOINTMENT OF BODIES ".

Commencement Information

I76 Sch. 2 para. 42 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

43. Omit Article 43.

Commencement Information

I77 Sch. 2 para. 43 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

44. In Article 44, for "Member States shall establish national helpdesks" substitute " The Agency must establish a helpdesk ".

Commencement Information

I78 Sch. 2 para. 44 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**[F88]Scotland or Wales**]**, 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 ";

[[F89](d) for paragraph 4 substitute—

"**4.** The Secretary of State may by regulations specify the information relating to emergency health response and preventative measures required for the purposes of this Article, following consultation with relevant stakeholders as referred to in paragraph 5.

5. Before making regulations, the Secretary of State must consult—

(a) the body or bodies appointed under paragraph 1,

(b) any person or body who the Secretary of State considers is representative of importers, if any,

(c) any person or body who the Secretary of State considers is representative of downstream users, if any, and

(d) any other person who the Secretary of State considers appropriate.

6. The Secretary of State's regulation-making function under paragraph 4 is subject to the consent requirement in Article 53B.".**]**

Textual Amendments

F88 Words in Sch. 2 para. 45(b) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 13(a)**

F89 Sch. 2 para. 45(d) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 13(b)**

Commencement Information

I79 Sch. 2 para. 45 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

46. Omit Articles 46 and 47.

Commencement Information

I80 Sch. 2 para. 46 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 [M27] ".

Commencement Information

I81 Sch. 2 para. 47 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M27 S.I. 2013/3134.

[[F90]48. In Article 49—

(a) in paragraph 3—

(i) in the first subparagraph, for "competent authority or the enforcement authorities of a Member State in which a supplier is established" substitute "competent authorities, enforcing authorities";

(ii) in the second subparagraph, after "authority" insert "in question";

(b) after paragraph 3 insert—

"**4.** For the purposes of this Article, "enforcing authorities" has the meaning given by regulation 18 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013.".**]**

Textual Amendments

F90 Sch. 2 para. 48 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 14**

Commencement Information

I82 Sch. 2 para. 48 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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".

Commencement Information

I83 Sch. 2 para. 49 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

50. Omit Article 51.

Commencement Information

I84 Sch. 2 para. 50 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**[F91]paragraphs 6 to 8**]**.

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—

(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 [M28]);

(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 [M29]) [F92]...

[F92](d) . . . . . .

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. [F93]. . . . . .

10. [F93]. . . . . .”

Textual Amendments

F91 Words in Sch. 2 para. 51 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 15(a)**

F92 Words in Sch. 2 para. 51 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 15(b)**

F93 Words in Sch. 2 para. 51 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 15(c)**

Commencement Information

I85 Sch. 2 para. 51 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M28 1998 c. 46.

M29 2006 c. 32. Section 58A was inserted by the Wales Act 2017 (c. 4).

52. In Article 53—

(a) for "Commission may" substitute " Secretary of State may by regulations ";

(b) omit the second and third sentences.

Commencement Information

I86 Sch. 2 para. 52 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

53. After Article 53, insert—

"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 [M30]) 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 [M31]) whether or not the exercise of the function also relates to a part of the United Kingdom other than Wales.

F94 **4.** . . . . . .

F94 **5.** . . . . . .

F94 **6.** . . . . . .

F94 **7.** . . . . . ."

Textual Amendments

F94 Words in Sch. 2 para. 53 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 16**

Commencement Information

I87 Sch. 2 para. 53 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M30 1998 c. 46.

M31 2006 c. 32.

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

Commencement Information

I88 Sch. 2 para. 54 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 " **[**F95GB**]** mandatory classification and labelling list or in the **[**F95GB**]** 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 **[**F95GB**]** mandatory classification and labelling list or in the **[**F95GB**]** 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 **[**F95GB**]** mandatory classification and labelling list or in the **[**F95GB**]** 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 **[**F95GB**]** mandatory classification and labelling list or in the **[**F95GB**]** 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 **[**F95GB**]** mandatory classification and labelling list or in the **[**F95GB**]** 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 **[**F95GB**]** mandatory classification and labelling list or in the **[**F95GB**]** notification database ".

Textual Amendments

F95 Word in Sch. 2 para. 55 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 17(a)**

Commencement Information

I89 Sch. 2 para. 55 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

56. In Annex II—

(a) in point 1.2.5, in the second paragraph, for "Part 3 of Annex VI" substitute " the **[**[F96]GB**]** 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 ".

Textual Amendments

F96 Word in Sch. 2 para. 56 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 17(b)**

Commencement Information

I90 Sch. 2 para. 56 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**[F97]GB**]** 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—

(a) in the title, for "harmonised" substitute " mandatory ";

(b) in point 1.1.1.1, for "Part 3" substitute " the **[**[F97]GB**]** mandatory classification and labelling list ";

(c) in point 1.1.1.4, in the fifth paragraph, for "Part 3" substitute " the **[**[F97]GB**]** mandatory classification and labelling list ";

(d) in point 1.1.1.5, in the first, second and fourth paragraphs, for "Part 3" substitute " the **[**F97GB**]** 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 **[**F97GB**]** 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 **[**F97GB**]** 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 **[**F97GB**]** 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 **[**F97GB**]** mandatory classification and labelling list ";

(iii) in Note L, Note M, and Note N, for "Part 3" substitute " the **[**F97GB**]** 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 **[**F97GB**]** 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 **[**F97GB**]** mandatory classification and labelling list ", and for "Table 3" substitute " the **[**F97GB**]** mandatory classification and labelling list ";

(i) in point 1.2.2, for "in Table 3" substitute " in the **[**F97GB**]** mandatory classification and labelling list ";

(j) in point 1.2.3 for "in Table 3" substitute " in the **[**F97GB**]** mandatory classification and labelling list ";

(k) in point 1.2.4, for "in Table 3" substitute " in the **[**F97GB**]** mandatory classification and labelling list ".

(5) Omit Part 3.

Textual Amendments

F97 Word in Sch. 2 para. 57 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 17(c)**

Commencement Information

I91 Sch. 2 para. 57 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**[F98]GB**]** 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 **[**[F98]GB**]** 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."

Textual Amendments

F98 Word in Sch. 2 para. 58 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 18**

Commencement Information

I92 Sch. 2 para. 58 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**[F99]GB**]** 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 **[**[F99]GB**]** 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 **[**[F99]GB**]** mandatory classification and labelling list ";

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

Textual Amendments

F99 Word in Sch. 2 para. 59 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 19**

Commencement Information

I93 Sch. 2 para. 59 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**F100GB**]** mandatory classification and labelling list ";

(b) after point (1) insert—

"(1A) In point (1)(c), the "**[**F100GB**]** 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."

Textual Amendments

F100 Word in Sch. 2 para. 60 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 20**

Commencement Information

I94 Sch. 2 para. 60 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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.

Commencement Information

I95 Sch. 2 para. 61 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 " **[**F101Great Britain**]** ";

(b) omit point (c);

(c) for "one or more Member States or the Union" substitute " **[**[F102]Great Britain**]** ".

Textual Amendments

F101 Words in Sch. 2 para. 62(3)(a) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 21(a)**

F102 Words in Sch. 2 para. 62(3)(c) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 21(b)**

Commencement Information

I96 Sch. 2 para. 62 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

[[F103](2) In paragraph 2, in the first subparagraph—

(a) in the opening sentence omit "Union";

(b) for point (b) substitute "the Medical Devices Regulations 2002";

(c) for point (c) substitute "the Veterinary Medicines Regulations 2013 and the Human Medicines Regulations 2012;

(d) for point (k) substitute "the Toys (Safety) Regulations 2011".**]**

(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".

Textual Amendments

F103 Sch. 2 para. 63(2) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 22**

Commencement Information

I97 Sch. 2 para. 63 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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;

[[F104](d) in point (k), for "the Union" substitute "Great Britain";**]**

(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 **[**F105IP completion 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 " **[**F106Great Britain**]** ";

(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;

(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.

[F107(ai) "appropriate fee" means the fee payable for the activity concerned in regulations made under section 43 of the Health and Safety at Work etc. Act 1974 where the competent authority is appointed in accordance with regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013;**]**

[F108(aj) "Devolved Authority" means—

(i) the Scottish Ministers, or

(ii) the Welsh Ministers."**]**

(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."

Textual Amendments

F104 Sch. 2 para. 64(2)(d) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 23(a)**

F105 Words in Sch. 2 para. 64(2)(f) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 23(b)**

F106 Words in Sch. 2 para. 64(2)(h)(ii) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 23(c)**

F107 Words in Sch. 2 para. 64(2)(k) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 23(d)(i)**

F108 Words in Sch. 2 para. 64(2)(k) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 23(d)(ii)**

Commencement Information

I98 Sch. 2 para. 64 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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.

Commencement Information

I99 Sch. 2 para. 65 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

(2) In paragraph 2, omit "evaluating".

(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."

Commencement Information

I100 Sch. 2 para. 66 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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.

Commencement Information

I101 Sch. 2 para. 67 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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—

"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."

Commencement Information

I102 Sch. 2 para. 68 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

69. After Article 8 insert—

"Article 8A

The [F109GB] List

The competent authority shall establish, maintain and make electronically available to the public a list of approved active substances ("the [F109GB] List")."

Textual Amendments

F109 Word in Sch. 2 para. 69 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 24**

Commencement Information

I103 Sch. 2 para. 69 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**F110GB**]** List established under Article 8A of this Regulation."

Textual Amendments

F110 Word in Sch. 2 para. 70(4) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 25**

Commencement Information

I104 Sch. 2 para. 70 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 ".

Commencement Information

I105 Sch. 2 para. 71 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

72. Omit Article 11.

Commencement Information

I106 Sch. 2 para. 72 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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."

