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

I1 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.** **[**[F1]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. **[**[F1]GB**]** notification database: the database established in accordance with Article 42 of Regulation (EC) No 1272/2008."

F1 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

I2 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 **[**[F2]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."

F2 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

I3 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 **[**F3GB**]** mandatory classification and labelling list ".

F3 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

I4 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 **[**F4GB**]** 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 **[**F4GB**]** mandatory classification and labelling list ".

F4 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

I5 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 **[**F5GB**]** mandatory classification and labelling list ";

(b) in point 3.2.1(a)(iv) and (vi), for "classification and labelling inventory" substitute " **[**F5GB**]** notification database ".

F5 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

I6 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 **[**F6GB**]** 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 **[**[F6]GB**]** mandatory classification and labelling list ".

F6 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

I7 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 **[**[F7]GB**]** 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 **[**[F7]GB**]** 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 **[**[F7]GB**]** 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 **[**[F7]GB**]** mandatory classification and labelling list ".

(5) In Note A, for "Part 3 of Annex VI to that Regulation" substitute " the **[**[F7]GB**]** mandatory classification and labelling list ".

(6) In Note D, for "Part 3 of Annex VI to Regulation (EC) No 1272/2008" substitute " the **[**[F7]GB**]** mandatory classification and labelling list ".

F7 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

I8 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

I9 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 **[**F8GB**]** 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 **[**F8GB**]** 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 **[**F8GB**]** 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 **[**F8GB**]** mandatory classification and labelling list ".

F8 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

I10 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

I11 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

I12 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 **[**F9GB**]** 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 " **[**F10GB**]** notification database of substances notified to the Agency after **[**F11IP 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 M1F12... ";

(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 M2 ";

(b) in point (b), for "Directive 2001/82/EC" substitute " the Veterinary Medicines Regulations 2013 M3 ";

(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 M4 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 ".

F9 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)**

F10 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)**

F11 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)**

F12 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

I13 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

M1 S.1. 2017/1075.
M2 S.I. 2012/1916.
M3 S.I. 2013/2033.
M4 S.I. 2002/618.

[F13 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.".**]**

F13 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

I14 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)

[[F14]**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".**]**

F14 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

I15 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 [M5] applies ".

Commencement Information

I16 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

M5 1986 c. 14.

17. In Article 10—

(a) in paragraph 3, for "harmonised" substitute " mandatory " and for "Part 3 of Annex VI" substitute " the **[**[F15]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 **[**[F15]GB**]** mandatory classification and labelling list ";

(ii) in the second subparagraph, for "Part 3 of Annex VI" substitute " the **[**[F15]GB**]** mandatory classification and labelling list ";

(c) in paragraph 5, for "classification and labelling inventory" substitute " **[**[F15]GB**]** notification database ".

F15 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

I17 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 **[**[F16]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 ".

F16 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

I18 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

I19 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

I20 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 **[**F17GB**]** mandatory classification and labelling list ";

(b) in point (b), for "Part 3 of Annex VI" substitute " the **[**F17GB**]** mandatory classification and labelling list " and for "classification and labelling inventory" substitute " **[**F17GB**]** notification database ";

(c) in point (c), for "Part 3 of Annex VI nor the classification and labelling inventory" substitute " the **[**F17GB**]** mandatory classification and labelling list nor the **[**F17GB**]** notification database ".

F17 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

I21 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 **[**F18GB**]** mandatory classification and labelling list ".

F18 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

I22 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

I23 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 **[**[F19]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 ".

F19 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

I24 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 **[**[F20]GB**]** mandatory classification and labelling list ".

F20 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

I25 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

I26 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

I27 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

I28 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

I29 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 **[**F21GB**]** NOTIFICATION DATABASE ".

F21 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

I30 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

I31 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 **[**F22GB**]** mandatory classification and labelling list ";

(v) omit "at Community level".

F22 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

I32 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)

[F23**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.".**]**

F23 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

I33 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)

[F24 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.".**]**

F24 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

I34 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 **[**[F25]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."

F25 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

I35 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

[F26GB] mandatory classification and labelling list

The Agency must establish, maintain and publish electronically a list (to be called "the **[**F26GB**]** 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."

F26 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

I36 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 " **[**F27GB**]** notification database ".

F27 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

I37 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

I38 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 " **[**F28GB**]** notification database ";

(b) in the second subparagraph, in the first sentence, after "notifier" insert " or has been notified before **[**F29IP 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 ".

F28 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)**

F29 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

I39 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 " **[**[F30]GB**]** notification database ".

