Draft Regulations laid before Parliament under paragraphs 1(1), 8F(1) and 12(1) of Schedule 7 to the European Union (Withdrawal) Act 2018 for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2020 No. 0000

EXITING THE EUROPEAN UNION

ENVIRONMENTAL PROTECTION

FEES AND CHARGES

HEALTH AND SAFETY

PESTICIDES

The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020

Made - - - - ***

Coming into force in accordance with regulation 1(2)

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SCHEDULE 1 — Amendment of Schedule 1 to the 2019 Regulations
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The Secretary of State makes the following Regulations, with the consent of the Treasury(**a**) in relation to paragraphs 5 to 12 and 22 of Schedule 1 and paragraphs 8, 23, 63 and 68 of Schedule 2 to these Regulations, in exercise of the powers conferred by sections 8(1) and 8C(1) of, and paragraphs 1 and 7 of Schedule 4 and paragraph 21(b) of Schedule 7 to, the European Union (Withdrawal) Act 2018(**b**) and by section 41(1) of, and paragraph 12 of Schedule 4 to, the European Union (Withdrawal Agreement) Act 2020(**c**).

In accordance with paragraphs 1(1), 8F(1)(**d**) and 12(1) of Schedule 7 to the European Union (Withdrawal) Act 2018, a draft of these Regulations has been laid before Parliament and approved by a resolution of each House of Parliament.

PART 1

Introduction

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020.

(2) These Regulations come into force immediately before IP completion day.

(3) Any amendment made by these Regulations has the same extent as the provision amended.

Interpretation

2. In these Regulations, "the 2019 Regulations" means the Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019(**e**).

PART 2

Amendment of subordinate legislation

Amendment of the 2019 Regulations

3. The 2019 Regulations are amended in accordance with regulations 4 to 10.

(**a**) Treasury consent is required pursuant to paragraph 3(1) of Schedule 4 to the European Union (Withdrawal) Act 2018.
(**b**) 2018 c.16. The European Union (Withdrawal) Act 2018 ("the 2018 Act") was amended by the European Union (Withdrawal Agreement) Act 2020 ("the 2020 Act"); section 8C of the 2018 Act was inserted by section 21 of the 2020 Act.
(**c**) 2020 c.1.
(**d**) Paragraph 8F of Schedule 7 to the 2018 Act was inserted by paragraph 51 of Schedule 5 to the 2020 Act.
(**e**) S.I. 2019/720, as amended by regulation 27 of S.I. 2019/1340 (which comes into force on IP completion day).

Amendment of regulation 2 of the 2019 Regulations

4. In regulation 2 of the 2019 Regulations (Amendments to retained EU law), in paragraph (1) (domestic subordinate legislation corrected by the 2019 Regulations) omit the following—

(a) sub-paragraph (b) (the Health and Safety (Enforcing Authority) Regulations (Northern Ireland) 1999);

(b) sub-paragraph (e) (the Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003);

(c) sub-paragraph (f) (the Dangerous Substances and Explosive Atmospheres Regulations (Northern Ireland) 2003);

(d) sub-paragraph (i) (the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013);

(e) sub-paragraph (l) (the Explosives (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2015);

(f) sub-paragraph (m) (the Biocidal Products (Fees and Charges) Regulations (Northern Ireland) 2015);

(g) sub-paragraph (n) (the Control of Major Accident Hazards Regulations (Northern Ireland) 2015);

(h) sub-paragraph (o) (the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015).

Amendment of regulation 4 of the 2019 Regulations

5. For regulation 4 of the 2019 Regulations (Transitional provision in relation to Regulation (EC) No 1272/2008) substitute—

"**Revocation of Commission Delegated Regulation (EU) No 492/2014**

4. Commission Delegated Regulation (EU) No 492/2014 of 7 March 2014 supplementing Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the rules for the renewal of authorisations of biocidal products subject to mutual recognition is revoked.".