Commencement Information

I107 Sch. 2 para. 73 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

74. In Article 13—

(a) in paragraph 1, for "Agency" substitute " competent authority ";

(b) omit paragraph 3;

(c) omit paragraph 4.

Commencement Information

I108 Sch. 2 para. 74 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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—

"**4A.** The competent authority shall update the **[**[F111]GB**]** 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 ".

Textual Amendments

F111 Word in Sch. 2 para. 75(6) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 26**

Commencement Information

I109 Sch. 2 para. 75 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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."

Commencement Information

I110 Sch. 2 para. 76 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

77. Omit Article 16.

Commencement Information

I111 Sch. 2 para. 77 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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.

Commencement Information

I112 Sch. 2 para. 78 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

[F112 78A. After Article 17 insert—

"**Article 17A NI Product Market Access**

1. Subject to paragraphs 5-8, a biocidal product is to be treated as if it was authorised by the competent authority under Article 30 or, where relevant, Article 26, under the same terms and conditions as the product is authorised or permitted in Northern Ireland where—

(a) each of the following conditions are met—

(i) the biocidal product—

(aa) is a qualifying Northern Ireland good, and

(bb) has a Relevant NI Permission at that time;

(ii) the authorisation holder or the person with a Relevant NI Permission (as the case may be) is established in Northern Ireland;

(iii) all the active substances in the biocidal product are entered in—

(aa) the list prepared pursuant to Article 8A (the GB List), or

(bb) the list prepared pursuant to Article 24A (the Simplified Active Substance List);

(iv) the person referred to in point (a)(ii) notifies the competent authority no later than 90 days in advance of making the biocidal product available on the market by submitting in full to the competent authority the information that the person submitted in their application under Regulation (EU) No 528/2012 as it has effect in EU law to the evaluating competent authority, reference Member State or Northern Ireland competent authority (as the case may be), for the Relevant NI Permission together with a copy of any relevant NI authorisation or permit;

(v) the competent authority takes no action pursuant to paragraph 2;

(b) if the person referred to in point (a)(ii) intends to make any changes to the product, that person notifies the competent authority no later than 90 days in advance of the date on which such changes will apply, with the information submitted to the reference Member State pursuant to Article 5 of Commission Implementing Regulation (EU) No 354/2013 as it has effect in EU law, or for administrative changes other than those referred to in the second subparagraph of Article 6(2) of that Regulation, that person notifies the competent authority within 12 months of making the change;

(c) if the person referred to in point (a)(ii) intends to renew the authorisation of the product in Northern Ireland, that person notifies the competent authority no later than 90 days in advance of the date of renewal by submitting in full the information that the person submitted to the reference Member State pursuant to Articles 31(1) or 45(1) of Regulation (EU) No 528/2012 as it has effect in EU law or, where relevant, Article 2 of Commission Delegated Regulation (EU) No 492/2014 as it has effect in EU law.

2. The competent authority may prohibit a biocidal product notified under paragraph 1 from being made available on the market in Great Britain where—

(a) such action can be justified on any of the following grounds—

(i) the protection of the environment,

(ii) public policy or security,

(iii) the protection of health and life of humans, particularly of vulnerable groups, or of animals or plants,

(iv) the protection of national treasures possessing artistic, historic or archaeological value,

(v) the target organisms not being present in harmful quantities, or

(b) the competent authority considers that the biocidal product does not meet the criteria set out in Articles 19 or 25.

3. The competent authority may amend the terms and conditions under which a biocidal product may be made available on the market in Great Britain where—

(a) this can be justified on the grounds in paragraph 2(a), or

(b) the competent authority considers that the biocidal product does not meet the criteria set out in Articles 19 or 25.

4. Where the competent authority intends to take action under paragraphs 2 or 3, or identifies concerns as to whether the biocidal product meets the criteria in Articles 19 or 25, the competent authority—

(a) must inform the notifier, and

(b) may request additional information.

5. The period of 90 days referred to in paragraphs 1(a)(iv), (b) and (c) is suspended—

(a) where the competent authority takes action under paragraph 4(b), until the competent authority receives the additional information, and

(b) from the point when the competent authority receives the additional information, for a further period of 90 days to allow the competent authority to consider that additional information.

6. Where any information submitted to the competent authority under this Article includes one or more letters of access, the competent authority may reject the letter of access where it does not hold the relevant data.

7. Where the additional information has not been submitted to the competent authority within 90 days of a request under paragraph 4(b), the notification made under paragraph 1 is to be treated as withdrawn.

8. Where the competent authority has amended the terms and conditions under which a biocidal product may be made available on the market under paragraph 3, that product must not be made available and used in Great Britain other than under those amended terms and conditions.

9. Where a biocidal product has been treated as authorised due to meeting the requirements of paragraph 1 but ceases to satisfy those requirements—

(a) there is deemed to be a cancellation of the authorisation of that product by the competent authority, and

(b) the period of grace provided for in Article 52 applies.

10. For the purposes of this Article—

(a) "NI competent authority" means the competent authority appointed by regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013;

(b) "qualifying Northern Ireland good" has the meaning given by regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018;

(c) "Relevant NI Permission" means any of the following—

(i) a national authorisation granted by the NI competent authority under Article 30 of Regulation (EU) No 528/2012 as it has effect in EU law or under Article 5 of Regulation (EU) No 414/2013 as it has effect in EU law;

(ii) an authorisation granted by mutual recognition by the NI competent authority under Articles 33 or 34 of Regulation (EU) No 528/2012 as it has effect in EU law;

(iii) a Union authorisation granted by the Commission under Article 44 of Regulation (EU) No 528/2012 as it has effect in EU law or under Article 6 of Regulation (EU) No 414/2013 as it has effect in EU law;

(iv) an authorisation granted by the NI competent authority under the simplified procedure in accordance with Article 26 of Regulation (EU) No 528/2012 as it has effect in EU law or Article 6a of Regulation (EU) No 414/2013 as it has effect in EU law;

(v) a biocidal product permitted on the market by the NI competent authority under the Parallel Trade procedure in Article 53(1) of Regulation (EU) No 528/2012 as it has effect in EU law;

(vi) a critical use permit granted in Northern Ireland under Article 55(1) of Regulation (EU) No 528/2012 as it has effect in EU law;

(vii) a provisional authorisation under Article 55(2) of Regulation (EU) No 528/2012 as it has effect in EU law;

(viii) a cultural heritage authorisation granted under Article 55(3) of Regulation (EU) No 528/2012 as it has effect in EU law;

(ix) an essential use authorisation granted under regulation 12 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013.".**]**

Textual Amendments

F112 Sch. 2 para. 78A inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 27**

Commencement Information

I113 Sch. 2 para. 78A in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

79. Omit Article 18.

Commencement Information

I114 Sch. 2 para. 79 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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.

Commencement Information

I115 Sch. 2 para. 80 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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.

Commencement Information

I116 Sch. 2 para. 81 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

82. In Article 21, omit paragraph 3.

Commencement Information

I117 Sch. 2 para. 82 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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.

Commencement Information

I118 Sch. 2 para. 83 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

84. Omit Article 24.

Commencement Information

I119 Sch. 2 para. 84 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

85. Before Article 25, insert—

"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."

Commencement Information

I120 Sch. 2 para. 85 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 ".

Commencement Information

I121 Sch. 2 para. 86 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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)".

Commencement Information

I122 Sch. 2 para. 87 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

88. Omit Article 27.

Commencement Information

I123 Sch. 2 para. 88 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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."

Commencement Information

I124 Sch. 2 para. 89 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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.

Commencement Information

I125 Sch. 2 para. 90 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

91. In Article 30, omit "receiving" in each place it occurs.

Commencement Information

I126 Sch. 2 para. 91 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 ".

Commencement Information

I127 Sch. 2 para. 92 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

93. Omit Articles 32 to 46.

Commencement Information

I128 Sch. 2 para. 93 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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.

Commencement Information

I129 Sch. 2 para. 94 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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.

Commencement Information

I130 Sch. 2 para. 95 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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.

Commencement Information

I131 Sch. 2 para. 96 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

97.—(1) Article 50 is amended as follows.

(2) Omit paragraph 1.

(3) In paragraph 2—

(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 ".

Commencement Information

I132 Sch. 2 para. 97 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

98. Omit Article 51.

Commencement Information

I133 Sch. 2 para. 98 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

Commencement Information

I134 Sch. 2 para. 99 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

100. Omit Article 53.

Commencement Information

I135 Sch. 2 para. 100 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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.

Commencement Information

I136 Sch. 2 para. 101 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 [M32]);

(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 [M33]) [F113]...

[F113](d) . . . . . .

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).

[F114]**7.** . . . . . .

[F114]**8.** . . . . . .

[[F115]**7].** 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 **[**[F116]Devolved Authority**]** and the Secretary of State giving reasons for the decision."

Textual Amendments

F113 Words in Sch. 2 para. 102 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 28(a)**

F114 Words in Sch. 2 para. 102 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 28(b)**

F115 Words in Sch. 2 para. 102 renumbered (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 28(c)**

F116 Words in Sch. 2 para. 102 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 28(d)**

Commencement Information

I137 Sch. 2 para. 102 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M32 1998 c.46

M33 2006 c.32; section 58A was inserted by the Wales Act 2017 (c.4).

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

(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.

Commencement Information

I138 Sch. 2 para. 103 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

104. In Article 57, omit " 27,".

Commencement Information

I139 Sch. 2 para. 104 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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."

Commencement Information

I140 Sch. 2 para. 105 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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.

Commencement Information

I141 Sch. 2 para. 106 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**[F117]IP completion 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 **[**[F117]IP completion 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 **[**[F117]IP completion 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 **[**[F117]IP completion day**]**."