F30 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

I40 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 " **[**[F31]GB**]** 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 **[**[F31]GB**]** 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 " **[**[F31]GB**]** notification database ";

(iii) for the third subparagraph, substitute—

"Information in the **[**[F31]GB**]** 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 " **[**[F31]GB**]** 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 **[**[F31]GB**]** mandatory classification and labelling list;";

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

(e) in paragraph 3, in the second subparagraph, for "37(5)" substitute " **[**[F32]37(4)(b) and Article 37A(8)**]** ".

F31 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)**

F32 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

I41 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

I42 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

I43 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

I44 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 **[**F33Scotland 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 ";

[F34(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.".**]**

F33 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)**

F34 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

I45 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

I46 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 [M6] ".

Commencement Information

I47 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

M6 S.I. 2013/3134.

[[F35]**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.".**]**

F35 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

I48 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

I49 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

I50 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 **[**[F36]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 [M7]);

(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 [M8]) [F37]...

[F37](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. [F38] . . . . . .

10. [F38] . . . . . ."

F36 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)**

F37 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)**

F38 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

I51 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

M7 1998 c. 46.

M8 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

I52 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 [M9]) 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 [M10]) whether or not the exercise of the function also relates to a part of the United Kingdom other than Wales.

[F39]**4.** . . . . . .

[F39]**5.** . . . . . .

[F39]**6.** . . . . . .

[F39]**7.** . . . . . ."

F39 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

I53 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

M9 1998 c. 46.

M10 2006 c. 32.

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

Commencement Information

I54 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 " **[**[F40]GB**]** mandatory classification and labelling list or in the **[**[F40]GB**]** 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 **[**[F40]GB**]** mandatory classification and labelling list or in the **[**[F40]GB**]** 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 **[**[F40]GB**]** mandatory classification and labelling list or in the **[**[F40]GB**]** 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 **[**[F40]GB**]** mandatory classification and labelling list or in the **[**[F40]GB**]** 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 **[**[F40]GB**]** mandatory classification and labelling list or in the **[**[F40]GB**]** 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 **[**[F40]GB**]** mandatory classification and labelling list or in the **[**[F40]GB**]** notification database ".

F40 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

I55 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 **[**[F41]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 ".

F41 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

I56 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 **[**[F42]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 **[**[F42]GB**]** mandatory classification and labelling list ";

(c) in point 1.1.1.4, in the fifth paragraph, for "Part 3" substitute " the **[**[F42]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 **[**[F42]GB**]** 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 **[**[F42]GB**]** 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 **[**[F42]GB**]** 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 **[**[F42]GB**]** 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 **[**[F42]GB**]** mandatory classification and labelling list ";

(iii) in Note L, Note M, and Note N, for "Part 3" substitute " the **[**[F42]GB**]** 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 **[**[F42]GB**]** 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 **[**[F42]GB**]** mandatory classification and labelling list ", and for "Table 3" substitute " the **[**[F42]GB**]** mandatory classification and labelling list ";

(i) in point 1.2.2, for "in Table 3" substitute " in the **[**[F42]GB**]** mandatory classification and labelling list ";

(j) in point 1.2.3 for "in Table 3" substitute " in the **[**[F42]GB**]** mandatory classification and labelling list ";

(k) in point 1.2.4, for "in Table 3" substitute " in the **[**[F42]GB**]** mandatory classification and labelling list ".

(5) Omit Part 3.

F42 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

I57 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 **[**[F43]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 **[**[F43]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."

F43 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

I58 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 **[**[F44]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 **[**[F44]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 **[**[F44]GB**]** mandatory classification and labelling list ";

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

F44 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

I59 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 **[**F45GB**]** mandatory classification and labelling list ";

(b) after point (1) insert—

"(1A) In point (1)(c), the "**[**F45GB**]** 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."

F45 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

I60 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

I61 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 " **[**F46Great Britain**]** ";

(b) omit point (c);

(c) for "one or more Member States or the Union" substitute " **[**F47Great Britain**]** ".

F46 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)**

F47 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

I62 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.

[F48(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".

F48 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

I63 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;

[F49(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 **[**F50IP 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 " **[**F51Great 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.

[F52(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;**]**

[F53(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."

F49 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)**

F50 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)**

F51 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)**

F52 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)**

F53 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

I64 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

I65 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

I66 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

I67 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

I68 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 [F54GB] List

The competent authority shall establish, maintain and make electronically available to the public a list of approved active substances ("the [F54GB] List")."

F54 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

I69 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 **[**F55GB**]** List established under Article 8A of this Regulation."

F55 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

I70 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

I71 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

I72 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

I73 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

I74 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 **[**[F56]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 ".