Amendment of regulation 5 of the 2019 Regulations

6. For regulation 5 of the 2019 Regulations (Transitional provision in relation to Regulation (EU) No 649/2012), substitute—

"**Savings and transitional arrangements**

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

Amendment of Schedule 1 to the 2019 Regulations

7. Schedule 1 to the 2019 Regulations (Amendments to subordinate legislation) is amended in accordance with Schedule 1.

Amendment of Schedule 2 to the 2019 Regulations

8. Schedule 2 to the 2019 Regulations (Amendments to retained direct EU legislation) is amended in accordance with Schedule 2.

Amendment of Schedule 3 to the 2019 Regulations

9. Schedule 3 to the 2019 Regulations (Amendments to Annex II to the EEA Agreement) is amended in accordance with Schedule 3.

Insertion of Schedule 4 into the 2019 Regulations

10. After Schedule 3 to the 2019 Regulations, insert a new Schedule 4 (Savings, transitional and consequential provision), as provided for in Schedule 4.

Signed by authority of the Secretary of State for Work and Pensions

Name
Parliamentary Under Secretary of State
Department for Work and Pensions

Date

We consent

Name
Name
Two of the Lords Commissioners of Her Majesty's Treasury

Date

SCHEDULE 1

Regulation 7

Amendment of Schedule 1 to the 2019 Regulations

Amendment of Schedule 1 to the 2019 Regulations

1. Schedule 1 to the 2019 Regulations (Amendments to subordinate legislation) is amended in accordance with paragraphs 2 to 24.

Amendments relating to the Health and Safety (Enforcing Authority) Regulations (Northern Ireland) 1999

2. Omit paragraph 2 and the heading above it.

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

3. Omit paragraph 5 and the heading above it.

Amendments relating to the Dangerous Substances and Explosive Atmospheres Regulations (Northern Ireland) 2003

4. Omit paragraph 6 and the heading above it.

Amendments relating to the Plant Protection Products (Fees and Charges) Regulations 2011 ("the PPP Fees and Charges Regulations")

5.—(1) Paragraph 8 (amendment of regulation 2(1) of the PPP Fees and Charges Regulations(**a**)) is amended as follows.

(2) After sub-paragraph (2) insert—

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

""Great Britain competent authorities" means—

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

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

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

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

(3) In sub-paragraph (3), for the definition of "MRL compliance" being inserted by that sub-paragraph substitute—

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

(4) After sub-paragraph (3) insert—

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

""the MRL Regulation" means—

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

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

(5) In sub-paragraph (4), in the definition of "MRL supplementary information requirement" being inserted by that sub-paragraph, after "requested" insert "by a Great Britain competent authority".

(6) After sub-paragraph (4) insert—

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

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

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

""Regulation 1107/2009" means—

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

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

(**a**) Here and in other parenthesised text throughout this instrument, "PPP" stands for "Plant Protection Products".

(7) In sub-paragraph (5), in the definition of "standalone MRL application" being inserted by that sub-paragraph, after "application" insert "to a Great Britain competent authority".

6. For paragraph 9 (omission of regulation 3 of the PPP Fees and Charges Regulations), substitute—

"**9.** Regulation 3 is amended as follows—

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

(b) in paragraph (1)—

(i) omit "of the Member State";

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

(c) omit paragraph (2).".

7. For paragraph 10 (amendment of regulation 4 of the PPP Fees and Charges Regulations) substitute—

"**10.** Regulation 4 is amended as follows—

(a) in paragraph 1—

(i) omit sub-paragraph (b);

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

(b) after paragraph 1, insert—

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

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

(c) in paragraph 2—

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

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

(d) after paragraph 2, insert—

"(2A) A Great Britain competent authority may charge fees for the evaluation of supplementary information provided in accordance with Article 14(3) of the MRL Regulation and such fees are payable in accordance with Schedule 3.";

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

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

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

8. In paragraph 12 (amendment of regulation 7(2) of the PPP Fees and Charges Regulations), after paragraph (a) insert—

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

9. For paragraph 13 (amendment of regulation 8(6) of the PPP Fees and Charges Regulations), substitute—

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

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

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

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

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

10.—(1) Paragraph 14 (amendment of Schedule 1 to the PPP Fees and Charges Regulations) is amended as follows.