Textual Amendments

F117 Words in Sch. 2 para. 107(3) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 29**

Commencement Information

I142 Sch. 2 para. 107 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

[F118108. In Article 62(2)—

(a) in the first subparagraph, after point (b)—

(i) in the first place it occurs, for "Agency" substitute "competent authority";

(ii) omit "Agency or to a";

(iii) after "under this Regulation" insert "or Regulation (EU) No 528/2012 as it had effect immediately before IP completion day";

(iv) for "The Agency shall" substitute "The competent authority must";

(v) at the end, insert "and whether the competent authority has access to the tests or studies";

(b) in the second subparagraph—

(i) omit "Agency or to a";

(ii) after "under this Regulation" insert "or Regulation (EU) No 528/2012 as it had effect immediately before IP completion day";

(iii) for "the Agency shall" substitute "and where the competent authority has access to the tests or studies the competent authority must".**]**

Textual Amendments

F118 Sch. 2 para. 108 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 30**

Commencement Information

I143 Sch. 2 para. 108 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 ".

Commencement Information

I144 Sch. 2 para. 109 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 ".

Commencement Information

I145 Sch. 2 para. 110 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 ";

[F119(b) in the second subparagraph, for "on the Union market" substitute "on the market in Great Britain";]

(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.

Textual Amendments

F119 Sch. 2 para. 111(3)(b) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 31**

Commencement Information

I146 Sch. 2 para. 111 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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".

Commencement Information

I147 Sch. 2 para. 112 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

(2) In paragraph 1—

(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 ".

Commencement Information

I148 Sch. 2 para. 113 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

114. In Article 68, omit paragraph 2.

Commencement Information

I149 Sch. 2 para. 114 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(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";

[[F120](b) in point (o), for "Directive 2000/45/EC" substitute "the Control of Substances Hazardous to Health Regulations 2002.**]**

(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 ".

Textual Amendments

F120 Sch. 2 para. 115(3)(b) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 32**

Commencement Information

I150 Sch. 2 para. 115 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

116. Omit Article 70.

Commencement Information

I151 Sch. 2 para. 116 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 ".

(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.

Commencement Information

I152 Sch. 2 para. 117 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

118. Omit Articles 74 to 76.

Commencement Information

I153 Sch. 2 para. 118 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

119. For Article 77, substitute—

"Article 77

Appeals

[[F121]**1.** Decisions of the competent authority taken pursuant to this Regulation may be appealed against in accordance with regulation 14 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013.**]**

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."

Textual Amendments

F121 Words in Sch. 2 para. 119 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 33**

Commencement Information

I154 Sch. 2 para. 119 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

120. Omit Article 78.

Commencement Information

I155 Sch. 2 para. 120 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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."

Commencement Information

I156 Sch. 2 para. 121 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

122. Omit Article 80.

Commencement Information

I157 Sch. 2 para. 122 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

123.—(1) Article 81 is amended as follows.

(2) For the heading, substitute " The competent authority ".

(3) For paragraph 1, substitute—

[[F122]"**1.** The competent authority responsible for the application of this Regulation—

(a) is the competent authority as appointed by regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013, and

(b) must have a sufficient number of suitably qualified and experienced staff to enable the obligations provided for in this Regulation to be carried out efficiently and effectively."**]**.

(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.

Textual Amendments

F122 Words in Sch. 2 para. 123(3) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 34**

Commencement Information

I158 Sch. 2 para. 123 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

124. Omit Articles 82, 83 and 84.

Commencement Information

I159 Sch. 2 para. 124 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**F123paragraphs 2 and 3**]**.

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 M34) 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 M35) whether or not the exercise of the function also relates to a part of the United Kingdom other than Wales.

F124**4.** . . . . . .

F124**5.** . . . . . .

F124**6.** . . . . . .

F124**7.** . . . . . ."

Textual Amendments

F123 Words in Sch. 2 para. 125 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 35(a)**

F124 Words in Sch. 2 para. 125 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 35(b)**

Commencement Information

I160 Sch. 2 para. 125 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M34 1998 c. 46.

M35 2006 c. 32.

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."

Commencement Information

I161 Sch. 2 para. 126 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

Commencement Information

I162 Sch. 2 para. 127 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

128. Omit Article 87.

Commencement Information

I163 Sch. 2 para. 128 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**[F125]paragraphs 3 to 5**]**.

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;

(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) [F126]...

[F126](d) . . . . . .

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).

[F127]**6.** . . . . . .

[F127]**7.** . . . . . .

[[F128]**6].** 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 **[**[F129]other Devolved Authority**]** and the Secretary of State giving reasons for the decision."

Textual Amendments

F125 Words in Sch. 2 para. 129 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 36(a)**

F126 Words in Sch. 2 para. 129 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 36(b)**

F127 Words in Sch. 2 para. 129 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 36(c)**

F128 Words in Sch. 2 para. 129 renumbered (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 36(d)**

F129 Words in Sch. 2 para. 129 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 36(e)**

Commencement Information

I164 Sch. 2 para. 129 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

(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.”

Commencement Information

I165 Sch. 2 para. 130 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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.

Commencement Information

I166 Sch. 2 para. 131 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

132. In Article 91, in the first subparagraph—

(a) for “has” substitute “ had ”;

(b) for “authorities” substitute “ authority ”.

Commencement Information

I167 Sch. 2 para. 132 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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."

Commencement Information

I168 Sch. 2 para. 133 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 ".

Commencement Information

I169 Sch. 2 para. 134 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**F130IP completion day**]** or issued by the Secretary of State after **[**F130IP completion day**]** ".

(3) Omit paragraph 2.

Textual Amendments

F130 Words in Sch. 2 para. 135(2)(b) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 37**

Commencement Information

I170 Sch. 2 para. 135 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(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."

Commencement Information

I171 Sch. 2 para. 136 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

PROSPECTIVE

F131 137. . . . . . .

Textual Amendments

F131 Sch. 2 para. 137 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 38**

138. Omit Article 97.

Commencement Information

I172 Sch. 2 para. 138 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

139. Omit Annex I.

Commencement Information

I173 Sch. 2 para. 139 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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".

Commencement Information

I174 Sch. 2 para. 140 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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".

Commencement Information

I175 Sch. 2 para. 141 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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.

Commencement Information

I176 Sch. 2 para. 142 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 " **[**F132Great Britain**]** ".

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

[F133(14) In paragraph 77, for "the Member State or, where appropriate, in the Union" substitute "Great Britain".**]**

Textual Amendments

F132 Words in Sch. 2 para. 143(12) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 39(a)**

F133 Sch. 2 para. 143(14) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 39(b)**

Commencement Information

I177 Sch. 2 para. 143 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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.

Commencement Information

I178 Sch. 2 para. 144 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

[F134**145.** In Article 1—

(a) in paragraph 1, in the second subparagraph—

(i) for "the Union" substitute "Great Britain";

(ii) for "to Parties and other countries" substitute "to Parties, other countries and Northern Ireland";

(b) in paragraph 2—

(i) for "the Member States" substitute "Great Britain";

(ii) for "to other Parties or other countries" substitute "to other Parties, other countries or Northern Ireland";

(iii) for "of those Parties or other countries" substitute "of those Parties, other countries or Northern Ireland".**]**

Textual Amendments

F134 Sch. 2 para. 145 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 40**

Commencement Information

I179 Sch. 2 para. 145 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

[F135(2) In paragraph 1, in point (b), for "the Union or a Member State" substitute "Great Britain";**]**

(3) In paragraph 2—

(a) in point (b), for the words from "Council" to the end substitute " the Ionising Radiations Regulations 2017 M36F136... ";

(b) in point (c), for the words from "Directive" to the end substitute " the Waste (England and Wales) Regulations 2011 M37**[**F137and the Waste (Scotland) Regulations 2011**]** ";

(c) in point (g), for the words from "Directive" to the end substitute " the Genetically Modified Organisms (Deliberate Release) Regulations 2002 M38, the Genetically Modified Organisms (Deliberate Release) **[**F138(Scotland) Regulations 2002 and the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002**]** ";

(d) in point (h)—

(i) for the words from "Directive 2001/83/EC" to "use" substitute " the Human Medicines Regulations 2012 M39 ";

(ii) for the words from "Directive 2001/82/EC" to "products" substitute " the Veterinary Medicines Regulations 2013 M40 ".

[F139(4) In paragraph 3—

(a) in the first subparagraph, after "each importing country" insert ", or to Northern Ireland,";

(b) in the second subparagraph, for "using the Database referred to in Article 6(1)(a)" substitute "from the exporter's Designated National Authority".**]**

Textual Amendments

F135 Sch. 2 para. 146(2) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 41(a)**

F136 Words in Sch. 2 para. 146(3)(a) omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 41(b)(i)**

F137 Words in Sch. 2 para. 146(3)(b) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 41(b)(ii)**

F138 Words in Sch. 2 para. 146(3)(c) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 41(b)(iii)**

F139 Sch. 2 para. 146(4) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 41(c)**

Commencement Information

I180 Sch. 2 para. 146 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M36 S.I. 2017/1075.
M37 S.I. 2011/988.
M38 S.I. 2002/2443.
M39 S.I. 2012/1916.
M40 S.I. 2013/2033.

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 " **[**F140the GB PIC list**]** ".

(5) In point (8)—

(a) in the first sentence, for "within the Union or a Member State" substitute " by retained EU law ";

[F141(b) in the second sentence—

(i) for "the Union" substitute "Great Britain";

(ii) for "Annex I" substitute "the GB PIC list"**]**.

(6) In point (9)—

(a) before "Annex III" insert " both ";

(b) for "Annex I to this Regulation" substitute " the **[**F142GB PIC list**]** ".

(7) In point (10)—

(a) in point (a), for "the Union" substitute " retained EU law ";

[F143(b) in point (b), for "Union" substitute "Great Britain"**]**.