F56 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

I75 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

I76 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

I77 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

I78 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)

[F57 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.".**]**

F57 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

I79 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

I80 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

I81 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

I82 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

I83 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

I84 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

I85 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

I86 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

I87 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

I88 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

I89 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

I90 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

I91 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

I92 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

I93 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

I94 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

I95 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

I96 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

I97 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

I98 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

I99 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

I100 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

I101 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

I102 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 [M11]);

(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 [M12]) [F58]...

[F58](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).

[F59]**7.** . . . . . .

[F59]**8.** . . . . . .

[[F60]**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 **[**[F61]Devolved Authority**]** and the Secretary of State giving reasons for the decision."

F58 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)**

F59 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)**

F60 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)**

F61 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

I103 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

M11 1998 c.46

M12 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

I104 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

I105 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

I106 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

I107 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 **[**[F62]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 **[**[F62]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 **[**[F62]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 **[**[F62]IP completion day**]**."

F62 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

I108 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)

[[F63]**108.** 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".**]**

F63 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

I109 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

I110 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

I111 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 ";

[[F64](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.

F64 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

I112 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

I113 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

I114 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

I115 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";

[[F65](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 ".

F65 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

I116 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

I117 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

I118 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

I119 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

[[F66]**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."

F66 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

I120 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

I121 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

I122 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

I123 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—

[[F67]"**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.

F67 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

I124 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

I125 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 **[**F68paragraphs 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 M13) 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 M14) whether or not the exercise of the function also relates to a part of the United Kingdom other than Wales.

F69**4.** . . . . . .

F69**5.** . . . . . .

F69**6.** . . . . . .

F69**7.** . . . . . ."

F68 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)**

F69 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

I126 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
M13 1998 c. 46.
M14 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
I127 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
I128 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
I129 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 **[**[F70]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) [F71]...

[F71](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).

[F72]**6.** . . . . . .

[F72]**7.** . . . . . .

[[F73]**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 **[**[F74]other Devolved Authority**]** and the Secretary of State giving reasons for the decision."

F70 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)**

F71 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)**

F72 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)**

F73 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)**

F74 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

I130 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

I131 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

I132 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

I133 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

I134 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

I135 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 **[**F75IP completion day**]** or issued by the Secretary of State after **[**F75IP completion day**]** ".

(3) Omit paragraph 2.

F75 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

I136 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

I137 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

[F76]137. . . . . . .

F76 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

I138 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

I139 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

I140 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

I141 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

I142 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 " **[**[F77]Great Britain**]** ".

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

[[F78](14) In paragraph 77, for "the Member State or, where appropriate, in the Union" substitute "Great Britain".**]**

F77 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)**

F78 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

I143 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

I144 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)

[[F79]**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".**]**

F79 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

I145 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.

[F80(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 M15F81... ";

(b) in point (c), for the words from "Directive" to the end substitute " the Waste (England and Wales) Regulations 2011 M16**[**F82and 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 M17, the Genetically Modified Organisms (Deliberate Release) **[**F83(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 M18 ";

(ii) for the words from "Directive 2001/82/EC" to "products" substitute " the Veterinary Medicines Regulations 2013 M19 ".

[F84(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".**]**

F80 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)**

F81 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)**

F82 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)**

F83 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)**

F84 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

I146 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

M15 S.I. 2017/1075.

M16 S.I. 2011/988.

M17 S.I. 2002/2443.

M18 S.I. 2012/1916.

M19 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 " **[**F85the 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 ";

[F86(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 **[**F87GB PIC list**]** ".

(7) In point (10)—

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

[F88(b) in point (b), for "Union" substitute "Great Britain"**]**.

(8) In point (11)—

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

[F89(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 **[**F90Great Britain**]**:

(a) made in accordance with **[**F91sections 33(4), 35 or 36**]** of the Taxation (Cross-border Trade) Act 2018 M20; 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 **[**F92Great Britain**]**."

(12) In point (17) for the words from "physical" to the end substitute " importation into **[**F93Great Britain**]** and release to a customs procedure, other than a transit procedure by which chargeable goods may be moved between places in **[**F93Great Britain**]**, of any chemical ".

[F94(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"**]**.

[F95(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 M21 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) '**[**F96GB PIC list**]**' means the list established and maintained in accordance with Articles 7 and 23."

F85 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)**

F86 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)**

F87 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)**

F88 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)**

F89 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)**

F90 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)**

F91 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)**

F92 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)**

F93 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)**

F94 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)**

F95 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)**

F96 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

I147 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

M20 2018 c. 22.

M21 S.I. 2013/1506.