(2) In sub-paragraph (2)—

(a) paragraph (a) becomes paragraph (b), and paragraph (b) becomes paragraph (c);

(b) above the paragraph re-numbered as paragraph (b), insert—

“(a) in the first sentence, after “product-related applications” insert “to a United Kingdom competent authority”;”;

(3) After sub-paragraph (2) insert—

“(2A) After paragraph 1, insert—

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

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

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

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

(4) In sub-paragraph (3), for paragraph (b) substitute—

“(b) in the first sentence—

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

(ii) for “or synergist” substitute “, synergist or basic substance”.”.

(5) After sub-paragraph (3) insert—

“(3A) In paragraph 3, after “organisation” insert “by a United Kingdom competent authority”.”.

11.—(1) Paragraph 15 (amendment of Schedule 2 to the PPP Fees and Charges Regulations) is amended as follows.

(2) In sub-paragraph (5)—

(a) for paragraph (a) substitute—

“(a) in the first sentence, for the words from the start to “product-related applications” substitute “Fees chargeable by a Great Britain competent authority for import tolerances”;”;

(b) in paragraph (c)—

(i) in paragraph (i), in the note (1) which that paragraph substitutes, in both places it occurs, for “the United Kingdom” substitute “Great Britain”;

(ii) in paragraphs (ii)(bb) and (iii)(bb), for "the United Kingdom" substitute "Great Britain".

(3) In sub-paragraph (6)—

(a) in the new paragraph 2 which that sub-paragraph inserts, in the sentence above the table, after "Fees" insert "chargeable by a Great Britain competent authority";

(b) in the notes which follow the new paragraph 2 which that sub-paragraph inserts, in each place it occurs, for "the United Kingdom" substitute "Great Britain".

12. In paragraph 16 (insertion of Schedule 3 to the PPP Fees and Charges Regulations), in the new Schedule 3 which that paragraph inserts, in the heading and in the sentence above the table, after "Fees" insert "chargeable by a Great Britain competent authority".

Amendments relating to the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013

13. In paragraph 18—

(a) in sub-paragraph (c), for "the United Kingdom" substitute "Great Britain";

(b) in sub-paragraph (d), in the new definition of "Devolved Authority" which that sub-paragraph inserts—

(i) at the end of paragraph (a), insert "or";

(ii) at the end of paragraph (b), omit ", or";

(iii) omit paragraph (c);

(c) for sub-paragraph (e) substitute—

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

""the PIC Regulation" means—

(a) in relation to Great Britain, Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals, of which Annexes II, IV and VI are to be read as amended from time to time;

(b) in relation to Northern Ireland, Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals as it has effect in EU law;";";

(d) after paragraph (e) insert—

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

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

14. In paragraph 20—

(a) for the new regulation 7(2) which that paragraph inserts, substitute—

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

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

(b) in relation to Northern Ireland, the chemicals listed in Annex I to the PIC Regulation;";

(b) for the new paragraph 7(3) which that paragraph inserts, substitute—

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

15. In paragraph 21(b), in the new paragraph (4) which that paragraph substitutes, for "the second subparagraph of 89(3)" substitute "79".

16. In paragraph 22(a), in the new paragraph (1) which it inserts, for the words from "Article 22" to the end substitute "Article 22 of the Review Regulation".

17. For paragraph 23 substitute—

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

(2) In paragraph (1)—

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

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

(3) In paragraph (2)—

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

(b) above paragraph (a) insert—

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

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

(d) before sub-paragraph (m) insert—

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

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

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

(e) after paragraph (n) insert—

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

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

(f) after paragraph (o) insert—

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

(4) After paragraph (2) insert—

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

(5) Omit paragraph (3).