(8) In point (11)—

(a) in point (a), for "the Union" substitute " retained EU law ";

[F144(b) in point (b), for "Union" substitute "Great Britain"**]**.

(9) Omit point (12).

(10) Omit point (15).

(11) For point (16) substitute—

"(16) 'export' means the export of chemicals from **[**F145Great Britain**]**:

(a) made in accordance with **[**F146sections 33(4), 35 or 36**]** of the Taxation (Cross-border Trade) Act 2018 M41; 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 **[**F147Great Britain**]**."

(12) In point (17) for the words from "physical" to the end substitute " importation into **[**F148Great Britain**]** and release to a customs procedure, other than a transit procedure by which chargeable goods may be moved between places in **[**F148Great Britain**]**, of any chemical ".

[F149(13) In point (18)—

(a) in point (a)—

(i) for "Party or other country" substitute "Party, other country or Northern Ireland";

(ii) for "the customs territory of the Union" substitute "Great Britain";

(b) in point (b), for "the customs territory of the Union" substitute "Great Britain";

(c) in point (c), in both places it occurs, for "the Union" substitute "Great Britain"**]**.

[F150(14) In point (19), for "the customs territory of the Union" substitute "Great Britain"**]**.

(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 M42 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) '**[**F151GB PIC list**]**' means the list established and maintained in accordance with Articles 7 and 23."

Textual Amendments

F140 Words in Sch. 2 para. 147(4)(b) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 42(a)**

F141 Sch. 2 para. 147(5)(b) substituted for Sch. 2 para. 147(5)(b)(c) (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 42(b)**

F142 Words in Sch. 2 para. 147(6)(b) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 42(c)**

F143 Sch. 2 para. 147(7)(b) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 42(d)**

F144 Sch. 2 para. 147(8)(b) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 42(e)**

F145 Words in Sch. 2 para. 147(11) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 42(f)(i)**

F146 Words in Sch. 2 para. 147(11) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 42(f)(ii)**

F147 Words in Sch. 2 para. 147(11) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 42(f)(iii)**

F148 Words in Sch. 2 para. 147(12) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 42(g)**

F149 Sch. 2 para. 147(13) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 42(h)**

F150 Sch. 2 para. 147(14) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 42(i)**

F151 Words in Sch. 2 para. 147(17) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 42(j)**

Commencement Information

I181 Sch. 2 para. 147 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M41 2018 c. 22.

M42 S.I. 2013/1506.

148. Omit Article 4.

Commencement Information

I182 Sch. 2 para. 148 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

(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—

[[F152]"(2)**]** The Designated National Authority must:

(a) transmit **[**[F153]Great Britain**]** export notifications to **[**[F154]other Parties, countries and Northern Ireland**]** pursuant to Article 8; and

(b) receive information from the Secretariat more generally.

[F152(2A)**]** 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) **[**F155Great Britain**]** import responses for chemicals subject to the PIC procedure pursuant to Article 13.

[F152(2B)**]** 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.

Textual Amendments

F152 Words in Sch. 2 para. 149(4) renumbered (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 43(a)**

F153 Words in Sch. 2 para. 149(4) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 43(b)(i)**

F154 Words in Sch. 2 para. 149(4) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 43(b)(ii)**

F155 Words in Sch. 2 para. 149(4) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 43(c)**

Commencement Information

I183 Sch. 2 para. 149 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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."

Commencement Information

I184 Sch. 2 para. 150 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**[F156]GB 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 **[**[F157]GB PIC list**]** to one or more of the following groups:

(a) Part 1 of the **[**[F157]GB 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 **[**[F157]GB 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 **[**F157GB 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 **[**F157GB 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 **[**F157GB 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 **[**F158GB PIC list**]** ";

(b) for the words "by means of the Database" substitute " via its website ".

Textual Amendments

F156 Words in Sch. 2 para. 151(3) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 44**

F157 Words in Sch. 2 para. 151(4) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 44**

F158 Words in Sch. 2 para. 151(5) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 44**

Commencement Information

I185 Sch. 2 para. 151 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

[F159(2) In paragraph 1—

(a) for "Annex I" substitute "the GB PIC list";

(b) for the words from "importing Party" to the end substitute "importing Party, other country or Northern Ireland".**]**

(3) In paragraph 2—

(a) in the first subparagraph—

[F160(i) for "the Union" substitute "Great Britain";**]**

[F161(ii) for "to a Party or other country" substitute "to a Party, other country or Northern Ireland";**]**

[F162(iii)**]** for "designated national authority of the Member State in which he is established (the 'exporter's Member State')" substitute " exporter's Designated National Authority ";

[F162(iv)**]** for "that designated national authority" substitute " the Designated National Authority ";

[F162(v)**]** 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;

[[F163](c) in the third subparagraph—

(i) for "The Agency shall, on behalf of the Commission" substitute "The Designated National Authority must";

(ii) after the words "designated national authority of the importing Party" insert "or Northern Ireland";**]**

(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,";

[[F164](v) for "importing Parties and other countries" substitute "importing Parties, other countries and Northern Ireland";**]**

[[F165](vi) for "by means of the Database" substitute "via its website".**]**

[[F166](4) In paragraph (3)—

(a) in the first place it occurs, for "Agency" substitute "Designated National Authority";

(b) for "importing Party or other country" substitute "importing Party, other country or Northern Ireland";

(c) for "Annex I" substitute "the GB PIC list";

(d) in the first place it occurs, omit ", on behalf of the Commission,";

(e) in the second place it occurs, for "Agency" substitute "Designated National Authority";

(f) in the second place it occurs, omit ", on behalf of the Commission,";

(g) after "of the importing Party" insert "or Northern Ireland".**]**

(5) In paragraph 4, for "Union legislation" substitute " retained EU law ".

[[F167](6) In paragraph 5—

(a) in both places the words occur, for "the importing Party or other country" substitute "the importing Party, other country or Northern Ireland";

(b) for the words from "designated" to the end substitute "exporter's Designated National Authority".**]**

[[F168](7) In paragraph 6—

(a) in the first subparagraph—

(i) in point (b), at the end, insert ", or in the case of Northern Ireland where such a response has been provided to the Secretariat indicating whether or not it consents to the import of the chemical";

(ii) in point (c)—

(aa) for "Commission" substitute "Designated National Authority";

(bb) omit the words from "and has forwarded" to the end";

(b) in the second subparagraph, at the end, insert ", or in the case of Northern Ireland, where export notification by exporting Parties is explicitly required through the import decision relating to Northern Ireland or otherwise";

(c) in the third subparagraph—

(i) in point (a), after "designated national authority of the importing Party", insert "or Northern Ireland";

(ii) in point (b)—

(aa) for "Commission" substitute "Designated National Authority";

(bb) after "designated national authority of the importing Party" insert "or Northern Ireland";

(cc) for the words from "and has forwarded" to the end substitute "and has made it publicly available via its website".**]**

[[F169](8) In paragraph 7—

(a) for the words from "The Commission" to "Agency" substitute "The Designated National Authority";

(b) for "importing Parties and other countries" substitute "importing Parties, other countries and Northern Ireland".**]**

(9) Omit paragraph 8.

Textual Amendments

F159 Sch. 2 para. 152(2) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 45(2)**

F160 Sch. 2 para. 152(3)(a)(i) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 45(3)(a)(i)**

F161 Sch. 2 para. 152(3)(a)(ii) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 45(3)(a)(iii)**

F162 Sch. 2 para. 152(3)(a)(ii)-(iv) renumbered as Sch. 2 para. 152(3)(a)(iii)-(v) (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 45(3)(a)(ii)**

F163 Sch. 2 para. 152(3)(c) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 45(3)(b)**

F164 Sch. 2 para. 152(3)(d)(v) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 45(3)(c)(i)**

F165 Sch. 2 para. 152(3)(d)(vi) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 45(3)(c)(ii)**

F166 Sch. 2 para. 152(4) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 45(4)**

F167 Sch. 2 para. 152(6) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 45(5)**

F168 Sch. 2 para. 152(7) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 45(6)**

F169 Sch. 2 para. 152(8) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 45(7)**

Commencement Information

I186 Sch. 2 para. 152 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**F170Great Britain**]** of a chemical the manufacture, use, handling, consumption, transport or sale of which is subject to prohibition or severe restriction **[**F171under the legislation of a Party, other country or Northern Ireland**]**, ";

[F172(iii) for the words from "each Party" to the end substitute "each Party, other country or Northern Ireland"**]**;

(c) omit the third subparagraph.

(3) Omit paragraph 2.

Textual Amendments

F170 Words in Sch. 2 para. 153(2)(b)(ii) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 46(a)(i)**

F171 Words in Sch. 2 para. 153(2)(b)(ii) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 46(a)(ii)**

F172 Sch. 2 para. 153(2)(b)(iii) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 46(b)**

Commencement Information

I187 Sch. 2 para. 153 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

[F173(2) In paragraph 1—

(a) in the first subparagraph

(i) in point (a), for "Annex I" substitute "Part 1, 2 or 3 of the GB PIC list";

(ii) in point (c), for "Annex I" substitute "the GB PIC list";

(iii) in the words which follow point (c)—

(aa) for "designated national authority of the exporter's Member State" substitute "exporter's Designated National Authority";

(bb) for "each Party or other country" substitute "each Party, other country or Northern Ireland";

(cc) for "a Party or other country" substitute "a Party, other country or Northern Ireland";

(b) in the second subparagraph, in both places it occurs, for "the Union" substitute "Great Britain".**]**

(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 ".

Textual Amendments

F173 Sch. 2 para. 154(2) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 47**

Commencement Information

I188 Sch. 2 para. 154 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**F174GB PIC list**]** ".

(3) In paragraph 2—

(a) for "Annex I" substitute " the **[**F175GB 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 **[**F176GB 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.