148. Omit Article 4.

Commencement Information

I148 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—

[[F97]"(2)**]** The Designated National Authority must:

(a) transmit **[**[F98]Great Britain**]** export notifications to **[**[F99]other Parties, countries and Northern Ireland**]** pursuant to Article 8; and

(b) receive information from the Secretariat more generally.

[[F97](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) **[**[F100]Great Britain**]** import responses for chemicals subject to the PIC procedure pursuant to Article 13.

[[F97](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.

F97 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)**

F98 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)**

F99 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)**

F100 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

I149 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

I150 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 **[**F101GB 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 **[**F102GB PIC list**]** to one or more of the following groups:

(a) Part 1 of the **[**F102GB 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 **[**F102GB 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 **[**F102GB 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 **[**F102GB 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 **[**F102GB 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 **[**F103GB PIC list**]** ";

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

F101 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**

F102 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**

F103 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

I151 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.

[[F104](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—

[[F105](i) for "the Union" substitute "Great Britain";**]**

[[F106](ii) for "to a Party or other country" substitute "to a Party, other country or Northern Ireland";**]**

[[F107](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 ";

[[F107](iv)**]** for "that designated national authority" substitute " the Designated National Authority ";

[[F107](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;

[[F108](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,";

[[F109](v) for "importing Parties and other countries" substitute "importing Parties, other countries and Northern Ireland";**]**

[[F110](vi) for "by means of the Database" substitute "via its website".**]**

[[F111](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 ".

[[F112](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".**]**

[[F113](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".**]**

[[F114](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.

F104 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)**

F105 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)**

F106 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)**

F107 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)**

F108 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)**

F109 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)**

F110 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)**

F111 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)**

F112 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)**

F113 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)**

F114 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

I152 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 **[**F115Great Britain**]** of a chemical the manufacture, use, handling, consumption, transport or sale of which is subject to prohibition or severe restriction **[**F116under the legislation of a Party, other country or Northern Ireland**]**, ";

[F117(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.

F115 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)**

F116 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)**

F117 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

I153 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.

[[F118](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 ".

F118 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

I154 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 **[**F119GB PIC list**]** ".

(3) In paragraph 2—

(a) for "Annex I" substitute " the **[**F120GB 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 **[**F121GB 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 **[**F122and the Welsh Ministers**]** ";

(iv) for "propose" substitute " take ";

(v) omit "at Union level";

(vi) omit "within the Union".

(8) Omit paragraph 8.

F119 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)**

F120 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)**

F121 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)**

F122 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

I155 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 **[**[F123]GB PIC list**]**, the Secretary of State ".

F123 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

I156 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 **[**F124and 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."

F124 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

I157 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 ".

[F125(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".**]**

[[F126](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.

[[F127](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".**]**

F125 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)**

F126 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)**

F127 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

I158 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 **[**F128GB PIC list**]** ";

(b) in paragraph 2—

[F129(i) for "the Union" substitute "Great Britain";**]**

(ii) for "Annex V" substitute " Part 4 or 5 of the **[**F130GB PIC list**]** ".

F128 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)**

F129 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)**

F130 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

I159 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 **[**F131GB 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 ".

F131 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

I160 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 ";

[F132(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 **[**F133GB PIC list**]** ";

[F134(c) in paragraph 3, for "Party or other country" substitute "Party, other country or Northern Ireland".**]**

F132 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)**

F133 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)**

F134 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

I161 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 **[**F135GB 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.

F135 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

I162 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

I163 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—

[[F136](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 [M22] and the Environmental Information (Scotland) Regulations 2004 [M23] ";

(d) in paragraph 4, for "Agency" substitute " Designated National Authority ".

F136 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

I164 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

M22 S.I. 2004/3391.

M23 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

I165 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

I166 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 **[**F137GB 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 **[**F138GB 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 **[**F139GB PIC list**]** ";

(d) in paragraph 3—

(i) after "The" insert " Secretary of State must take the ";

(ii) for "Annex I" substitute " the **[**F140GB 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."

F137 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**

F138 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**

F139 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**

F140 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

I167 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 **[**F141paragraphs 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 M24) 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 M25) whether or not the exercise of the function also relates to a part of the United Kingdom other than Wales.

F142**4.** . . . . . .

F142**5.** . . . . . .

F142 **6.** . . . . . .

F142 **7.** . . . . . ”

F141 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)**

F142 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

I168 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

M24 1998 c. 46.

M25 2006 c. 32.

169. Omit Articles 24 to 31.

Commencement Information

I169 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

I170 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 **[**F143GB 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 **[**F144GB 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 ”.