(6) In paragraph (4)—

(a) in sub-paragraph (a)—

(i) for "(g)" substitute "(e)";

(ii) after "(j)" insert "(la), (lc),";

(b) in sub-paragraph (b) omit "and 2(l)";

(c) in sub-paragraph (d) omit ", (k)";

(d) after sub-paragraph (d) insert—

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

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

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

Amendments relating to the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013

18. Omit paragraphs 30 to 39, and the heading above paragraph 30.

Amendments relating to the Genetically Modified Organisms (Contained Use) Regulations 2014

19. In paragraph 40(3), in the new regulation 33A which that paragraph inserts, in both places it occurs, for "exit day" substitute "IP completion day".

Amendments relating to the Control of Major Accident Hazards Regulations 2015

20. In paragraph 41(2), for "UK" substitute "GB".

Amendments relating to the Explosives (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2015

21. Omit paragraph 42 and the heading above it.

Amendments relating to the Biocidal Products (Fees and Charges) Regulations (Northern Ireland) 2015

22. Omit paragraph 43 and the heading above it.

Amendments relating to the Control of Major Accident Hazards Regulations (Northern Ireland) 2015

23. Omit paragraph 44 and the heading above it.

Amendments relating to the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015

24. Omit paragraph 45 and the heading above it.

SCHEDULE 2

Regulation 8

Amendment of Schedule 2 to the 2019 Regulations

1. Schedule 2 to the 2019 Regulations (Amendments to retained direct EU legislation) is amended in accordance with paragraphs 2 to 72.

Amendments relating to Regulation (EC) No 1907/2006 ("the REACH Regulation")

2. In the following paragraphs, in each place it occurs, for "UK" substitute "GB"—

(a) paragraph 2 (amendment of Article 3 of the REACH Regulation);

(b) paragraph 3 (amendment of Article 15 of the REACH Regulation);

(c) paragraph 4 (amendment of Article 59 of the REACH Regulation);

(d) paragraph 5 (amendment of Annex I to the REACH Regulation);

(e) paragraph 6 (amendment of Annex II to the REACH Regulation);

(f) paragraph 7 (amendment of Annex XVII to the REACH Regulation);

(g) paragraph 8 (amendment of the foreword to Appendices 1 to 6 to the REACH Regulation);

(h) paragraph 10 (amendment of Appendix 2 to the REACH Regulation).

Amendments relating to Regulation (EC) No 1272/2008 ("the CLP Regulation")

3. In paragraph 13 (amendment of Article 1 of the CLP Regulation(**a**))—

(a) in sub-paragraph (2)(c), for "UK" substitute "GB";

(b) in sub-paragraph (2)(d)—

(i) for "UK" substitute "GB";

(ii) for "exit day" substitute "IP completion day";

(c) in sub-paragraph (3)(a), omit "and the Ionising Radiations Regulations (Northern Ireland) 2017".

4. For paragraph 14 (amendment of Article 2 of the CLP Regulation) substitute—

"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—

(**a**) Here and in other parenthesised text throughout this instrument, "CLP" stands for "classification, labelling and packaging".

"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.".".

5. For paragraph 15 (amendment of Article 4 of the CLP Regulation) substitute—

"**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".".

6. In the following paragraphs, in each place it occurs, for "UK" substitute "GB"—

(a) paragraph 17 (amendment of Article 10 of the CLP Regulation);

(b) paragraph 18 (amendment of Article 15 of the CLP Regulation);

(c) paragraph 21 (amendment of Article 18 of the CLP Regulation);

(d) paragraph 22 (amendment of Article 21 of the CLP Regulation);

(e) paragraph 24 (amendment of Article 25 of the CLP Regulation);

(f) paragraph 25 (amendment of Article 26 of the CLP Regulation);

(g) paragraph 30 (amendment of the heading for Title V of the CLP Regulation);

(h) paragraph 32 (amendment of Article 36 of the CLP Regulation).

7. For paragraph 33 (amendment of Article 37 of the CLP Regulation) substitute—

"**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. ".".