(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 **[**F177and the Welsh Ministers**]** ";

(iv) for "propose" substitute " take ";

(v) omit "at Union level";

(vi) omit "within the Union".

(8) Omit paragraph 8.

Textual Amendments

F174 Words in Sch. 2 para. 155(2)(b) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 48(a)**

F175 Words in Sch. 2 para. 155(3)(a) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 48(a)**

F176 Words in Sch. 2 para. 155(4)(a)(ii) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 48(a)**

F177 Words in Sch. 2 para. 155(7)(b)(iii) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 48(b)**

Commencement Information

I189 Sch. 2 para. 155 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

156. In Article 12, for the words from "Annex" to "the Commission" substitute " the **[**F178GB PIC list**]**, the Secretary of State ".

Textual Amendments

F178 Words in Sch. 2 para. 156 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 49**

Commencement Information

I190 Sch. 2 para. 156 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**F179and the Welsh Ministers**]** ";

(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."

Textual Amendments

F179 Words in Sch. 2 para. 157(6)(b) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 50**

Commencement Information

I191 Sch. 2 para. 157 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 ".

[[F180](6) In paragraph (6)—

(a) in the first subparagraph—

(i) in the first line, for "Annex I" substitute "the GB PIC list";

(ii) in point (a)—

(aa) for the words from "designated national authority of the exporter's" to "Agency" substitute "exporter's Designated National Authority";

(bb) after "importing Party" insert "or Northern Ireland";

(iii) in point (b)—

(aa) for "Annex I" substitute "the GB PIC list";

(bb) at the end, insert ", or in the case of Northern Ireland the European Union has given consent to import";

(b) in the second subparagraph—

(i) for "Annex I" substitute "the GB 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) in the first two places it occurs, for "Agency" substitute "Designated National Authority";

(ii) for "shall, on behalf of the Commission," substitute "must";

(iii) for the words from "unless" to "forwarded it to the Agency" substitute "to the designated national authority of the importing Party or Northern Ireland or to an appropriate authority in the importing other country";

(iv) in the last place it occurs, for "Agency" substitute "Designated National Authority".**]**

[[F181](7) In paragraph (7)—

(a) in the first subparagraph—

(i) in the first place it occurs, for "Annex I" substitute "the GB 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 the opening sentence and in point (a), for "importing Party or other country" substitute "importing Party, other country or Northern Ireland";

(v) in point (b)—

(aa) for "a Party or other country" substitute "a Party, other country or Northern Ireland";

(bb) for "Annex I" substitute "the GB PIC list";

(cc) at the end, insert "or used in or imported into Northern Ireland (as appropriate)";

(b) in the second subparagraph, for "Annex I" substitute "the GB PIC list";

(c) in the third subparagraph—

(i) for "Annex I" substitute "the GB 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) for "importing Party or other country" substitute "importing Party, other country or Northern Ireland";

(v) 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.

[F182(10) In paragraph 11—

(a) for "importing Party or other country" substitute "importing Party, other country or Northern Ireland";

(b) for "Union legislation" substitute "retained EU law".**]**

Textual Amendments

F180 Sch. 2 para. 158(6) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 51(2)**

F181 Sch. 2 para. 158(7) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 51(3)**

F182 Sch. 2 para. 158(10) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 51(4)**

Commencement Information

I192 Sch. 2 para. 158 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

159. In Article 15—

(a) in paragraph 1, in point (a), for "Annex I" substitute " the **[**F183GB PIC list**]** ";

(b) in paragraph 2—

[F184(i) for "the Union" substitute "Great Britain";**]**

(ii) for "Annex V" substitute " Part 4 or 5 of the **[**F185GB PIC list**]** ".

Textual Amendments

F183 Words in Sch. 2 para. 159(a) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 52(a)**

F184 Sch. 2 para. 159(b)(i) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 52(b)(i)**

F185 Words in Sch. 2 para. 159(b)(ii) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 52(b)(ii)**

Commencement Information

I193 Sch. 2 para. 159 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

160. In Article 16—

(a) in paragraph 2—

(i) for "Annex I" substitute " the **[**F186GB 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 ".

Textual Amendments

F186 Words in Sch. 2 para. 160(a)(i) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 53**

Commencement Information

I194 Sch. 2 para. 160 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(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 ";

[F187(iii) for "the importing Parties or other countries" substitute "importing Parties, other countries or Northern Ireland";**]**

(b) in paragraph 2, for "Annex I" substitute " Part 1, 2 or 3 of the **[**F188GB PIC list**]** ";

[F189(c) in paragraph 3, for "Party or other country" substitute "Party, other country or Northern Ireland".**]**

Textual Amendments

F187 Sch. 2 para. 161(a)(iii) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 54(a)**

F188 Words in Sch. 2 para. 161(b) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 54(b)**

F189 Sch. 2 para. 161(c) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 54(c)**

Commencement Information

I195 Sch. 2 para. 161 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**[F190]GB 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.

Textual Amendments

F190 Words in Sch. 2 para. 162(3)(a)(ii) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 55**

Commencement Information

I196 Sch. 2 para. 162 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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.

Commencement Information

I197 Sch. 2 para. 163 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

164. In Article 20—

[[F191](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 sub-paragraph—

(aa) for the words from the beginning to "Agency as necessary" substitute "The Secretary of State,";

(bb) in point (b), for "Parties and other countries" substitute "a Party, other country or Northern Ireland";

(b) in paragraph 2—

(i) for the words from the beginning to "Agency" substitute "The Secretary of State and the Designated National Authority";

(ii) for "a Party or other country" substitute "a Party, other country or Northern Ireland"**]**;

(c) in paragraph 3, for the words from "Directive" to "environmental information" substitute " the Environmental Information Regulations 2004 [M43] and the Environmental Information (Scotland) Regulations 2004 [M44] ";

(d) in paragraph 4, for "Agency" substitute " Designated National Authority ".

Textual Amendments

F191 Sch. 2 para. 164(a)(b) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 56**

Commencement Information

I198 Sch. 2 para. 164 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M43 S.I. 2004/3391.

M44 S.S.I. 2004/520.

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 ".

Commencement Information

I199 Sch. 2 para. 165 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

166. Omit Article 22.

Commencement Information

I200 Sch. 2 para. 166 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

167. In Article 23—

(a) in the heading, for "annexes" substitute " the **[**F192GB 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 **[**F193GB 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 **[**F194GB PIC list**]** ";

(d) in paragraph 3—

(i) after "The" insert " Secretary of State must take the ";

(ii) for "Annex I" substitute " the **[**F195GB PIC list**]** ";

(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."

Textual Amendments

F192 Words in Sch. 2 para. 167(a) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 57**

F193 Words in Sch. 2 para. 167(b)(ii) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 57**

F194 Words in Sch. 2 para. 167(c)(ii) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 57**

F195 Words in Sch. 2 para. 167(d)(ii) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 57**

Commencement Information

I201 Sch. 2 para. 167 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**F196paragraphs 2 and 3**]**.

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 M45) 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 M46) whether or not the exercise of the function also relates to a part of the United Kingdom other than Wales.

F197**4.** . . . . . .

F197**5.** . . . . . .

F197**6.** . . . . . .

F197**7.** . . . . . ."

Textual Amendments

F196 Words in Sch. 2 para. 168 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 58(a)**

F197 Words in Sch. 2 para. 168 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 58(b)**

Commencement Information

I202 Sch. 2 para. 168 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M45 1998 c. 46.

M46 2006 c. 32.

169. Omit Articles 24 to 31.

Commencement Information

I203 Sch. 2 para. 169 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

170. Omit Annex I.

Commencement Information

I204 Sch. 2 para. 170 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**[F198]GB 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 **[**[F199]GB 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 ".

[[F200](6) In paragraph 8—

(a) in the first line, for "the Union" substitute "Great Britain";

(b) in paragraph (a), for "Union" substitute "Great Britain";

(c) in paragraph (b), for "Annex I of the Regulation" substitute "Parts 1, 2 and 3 of the GB PIC list".**]**

Textual Amendments

F198 Words in Sch. 2 para. 171(3)(a) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 59(a)**

F199 Words in Sch. 2 para. 171(4) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 59(a)**

F200 Sch. 2 para. 171(6) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 59(b)**

Commencement Information

I205 Sch. 2 para. 171 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

172. Omit Annex III.

Commencement Information

I206 Sch. 2 para. 172 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

[F201 173. In Annex IV, in paragraph 1, in point (f), for "the Union" substitute "Great Britain".**]**

Textual Amendments

F201 Sch. 2 para. 173 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 60**

Commencement Information

I207 Sch. 2 para. 173 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

174. Omit Annex V.

Commencement Information

I208 Sch. 2 para. 174 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

175. Omit Annex VII.

Commencement Information

I209 Sch. 2 para. 175 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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.

(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 **[**F202GB**]** 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 **[**F202GB**]** 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."

Textual Amendments

F202 Word in Sch. 2 para. 176 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 61**

Commencement Information

I210 Sch. 2 para. 176 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**F203GB**]** 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 **[**F203GB**]** 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 **[**[F203]GB**]** 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 **[**[F203]GB**]** mandatory classification and labelling list" has the same meaning as in point 1.4.3.1 of Part A."

Textual Amendments

F203 Word in Sch. 2 para. 177 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 62**

Commencement Information

I211 Sch. 2 para. 177 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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.

Commencement Information

I212 Sch. 2 para. 178 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

179. In Article 2, in paragraph 2—

[[F204](a) in the first subparagraph, for "Agency" substitute "competent authority";**]**

[[F205](b) for the second subparagraph substitute—

"The opinion must 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 relations made under section 43 of the Health and Safety at Work etc. Act 1974 where the competent authority is appointed in accordance with regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013.";**]**

[[F206](c) in the third subparagraph, for "Agency" substitute "competent authority".**]**

Textual Amendments

F204 Sch. 2 para. 179(a) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 63(a)**

F205 Sch. 2 para. 179(b) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 63(b)**

F206 Sch. 2 para. 179(c) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 63(c)**

Commencement Information

I213 Sch. 2 para. 179 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

180. Omit Article 3.

Commencement Information

I214 Sch. 2 para. 180 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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".