[F145(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".**]**

F143 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)**

F144 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)**

F145 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

I171 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

I172 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)

[[F146]**173.** In Annex IV, in paragraph 1, in point (f), for "the Union" substitute "Great Britain".**]**

F146 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

I173 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

I174 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

I175 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 **[**F147GB**]** 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 **[**F147GB**]** 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."

F147 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

I176 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 **[**F148GB**]** 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 **[**F148GB**]** 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 **[**F148GB**]** 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 **[**F148GB**]** mandatory classification and labelling list" has the same meaning as in point 1.4.3.1 of Part A."

F148 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

I177 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

I178 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—

[F149(a) in the first subparagraph, for "Agency" substitute "competent authority";**]**

[F150(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.";**]**

[F151(c) in the third subparagraph, for "Agency" substitute "competent authority".**]**

F149 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)**

F150 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)**

F151 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

I179 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

I180 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

I181 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

I182 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

I183 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

I184 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

I185 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

I186 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

I187 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

I188 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

I189 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

I190 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

I191 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

I192 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

I193 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

I194 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)

[[F152]**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,".**]**

F152 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

I195 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

I196 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".

[[F153](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".**]**

F153 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

I197 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

I198 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

I199 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

I200 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

I201 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

I202 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

I203 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

I204 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

I205 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

I206 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

I207 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

I208 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.

[[F154](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.

F154 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

I209 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 **[**[F155]the 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).

F155 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

I210 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

I211 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

I212 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

I213 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 **[**F156IP completion day**]**, pursuant to the third subparagraph of Article 89(1) of that Regulation as it had effect immediately before **[**F156IP completion day**]**, not to approve a substance/product-type combination;

(iii) made after **[**F156IP 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 **[**F157IP 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 **[**F157IP completion day**]**; ".

[F158(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;"**]**.

[F159(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.".**]**

F156 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)**

F157 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)**

F158 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)**

F159 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

I214 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

I215 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

I216 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

I217 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 **[**[F160]IP 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 ".

F160 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

I218 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

I219 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

I220 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

I221 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

I222 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

I223 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

I224 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

I225 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

I226 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 **[**F161IP completion day**]** and the person placing the product on the market ";

(b) after the words "by the Commission" insert " before **[**F161IP completion day**]** or the competent authority after **[**F161IP completion day**]** ".

(4) After point (a) insert—

"(aa) the product was placed on the market after **[**F162IP 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 **[**F162IP 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 **[**F163or 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).

F161 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)**

F162 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)**

F163 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

I227 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

I228 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

I229 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

I230 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

I231 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

I232 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

I233 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 **[**[F164]Article 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 **[**F165Great Britain**]** subject to the conditions in **[**F166paragraph 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 **[**F167paragraphs 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 M26);

(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 M27)F168...

F168(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).

F169**7.** . . . . . .

F169**8.** . . . . . .

[F170**7].** Where the Secretary of State **[**F171exercises 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 **[**F172Devolved Authority**]** and the Secretary of State giving reasons for the decision.

[F170**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."

F164 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)**

F165 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)**

F166 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)**

F167 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)**

F168 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)**

F169 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)**

F170 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)**

F171 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)**

F172 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

I234 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

M26 1998 c. 46.

M27 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 **[***F173 IP completion day***]**

1. This Article applies where an application was made before **[**F173IP 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 **[**F173IP completion day**]** and where a decision on approval has not been made before **[**F173IP 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 **[**F174IP completion day**]** where the United Kingdom **[**F175competent authority**]** was the evaluating **[**F176competent authority**]** prior to **[**F17730 March 2019**]**; or

(b) 180 days after **[**F174IP completion day**]** where the United Kingdom **[**F175competent authority**]** was not the evaluating **[**F176competent authority**]** prior to **[**F17730 March 2019**]**.

[F178**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 **[**F179IP completion day**]** under Article 16 of Regulation (EU) No 1062/2014 as it had effect immediately before **[**F179IP 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 **[**F179IP 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 **[**F179IP 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 **[**F179IP 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 **[**F179IP 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 **[**F179IP 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 **[**F179IP completion day**]** but for which no declaration of compliance pursuant to Article 17(5) was made before **[**F179IP completion day**]**, the person may within 180 days of **[**F179IP 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 **[**F179IP 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 **[**F180IP completion day**]***

1. This Article applies where a dossier was submitted before **[**F180IP 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:

[F181(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**]**.

[F182**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).”**]**

F173 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)**

F174 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)**

F175 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)**

F176 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)**

F177 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)**

F178 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)**

F179 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)**

F180 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)**

F181 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)**

F182 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

I235 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

I236 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

I237 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

I238 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

I239 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

I240 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

I241 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)

Status:
This version of this schedule 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, SCHEDULE 2.