8. For paragraph 34 (insertion of Article 37A of the CLP Regulation) substitute—

"**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.".".

9. In the following paragraphs, in each place it occurs (including in new provisions being inserted and headings), for "UK" substitute "GB"—

(a) paragraph 35 (amendment of Article 38 of the CLP Regulation);

(b) paragraph 36 (insertion of Article 38A into the CLP Regulation);

(c) paragraph 37 (amendment of the heading for Chapter 2 of the CLP Regulation);

10. In paragraph 39 (amendment of Article 40 of the CLP Regulation)—

(a) in sub-paragraph (a), for "UK" substitute "GB";

(b) in sub-paragraph (b), for "exit day" substitute "IP completion day".

11. In paragraph 40 (amendment of Article 41 of the CLP Regulation), for "UK" substitute "GB".

12. In paragraph 41 (amendment of Article 42 of the CLP Regulation)—

(a) in each place it occurs (including in the amendment to the heading), for "UK" substitute "GB";

(b) in point (e), for "37(3)(b) and Article 37A(6)" substitute "37(4)(b) and Article 37A(8)".

13. In paragraph 45 (amendment of Article 45 of the CLP Regulation)—

(a) in sub-paragraph (b), in the new paragraph 1A which it inserts, for "Scotland, Wales or Northern Ireland" substitute "Scotland or Wales";

(b) for paragraph (d) substitute—

"(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.".".

14. For paragraph 48 (amendment of Article 49 of the CLP Regulation) substitute—

"**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.".".

15. In paragraph 51 (amendment of Article 52 of the CLP Regulation), in the new Article 52 which it substitutes—

(a) in paragraph 1(b), for "paragraphs 6 to 10" substitute "paragraphs 6 to 8";

(b) omit paragraph 6(d) (and the semicolon before it);

(c) omit paragraphs 9 and 10.

16. In paragraph 53 (insertion of Articles 53A and 53B into the CLP Regulation), in the new Article 53B which that paragraph inserts, omit paragraphs 4 to 7.

17. In the following paragraphs, in each place it occurs, for "UK" substitute "GB"—

(a) paragraph 55 (amendment of Annex I to the CLP Regulation);

(b) paragraph 56 (amendment of Annex II to the CLP Regulation);

(c) paragraph 57 (amendment of Annex VI to the CLP Regulation).

Amendments relating to Regulation (EU) No 544/2011 (Regulation on data requirements for active substances)

18. In paragraph 58 (amendment of the Annex to Regulation (EU) No 544/2011(**a**)), in both places it occurs, for "UK" substitute "GB".

Amendments relating to Regulation (EU) No 545/2011 (Regulation on data requirements for PPPs)

19. In paragraph 59 (amendment of the Annex to Regulation (EU) No 545/2011(**b**)), in each place it occurs, for "UK" substitute "GB".

Amendments relating to Regulation (EU) No 547/2011 (Regulation on labelling requirements for PPPs)

20. In paragraph 60 (amendment of Annex I to Regulation on labelling requirements for PPPs), in both places it occurs, for "UK" substitute "GB".

Amendments relating to Regulation (EU) No 528/2012 ("the Biocides Regulation")

21. In paragraph 62 (amendment of Article 1 of the Biocides Regulation), in sub-paragraph (3)—

(a) in paragraph (a), for "United Kingdom" substitute "Great Britain";

(**a**) Commission Regulation (EU) No 283/2013 repealed Regulation (EU) No 544/2011, but made transitional provision in Article 3 (Transitional measures as regards procedures concerning active substances) and Article 4 (Transitional measures as regards procedures concerning plant protection products) preserving the effect of Regulation (EU) No 544/2011 in relation to certain authorisations that were applied for before specified dates, of which some are still in effect.