Commencement Information

I215 Sch. 2 para. 181 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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).

Commencement Information

I216 Sch. 2 para. 182 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

Commencement Information

I217 Sch. 2 para. 183 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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,";

(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 ".

Commencement Information

I218 Sch. 2 para. 184 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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."

Commencement Information

I219 Sch. 2 para. 185 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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."

Commencement Information

I220 Sch. 2 para. 186 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

187. Omit Articles 9 to 13.

Commencement Information

I221 Sch. 2 para. 187 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 ".

Commencement Information

I222 Sch. 2 para. 188 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 ".

Commencement Information

I223 Sch. 2 para. 189 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 ".

Commencement Information

I224 Sch. 2 para. 190 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

191. In Article 17—

(a) for "a Member State, the Agency or the Commission" substitute " the competent authority ";

(b) for "requesting" substitute " competent ".

Commencement Information

I225 Sch. 2 para. 191 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

192. Omit Article 18.

Commencement Information

I226 Sch. 2 para. 192 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 ".

Commencement Information

I227 Sch. 2 para. 193 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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.

Commencement Information

I228 Sch. 2 para. 194 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

[[F207]**195.** In Article 1—

(a) after "which has been authorised and registered" insert "in the United Kingdom";

(b) after "and of the Council or" insert "authorised or registered in the United Kingdom in accordance with";

(c) after "Regulation (EU) No 528/2012," insert "or authorised or registered in Great Britain in accordance with this Regulation,".**]**

Textual Amendments

F207 Sch. 2 para. 195 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 64**

Commencement Information

I229 Sch. 2 para. 195 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 ".

Commencement Information

I230 Sch. 2 para. 196 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

(2) In the heading omit "national".

[[F208](3) In paragraph 1—

(a) after "by national authorisation" insert "in the United Kingdom (before IP completion day) or in Great Britain (from IP completion day)";

(b) after "for such an authorisation" insert "in Great Britain";

(c) omit the words from "that has granted" until the end.

(4) Omit paragraph 1a.

(5) In paragraph 2, for "paragraphs 2 and 4" substitute "paragraph 2".**]**

Textual Amendments

F208 Sch. 2 para. 197(3)-(5) substituted for Sch. 2 para. 197(3)(4) (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 65**

Commencement Information

I231 Sch. 2 para. 197 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

198. Omit Article 4.

Commencement Information

I232 Sch. 2 para. 198 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

Commencement Information

I233 Sch. 2 para. 199 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

200. Omit Article 4b.

Commencement Information

I234 Sch. 2 para. 200 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

201. In Article 5—

(a) in the heading omit "national";

(b) for "receiving competent authority" substitute " competent authority ".

Commencement Information

I235 Sch. 2 para. 201 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

202. Omit Article 6.

Commencement Information

I236 Sch. 2 para. 202 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

203. In Article 6a—

(a) in paragraph 1, for "receiving competent authority" substitute " competent authority ";

(b) omit paragraph 3.

Commencement Information

I237 Sch. 2 para. 203 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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".

Commencement Information

I238 Sch. 2 para. 204 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

205. Omit Article 8.

Commencement Information

I239 Sch. 2 para. 205 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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.

Commencement Information

I240 Sch. 2 para. 206 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 ".

Commencement Information

I241 Sch. 2 para. 207 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 ".

Commencement Information

I242 Sch. 2 para. 208 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

[[F209](2) In paragraph 1—

(a) in the first subparagraph—

(i) omit "evaluating";

(ii) for "assessment report and the conclusions of its evaluation" substitute "opinion";

(iii) for the words from "European Chemicals Agency" to "("the Agency")" substitute "Secretary of State, the Scottish Ministers and the Welsh Ministers";

(iv) in the first place it occurs, for "Annex I to" substitute "the Simplified Active Substance List under";

(v) in the first place it occurs, for "the assessment report and the conclusions" substitute "the opinion";

(vi) in the second place it occurs, for "Annex I to" substitute "the Simplified Active Substance List under";

(vii) in the second place it occurs, for "the assessment report and the conclusions" substitute "the opinion";

(b) in the second subparagraph—

(i) for "conclusions" substitute "opinion";

(ii) for "Agency" substitute "Secretary of State, the Scottish Ministers and the Welsh Ministers,";

(iii) in the first place it occurs, omit "evaluating";

(iv) for "assessment report and on the conclusions of the evaluation" substitute "opinion";

(v) in the second place it occurs, omit "evaluating";

(vi) 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.

Textual Amendments

F209 Sch. 2 para. 209(2) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 66**

Commencement Information

I243 Sch. 2 para. 209 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**F210the Scottish Ministers and the Welsh Ministers**]**, issue ".

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

(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).

Textual Amendments

F210 Words in Sch. 2 para. 210(3) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 67**

Commencement Information

I244 Sch. 2 para. 210 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

211. Omit Article 6.

Commencement Information

I245 Sch. 2 para. 211 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 ".

Commencement Information

I246 Sch. 2 para. 212 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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.

Commencement Information

I247 Sch. 2 para. 213 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**[F211]IP completion day**]**, pursuant to the third subparagraph of Article 89(1) of that Regulation as it had effect immediately before **[**[F211]IP completion day**]**, not to approve a substance/product-type combination;

(iii) made after **[**[F211]IP completion 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 **[**F212IP completion 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 **[**F212IP completion day**]**; ".

[F213(4) For point (d), substitute—

"(d) "competent authority" means the authority appointed in accordance with regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013;"**]**.

[F214(5) After point (d) insert—

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

(g) "Devolved Authority" means—

(i) the Scottish Ministers, or

(ii) the Welsh Ministers.".**]**

Textual Amendments

F211 Words in Sch. 2 para. 214(2) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 68(a)**

F212 Words in Sch. 2 para. 214(3) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 68(a)**

F213 Sch. 2 para. 214(4) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 68(b)**

F214 Sch. 2 para. 214(5) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 68(c)**

Commencement Information

I248 Sch. 2 para. 214 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 ".

Commencement Information

I249 Sch. 2 para. 215 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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."

Commencement Information

I250 Sch. 2 para. 216 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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".

(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,".

Commencement Information

I251 Sch. 2 para. 217 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

(2) In paragraph 1—

(a) for point (b) substitute—

"(b) where, before **[**F215IP completion 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 ".

Textual Amendments

F215 Words in Sch. 2 para. 218(2)(a) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 69**

Commencement Information

I252 Sch. 2 para. 218 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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."

Commencement Information

I253 Sch. 2 para. 219 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 ".

Commencement Information

I254 Sch. 2 para. 220 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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."

Commencement Information

I255 Sch. 2 para. 221 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

(2) For "Agency" in each place it occurs substitute " competent authority ".

(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 ".

Commencement Information

I256 Sch. 2 para. 222 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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".

Commencement Information

I257 Sch. 2 para. 223 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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.

Commencement Information

I258 Sch. 2 para. 224 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 ".

Commencement Information

I259 Sch. 2 para. 225 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

226. In Article 14, in paragraph 1, for "Agency" substitute " competent authority ".

Commencement Information

I260 Sch. 2 para. 226 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**F216IP completion day**]** and the person placing the product on the market ";

(b) after the words "by the Commission" insert " before **[**F216IP completion day**]** or the competent authority after **[**F216IP completion day**]** ".

(4) After point (a) insert—

"(aa) the product was placed on the market after **[**F217IP completion 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 **[**F217IP completion 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 **[**[F218]or in new, authoritative guidance published by the Competent Authority**]**;".

(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).

Textual Amendments

F216 Words in Sch. 2 para. 227(3) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 70(a)**

F217 Words in Sch. 2 para. 227(4) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 70(a)**

F218 Words in Sch. 2 para. 227(4) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 70(b)**

Commencement Information

I261 Sch. 2 para. 227 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 ".

Commencement Information

I262 Sch. 2 para. 228 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 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 ".

Commencement Information

I263 Sch. 2 para. 229 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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."

Commencement Information

I264 Sch. 2 para. 230 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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".

Commencement Information

I265 Sch. 2 para. 231 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 ".

Commencement Information

I266 Sch. 2 para. 232 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 ".

Commencement Information

I267 Sch. 2 para. 233 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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 **[**F219Article 89(7)**]** 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 **[**F220Great Britain**]** subject to the conditions in **[**F221paragraph 8**]** 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 **[**F222paragraphs 4 to 6**]**.

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 M47);

(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 M48)F223...

F223(d) . . . . . .

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).

F224**7.** . . . . . .

F224**8.** . . . . . .

[F225**7].** Where the Secretary of State **[**F226exercises 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 **[**F227Devolved Authority**]** and the Secretary of State giving reasons for the decision.

[F225**8].** 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."

Textual Amendments

F219 Words in Sch. 2 para. 234 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 71(a)**

F220 Words in Sch. 2 para. 234 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 71(b)(i)**

F221 Words in Sch. 2 para. 234 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 71(b)(ii)**

F222 Words in Sch. 2 para. 234 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 71(b)(iii)**

F223 Words in Sch. 2 para. 234 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 71(c)**

F224 Words in Sch. 2 para. 234 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 71(d)**

F225 Words in Sch. 2 para. 234 renumbered (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 71(e)**

F226 Words in Sch. 2 para. 234 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 71(f)(i)**

F227 Words in Sch. 2 para. 234 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 71(f)(ii)**

Commencement Information

I268 Sch. 2 para. 234 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M47 1998 c. 46.