(**b**) Commission Regulation (EU) No 284/2013 repealed Regulation (EU) No 545/2011, but made transitional provision in Article 3 (Transitional measures as regards procedures concerning active substances) and Article 4 (Transitional measures as regards procedures concerning plant protection products) preserving the effect of Regulation (EU) No 545/2011 in relation to certain authorisations that were applied for before specified dates, of which some are still in effect.

(b) in paragraph (c), for "the United Kingdom" substitute "Great Britain".

22. In paragraph 63 (amendment of Article 2 of the Biocides Regulation), for sub-paragraph (2) substitute—

"(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".".

23. In paragraph 64 (amendment of Article 3 of the Biocides Regulation), in sub-paragraph (2)—

(a) for paragraph (d) substitute—

"(d) in point (k), for "the Union" substitute "Great Britain";";

(b) in paragraph (f), in the new point (n) which it substitutes, for "exit day" substitute "IP completion day";

(c) in paragraph (h)(ii), for "the United Kingdom" substitute "Great Britain";

(d) in paragraph (k)—

(i) for the new point (ai) which it inserts, substitute—

"(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;";

(ii) after the new point (ai) which it inserts, for point (ah) (the second time this point number is used) substitute—

"(aj) "Devolved Authority" means—

(i) the Scottish Ministers, or

(ii) the Welsh Ministers.".

24. In paragraph 69 (insertion of Article 8A into the Biocides Regulation), in the new Article 8A which it inserts, in both places it occurs (including the heading), for "UK" substitute "GB".

25. In paragraph 70 (amendment of Article 9 of the Biocides Regulation), in sub-paragraph (4), in the new paragraph 2 which it substitutes, for "UK" substitute "GB".

26. In paragraph 75 (amendment of Article 14 of the Biocides Regulation), in sub-paragraph (6), in the new paragraph 4A which it inserts, for "UK" substitute "GB".

27. After paragraph 78 (amendment of Article 17 of the Biocides Regulation, insert—

"**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(**a**) 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

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(**a**) "reference Member State" has the meaning given by Article 33 of Regulation (EU) No 528/2012 as it has effect in EU law.

(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(**a**) 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;

(**a**) "Letter of access" has the meaning given by Article 3(1)(t) of Regulation (EU) No 528/2012 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.".".

28. In paragraph 102 (amendment of Article 55 of the Biocides Regulation), in the new Article 55 which it substitutes—

(a) omit paragraph 4(d) (and the semicolon which precedes it);

(b) omit paragraphs 7 and 8;

(c) re-number paragraph 9 as paragraph 7;

(d) in paragraph 7 (previously paragraph 9), in the second sentence, for "Devolved Authorities" substitute "Devolved Authority".

29. In paragraph 107 (amendment of Article 60 of the Biocides Regulation), in paragraph (3), in the new paragraphs 4 and 5 which it inserts, in each place it occurs, for "exit day" substitute "IP completion day".

30. For paragraph 108 (amendment of Article 62 of the Biocides Regulation), substitute—

"**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";

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

(iv) 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".".

31. In paragraph 111 (amendment of Article 65 of the Biocides Regulation), in sub-paragraph (3), for paragraph (b) substitute—

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

32. In paragraph 115 (amendment of Article 69 of the Biocides Regulation), in sub-paragraph (3), for paragraph (b) substitute—

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

33. In paragraph 119 (amendment of Article 77 of the Biocides Regulation), in the new Article 77 which it substitutes, for paragraph 1 substitute—

"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.".

34. In paragraph 123 (amendment of Article 81 of the Biocides Regulation), in paragraph (3), for the new paragraph 1 which it substitutes, substitute—

"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.".".

35. In paragraph 125 (insertion of new Articles 83A and 83B of the Biocides Regulation), in the new Article 83B which it inserts—

(a) in new paragraph 1, for "paragraphs 2 to 4" substitute "paragraphs 2 and 3";

(b) omit new paragraphs 4 to 7.