M48 2006 c. 32; section 58A was inserted by the Wales Act 2017 (c.4).

235. After Article 22 insert—

"Article 22A

Transitional measures for ongoing applications submitted before [F228IP completion day]

1. This Article applies where an application was made before [F228IP completion 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 **[**[F228]IP completion day**]** and where a decision on approval has not been made before **[**[F228]IP completion 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 **[**[F229]IP completion day**]** where the United Kingdom **[**[F230]competent authority**]** was the evaluating **[**[F231]competent authority**]** prior to **[**[F232]30 March 2019**]**; or

(b) 180 days after **[**[F229]IP completion day**]** where the United Kingdom **[**[F230]competent authority**]** was not the evaluating **[**[F231]competent authority**]** prior to **[**[F232]30 March 2019**]**.

[[F233]**3.** Where the applicant does not meet the requirements of this Article, the application is to be treated as having been withdrawn under Article 11(1)(b).**]**

Article 22B

Declaration of interest to notify

1. This Article applies where a declaration of interest to notify was submitted before **[**[F234]IP completion day**]** under Article 16 of Regulation (EU) No 1062/2014 as it had effect immediately before **[**[F234]IP completion 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.

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 **[**[F234]IP completion 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 **[**[F234]IP completion 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 **[**[F234]IP completion 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 **[**[F234]IP completion 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 **[**F234IP completion 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 **[**F234IP completion day**]** but for which no declaration of compliance pursuant to Article 17(5) was made before **[**F234IP completion day**]**, the person may within 180 days of **[**F234IP completion 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 **[**F234IP completion 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 **[**F235IP completion day**]***

1. This Article applies where a dossier was submitted before **[**F235IP completion day**]** for evaluation by a Member State in accordance with Article 14 of Commission Regulation (EC) No 1451/2007.

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:

[F236(a) 90 days of IP completion day, where the United Kingdom competent authority was the evaluating competent authority before 30 March 2019, or

(b) 180 days of IP completion day, where the United Kingdom competent authority was not the evaluating competent authority before 30 March 2019**]**.

[F237**3.** Where the applicant does not meet the requirements of this Article, the application will be treated as having been withdrawn under Article 11(1)(b).”**]**

Textual Amendments

F228 Words in Sch. 2 para. 235 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 72(a)(i)**

F229 Words in Sch. 2 para. 235 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 72(a)(ii)(aa)**

F230 Words in Sch. 2 para. 235 inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 72(a)(ii)(bb)**

F231 Words in Sch. 2 para. 235 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 72(a)(ii)(cc)**

F232 Words in Sch. 2 para. 235 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 72(a)(ii)(dd)**

F233 Words in Sch. 2 para. 235 inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 72(a)(iii)**

F234 Words in Sch. 2 para. 235 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 72(b)**

F235 Words in Sch. 2 para. 235 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 72(c)(i)**

F236 Words in Sch. 2 para. 235 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 72(c)(ii)**

F237 Words in Sch. 2 para. 235 inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 2 para. 72(c)(iii)**

Commencement Information

I269 Sch. 2 para. 235 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

236. Omit Article 23.

Commencement Information

I270 Sch. 2 para. 236 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

237. Omit Article 24.

Commencement Information

I271 Sch. 2 para. 237 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

238. In the text following Article 24, omit "This Regulation shall be binding in its entirety and directly applicable in all Member States."

Commencement Information

I272 Sch. 2 para. 238 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

239. In Annex I, in point (3), for "Annex 1 to regulation (EU) 528/2012" substitute " the Simplified Active Substance list ".

Commencement Information

I273 Sch. 2 para. 239 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

240. In Annex II omit the column entitled "Rapporteur Member State".

Commencement Information

I274 Sch. 2 para. 240 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

241. Omit Annex III.

Commencement Information

I275 Sch. 2 para. 241 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

SCHEDULE 3

Regulation 2(3)

AMENDMENTS TO ANNEX II TO THE EEA AGREEMENT

1. In Annex II to the EEA agreement, in Part 2—

[F238(a) omit point 12n (including the words from "The provisions of the Regulation" to the end);

(b) omit point 12o (including the words from "The provisions of the Regulation" to the end);**]**

(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)";

[F239(ii) omit "32020 R 0011: Commission Delegated Regulation (EU) 2020/11 of 29 October 2019 (OJ L 6, 10.1.2020, p. 8)"**]**;

[F240(iii)**]** 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.

Textual Amendments

F238 Sch. 3 para. 1(a)(b) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 3 para. 1(a)**

F239 Sch. 3 para. 1(c)(ii) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 3 para. 1(b)(ii)**

F240 Sch. 3 para. 1(c)(ii) renumbered as Sch. 3 para. 1(c)(iii) (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 3 para. 1(b)(i)**

Commencement Information

I276 Sch. 3 para. 1 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

[F241SCHEDULE 4

Regulation 5

Savings, transitional and consequential provision

Textual Amendments

F241 Sch. 4 inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 4**

Provision relating to Regulation (EC) No 1272/2008

1. In relation to Great Britain, a classification which, immediately before IP completion 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 is to be treated as if it were approved by the Secretary of State in accordance with Article 37A of Regulation (EC) No 1272/2008.

Commencement Information

I277 Sch. 4 para. 1 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Provision relating to Regulation (EU) No 528/2012

2.—(1) After Article 95 of 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, insert—

"**95A Transitional measures for simplified notification procedure**

1. Where, before IP completion day, a product was authorised in a country which was a Member State of the EU other than the United Kingdom in accordance with Article 26 of Regulation (EU) No 528/2012, and was 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 must grant an authorisation under Article 26 of this Regulation.

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

(a) the authorisation holder is not established in the United Kingdom within 12 months from IP completion day, or

(b) the authorisation holder does not supply the competent authority with relevant scientific and authorisation data by whichever is the earlier of the following—

(i) the date of any application for renewal or the date of any application for amendment of 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.

95B Transitional measures for mutual recognition applications

1. This Article applies where—

(a) an application for mutual recognition of a national authorisation of a biocidal product was made before IP completion day in accordance with Articles 33, 34 or 39 of Regulation (EU) No 528/2012, and

(b) a decision was not made before IP completion 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 is to be treated as having been made under Article 29 of this Regulation, and the time limits under Articles 29 and 30 are 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 following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

4. On receipt of the resubmitted application and data to the competent authority, the time limits under Articles 29 and 30 of this Regulation 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, before IP completion day, the United Kingdom was 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 is to be treated as having been made under Article 29 of this Regulation, and the time limits under Articles 29 and 30 apply from—

(a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or

(b) where the application relies on a letter of access, whichever is the later of the following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

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

8. Anything done before IP completion day by the United Kingdom competent authority, where the United Kingdom was either the Member State concerned or the reference Member State, is taken as having been done by the competent authority under this Regulation.

9. The resubmission of any application and data referred to in paragraph 3 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

10. The resubmission of any application and data referred to in paragraph 6 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

Article 95C Renewal of authorisations subject to mutual recognition under Regulation 492/2014

1. This Article applies where—

(a) an application for the renewal of a biocidal product authorisation subject to mutual recognition was made before IP completion day in accordance with Article 3 of Commission Delegated Regulation (EU) No 492/2014 of 7 March 2014 supplementing Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the rules for renewal of authorisations of biocidal products subject to mutual recognition, and

(b) a decision on the renewal of the authorisation was not made before IP completion day.

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

3. The application is to be treated as having been made under Article 31 of this Regulation and the time limits under Article 31 are 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 following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

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

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

6. The application is to be treated as having been made under Article 31 of this Regulation, and the time limits under Articles 30 and 31 apply 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 following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

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

8. The resubmission of any application and data referred to in paragraph 3 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

9. The resubmission of any application and data referred to in paragraph 6 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

10. Where the applicant or authorisation holder does not meet the requirements of this Article—

(a) the application must be rejected by the competent authority and Article 89(11) applies as if the application had been submitted in accordance with Article 89(9), and

(b) the authorisation must be cancelled by the competent authority and Article 52 applies.

Article 95D Transitional measure for national authorisation applications

1. This Article applies where—

(a) an application was made before IP completion day to the United Kingdom competent authority under Articles 29 or 31 of Regulation (EU) No 528/2012, and

(b) a decision was not made before IP completion day.

2. The application is to be treated as having been made under this Regulation and the time limits under Articles 29, 30 and 31 as appropriate apply 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 following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

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

4. Anything done before IP completion day by the United Kingdom competent authority as the receiving competent authority is taken as having been done by the competent authority under this Regulation.

5. The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

Article 95E Transitional measures simplified authorisation applications

1. This Article applies where—

(a) an application was made to the United Kingdom competent authority before IP completion day under Articles 25 or 26 of Regulation (EU) No 528/2012, and

(b) a decision was not made before IP completion day.

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

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

3. In a case where an application was made but the United Kingdom competent authority was not the receiving competent authority, the application is to be treated as having been made under this Regulation and the time limits under Article 26 apply 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 following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

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

5. Anything done before IP completion day by the United Kingdom competent authority as the receiving competent authority is taken as having been done by the competent authority under this Regulation.

6. The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

7. The resubmission of any application and data referred to in paragraph 3 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

Article 95F Transitional measures for applications for same biocidal product authorisations

1. This Article applies where—

(a) an application was made to the United Kingdom competent authority before IP completion day under Articles 3 or 4 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, and

(b) a decision was not made before IP completion day.

2. The application is to be treated as having been made under Articles 3 or 4 (as appropriate) of Regulation (EU) No 414/2013 and the time limits under those Articles are apply 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 following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

3. Where the applicant does not meet the requirements of this Article, the application must be rejected by the competent authority and Article 89(11) applies 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 must include relevant data for the reference product.

5. The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

Article 95G Transitional measures for Regulation (EU) No 528/2012 authorisations

1. This Article applies to authorisations granted by the United Kingdom competent authority before IP completion 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 must be cancelled and Article 52 of this Regulation will apply where—

(a) the authorisation holder is not established in the United Kingdom within 12 months after IP completion day, or

(b) the authorisation holder does not supply the competent authority with relevant scientific and authorisation data by whichever is the earlier of the following—

(i) the date of any application for renewal or for amendment of 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.

Article 95H Transitional measures for ongoing applications for Union authorisations

1. This Article applies where—

(a) an application for Union authorisation was made before IP completion day in accordance with Articles 42, 43 or 45 of Regulation (EU) No 528/2012, and

(b) a decision was not made before IP completion day.

2. Paragraph 3 applies where, before IP completion day, the United Kingdom competent authority was the evaluating competent authority for applications for Union authorisations made under Regulation (EU) No 528/2012.

3. The application is to be treated as being made under Articles 29 or 31 of this Regulation and the time limits under Articles 29, 30 or 31 are 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 following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

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 apply less any time which expired between the date of acceptance of the application and data under Articles 43, 44, 45 or 46 of Regulation (EU) No 528/2012 and exit day.

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

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

(a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or

(b) where the application relies on a letter of access, whichever is the later of the following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

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

8. Anything done before IP completion day by the United Kingdom competent authority as the evaluating competent authority is taken as having been done by the competent authority under this Regulation.

9. The resubmission of any application and data referred to in paragraph 3 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

10. The resubmission of any application and data referred to in paragraph 6 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

Article 95I Transitional measures for 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-IP completion day List") of active substances and persons having made submissions in relation to those active substances.

2. Subject to paragraph 3, from IP completion day the entries included in the Article 95 pre-IP completion day List are to be included in the list prepared pursuant to Article 95 of this Regulation ("the Article 95 List").

3. An entry on the Article 95 List must be removed if either of the following conditions are not met within 2 years from IP completion day—

(a) the person must be established in the United Kingdom;

(b) the person must provide to the competent authority any of the following—

(i) a complete dossier for the relevant active substance;

(ii) a reference to a complete active 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 a complete active substance dossier, where that dossier has been submitted to the competent authority within 2 years of IP completion 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.

5. A period of grace in excess of 180 days may only be granted under paragraph 4 in exceptional circumstances.

6. Where a period of grace is granted in accordance with paragraph 4, and the supplier of a biocidal product does not comply with the second subparagraph of Article 95(1) during that period, the prohibition in Article 95(2) applies.

Article 95J Transitional measure for active substance applications made to the United Kingdom competent authority before 30 March 2019 and subsequently reallocated

1. This Article applies where—

(a) an application was made to the United Kingdom competent authority as evaluating competent authority before 30 March 2019 under Article 7 of Regulation (EU) No 528/2012,

(b) the competent authority had not completed its evaluation of the application before IP completion day due to the evaluation being reallocated at EU level, and

(c) a decision was not made before IP completion day.

2. An application referred to in paragraph 1 is to be treated as if it were made under Article 7 of this Regulation, and the time limits in Articles 7 and 8 are suspended until—

(a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or

(b) where the application relies on a letter of access, whichever is the later of the following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

3. On receipt of the resubmitted application and data by the competent authority, the time limits under Articles 7 and 8 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—

(a) 30 March 2019 for active substances listed in the Annex to Commission Delegated Regulation (EU) 2019/227, or

(b) exit day for other substances.

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

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

6. The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

Article 95K Transitional measure for active substance applications made before IP completion day pursuant to Article 93 where the United Kingdom competent authority was not the evaluating competent authority

1. This Article applies where—

(a) an application to approve an active substance was made before IP completion day under Article 7 of Regulation (EU) No 528/2012 and in compliance with point (a) of Article 93,

(b) the United Kingdom competent authority was not the evaluating competent authority, and

(c) a decision was not made before IP completion day.

2. An application referred to in paragraph 1 is to be treated as if it were made under Article 7 of this Regulation, and the time limits under Articles 7 and 8 apply from—

(a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or

(b) where the application relies on a letter of access, whichever is the later of the following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

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

4. The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

Article 95L Transitional measures for renewal of an approval of an active substance

1. This Article applies where—

(a) an application for renewal of an approval of an active substance was made before IP completion day in accordance with Article 13 of Regulation (EU) No 528/2012, and

(b) a decision was not made before IP completion day.

2. Where the United Kingdom competent authority was the evaluating competent authority 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 are suspended until—

(a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or

(b) where the application relies on a letter of access, whichever is the later of the following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

3. On receipt of the resubmitted application and data by the competent authority, the time limits under Articles 13 and 14 of this Regulation apply less any time which expired between the date of acceptance of the application and data under Article 13 and 30 March 2019.

4. Where the United Kingdom competent authority was not the evaluating competent authority 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 apply from—

(a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or

(b) where the application relies on a letter of access, whichever is the later of the following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

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

6. Anything done before IP completion day by the United Kingdom competent authority as the evaluating competent authority under Regulation (EU) No 528/2012 is taken as having been done by the competent authority under this Regulation.

7. The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

8. The resubmission of any application and data referred to in paragraph 4 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

Article 95M Transitional measures for ongoing applications to change or amend authorisations

1. This Article applies where—

(a) an application was made before IP completion day to the United Kingdom competent authority under 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

(b) a decision was not made before IP completion day.

2. An application referred to in paragraph 1 is to be treated as having been made under Regulation (EU) No 354/2013 and the time limits under that Regulation apply from—

(a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or

(b) where the application relies on a letter of access, whichever is the later of the following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

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

4. For the purposes of this Article, data submitted by the applicant or the data owner for changes to authorisations issued under Commission Implementing Regulation (EU) No 414/2013 must include relevant data on the reference product.

5. The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

Article 95N Interpretation of Articles 95A to 95M

1. For the purposes of Articles 95A to 95M, the following definitions apply—

"evaluating competent authority" has the meaning given in Article 7 of Regulation (EU) No 528/2012 as it had effect immediately before IP completion day;

"Member State concerned" has the meaning given in Articles 33 and 34 of Regulation (EU) No 528/2012 as it had effect immediately before IP completion day;

"receiving competent authority" has the meaning given in Article 17 of Regulation (EU) No 528/2012 as it had effect immediately before IP completion day;

"reference Member State" has the meaning given in Articles 33 and 34 of Regulation (EU) No 528/2012 as it had effect immediately before IP completion day.".

Commencement Information

I278 Sch. 4 para. 2 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Provision relating to critical use permits

3.—(1) This paragraph applies where—

(a) before IP completion day, the United Kingdom competent authority granted a permit under the first subparagraph of Article 55(1) of Regulation (EU) No 528/2012 for a period not exceeding 180 days, and

(b) on receipt of a reasoned request from the United Kingdom competent authority, the Commission granted an extension of that permit under the third subparagraph of Article 55(1) of Regulation (EU) No 528/2012 until IP completion day.

(2) The extension referred to in paragraph (1)(b) is to be taken as having been granted for a period of 550 days from the date when the Commission granted the extension referred to.

Commencement Information

I279 Sch. 4 para. 3 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Provision relating to the Simplified Active Substance List

4.—(1) Any chemical which is included in Annex I to Regulation (EU) No 528/2012 immediately before IP completion day, is on IP completion day—

(a) if from categories 1 to 5 of Annex I, to be included in category A of the Simplified Active Substance List;

(b) if from category 6 of Annex I, to be included in category B of the Simplified Active Substance List;

(c) if from category 7 of Annex I, to be included in category C of the Simplified Active Substance List.

(2) In Regulation (EU) No 528/2012, in Article 95(6), for "categories 1 to 5 and category 7" substitute "categories A and C".

(3) In Regulation 1062/2014—

(a) in Article 3(1), for "category 1, 2, 3, 4, 5 or 6" substitute "categories A or B";

(b) in Article 6(1)(c), for "category 1, 2, 3, 4 or 5" substitute "category A";

(c) in Article 7(2), for "category 1, 2, 3, 4, 5 or 6" substitute "categories A or B".

Commencement Information

I280 Sch. 4 para. 4 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Provision relating to Regulation (EU) No 649/2012

5.—(1) A chemical which, immediately before IP completion day, is listed in Annex I or Annex V to 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 to be treated as having been included in the GB PIC list and assigned to one or more of five groups of chemicals in the GB PIC list by the Secretary of State on IP completion day in accordance with Article 7 of Regulation (EU) No 649/2012.

(2) In paragraph (1), "GB 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.

(3) This paragraph applies to the following—

(a) any export notification made by an exporter under Article 8 of Regulation (EU) No 649/2012, and

(b) any explicit consent received by an exporter through the exporter's designated national authority under Article 14(6) of that Regulation.

(4) Any export notification or explicit consent to which paragraph (3) applies, which continues to be effective on or after IP completion day by virtue of Part 3 of Schedule 8 to the European Union (Withdrawal) Act 2018, is to be treated as if it were made or obtained under Regulation (EU) No 649/2012 on or after IP completion day.

(5) Any export notification or explicit consent to which paragraph (3) applies, which was processed by the Designated National Authority for Great Britain during the months leading up to IP completion day in accordance with the rules which are provided for in these Regulations, is to be treated as if it were made or obtained under Regulation (EU) No 649/2012 on or after IP completion day.

Commencement Information

I281 Sch. 4 para. 5 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

EU implementing Regulations

6. Where, as a result of these Regulations, any provision of retained direct EU legislation imposes an obligation on the Secretary of State to make regulations, that obligation is to be treated as having been met in a case where, before IP completion day, the European Commission adopted a delegated act under that provision.**]**

Commencement Information

I282 Sch. 4 para. 6 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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.

Status:
This version of this Instrument contains provisions that are prospective.

Changes to legislation:
There are currently no known outstanding effects for the The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019.