36. In paragraph 129 (amendment of Article 88 of the Biocides Regulation), in the new Article 88 which it substitutes—

(a) in paragraph 2, at the end, for "paragraphs 3 to 7" substitute "paragraphs 3 to 5";

(b) omit paragraph 3(d) (and the semicolon which precedes it);

(c) omit paragraphs 6 and 7;

(d) re-number paragraph 8 to become paragraph 6;

(e) in paragraph 6 (re-numbered from paragraph 8), in the second sentence, for "other Devolved Authorities" substitute "other Devolved Authority".

37. In paragraph 135 (amendment of Article 94 of the Biocides Regulation), in sub-paragraph (2)(b), in both places it occurs, for "exit day" substitute "IP completion day".

38. Omit paragraph 137 (insertion of Articles 95A to 95L into the Biocides Regulation)(**a**).

39. In paragraph 143 (amendment of Annex VI to the Biocides Regulation)—

(a) in sub-paragraph 12, for "United Kingdom" substitute "Great Britain";

(b) for sub-paragraph 14 substitute—

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

Amendments relating to Regulation (EU) No 649/2012 ("the PIC Regulation")

40. For paragraph 145 (amendment of Article 1 of the PIC Regulation) substitute—

"**145.** In Article 1—

(**a**) The provisions that were inserted into the Biocides Regulation by paragraph 137 of Schedule 2 to SI 2019/720 are replaced, with amendments, by Schedule 4 to this instrument.

(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".".

41. In paragraph 146 (amendment of Article 2 of the PIC Regulation)—

(a) for sub-paragraph (2) substitute—

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

(b) in sub-paragraph (3)—

(i) in paragraph (a), omit "and the Ionising Radiations Regulations (Northern Ireland) 2017";

(ii) in paragraph (b), for the words from ", the Waste (Scotland)" to the end substitute "and the Waste (Scotland) Regulations 2011";

(iii) in paragraph (c), for the words from "(Scotland) Regulations 2002" to the end substitute "(Scotland) Regulations 2002 and the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002";

(c) for sub-paragraph (4) substitute—

"(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".".

42. In paragraph 147 (amendment of Article 3 of the PIC Regulation)—

(a) in sub-paragraph (4)(b), for "the UK PIC list" substitute "the GB PIC list";

(b) in sub-paragraph (5), for paragraphs (b) and (c) substitute—

"(b) in the second sentence—

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

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

(c) in sub-paragraph (6)(b), for "UK PIC list" substitute "GB PIC list";

(d) in sub-paragraph (7), for paragraph (b) substitute—

"(b) in point (b), for "Union" substitute "Great Britain";";

(e) in sub-paragraph (8), for paragraph (b) substitute—

"(b) in point (b), for "Union" substitute "Great Britain";";

(f) in sub-paragraph (11), in the new point (16) which it substitutes—

(i) in the first place it occurs, for "the United Kingdom" substitute "Great Britain";

(ii) in point (a), for "section 35 or 36" substitute "sections 33(4), 35 or 36";

(iii) in the second place it occurs, for "the United Kingdom" substitute "Great Britain";

(g) in sub-paragraph (12), in both places the words occur, for "the United Kingdom" substitute "Great Britain";

(h) for sub-paragraph (13) substitute—

"(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";";

(i) for sub-paragraph (14) substitute—

"(14) In point (19), for "the customs territory of the Union" substitute "Great Britain";";

(j) in sub-paragraph (17), in the new point (26) which it inserts, for "UK PIC list" substitute "GB PIC list".

43. In paragraph 149 (amendment of Article 5 of the PIC Regulation), in sub-paragraph (4), in the new paragraphs 1 to 3 which that sub-paragraph substitutes—

(a) paragraphs 1, 2 and 3 become paragraphs 2, 2A and 2B respectively;

(b) in the paragraph re-numbered as paragraph 2, in subparagraph (a)—

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

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

(c) in the paragraph re-numbered as paragraph 2A, in subparagraph (c), for "United Kingdom" substitute "Great Britain".

44. In paragraph 151 (amendment of Article 7 of the PIC Regulation), in sub-paragraphs (3), (4) and (5), in each place it occurs, for "UK PIC list" substitute "GB PIC list".

45.—(1) Paragraph 152 (amendment of Article 8 of the PIC Regulation) is amended as follows.

(2) For sub-paragraph (2) substitute—

"(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 sub-paragraph (3)—

(a) in paragraph (a)—

(i) for paragraph (i) substitute—

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

(ii) paragraphs (ii) to (iv) become paragraphs (iii) to (v);

(iii) after paragraph (i) insert a new paragraph (ii) as follows—

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

(b) for paragraph (c) substitute—

"(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";";

(c) in paragraph (d)—

(i) for paragraph (v) substitute—

"(v) for "importing Parties and other countries" substitute "importing Parties, other countries and Northern Ireland";";

(ii) after paragraph (v) insert—

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

(4) For sub-paragraph (4) substitute—

"(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) For sub-paragraph (6) substitute—

"(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".".

(6) For sub-paragraph (7) substitute—

"(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".".

(7) For sub-paragraph (8) substitute—

"(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".".

46. In paragraph 153 (amendment of Article 9 of the PIC Regulation)—

(a) in sub-paragraph (2)(b)(ii)—

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

(ii) for the words "under a Party's or other country's legislation" substitute "under the legislation of a Party, other country or Northern Ireland";

(b) after sub-paragraph (2)(b)(ii) insert—

"(iii) for the words from "each Party" to the end substitute "each Party, other country or Northern Ireland".".

47. In paragraph 154 (amendment of Article 10 of the PIC Regulation), for sub-paragraph (2) substitute—

"(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".".

48. In paragraph 155 (amendment of Article 11 of the PIC Regulation)—

(a) in sub-paragraphs (2)(b), (3)(a) and 4(a)(ii), for "UK PIC list" substitute "GB PIC list";

(b) in sub-paragraph (7)(b)(iii), for the words from ", the Welsh Ministers" to the end substitute "and the Welsh Ministers".

49. In paragraph 156 (amendment of Article 12 of the PIC Regulation), for "UK PIC list" substitute "GB PIC list".

50. In paragraph 157 (amendment of Article 13 of the PIC Regulation), in sub-paragraph (6)(b), for the words from ", the Welsh Ministers" to the end substitute "and the Welsh Ministers".

51.—(1) Paragraph 158 (amendment of Article 14 of the PIC Regulation) is amended as follows.

(2) For paragraph (6) substitute—

"(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".".

(3) For paragraph (7) substitute—

"(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.".

(4) For paragraph (10) substitute—

"(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".".

52. In paragraph 159 (amendment of Article 15 of the PIC Regulation)—

(a) in sub-paragraph (a), for "UK PIC list" substitute "GB PIC list";

(b) in sub-paragraph (b)—

(i) for paragraph (i) substitute—

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

(ii) in paragraph (ii), for "UK PIC list" substitute "GB PIC list".

53. In paragraph 160 (amendment of Article 16 of the PIC Regulation), in sub-paragraph (a)(i), for "UK PIC list" substitute "GB PIC list".

54. In paragraph 161 (amendment of Article 17 of the PIC Regulation)—

(a) after sub-paragraph (a)(ii) insert—

"(iii) for "the importing Parties or other countries" substitute "importing Parties, other countries or Northern Ireland";";

(b) in sub-paragraph (b), for "UK PIC list" substitute "GB PIC list";

(c) after sub-paragraph (b) insert—

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

55. In paragraph 162 (amendment of Article 18 of the PIC Regulation), in sub-paragraph (3)(a)(ii), for "UK PIC list" substitute "GB PIC list".

56. In paragraph 164 (amendment of Article 20 of the PIC Regulation), for paragraphs (a) and (b) substitute—

"(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".".

57. In paragraph 167 (amendment of Article 23 of the PIC Regulation), in sub-paragraphs (a), (b)(ii), (c)(ii) and (d)(ii), for "UK PIC list" substitute "GB PIC list".

58. In paragraph 168 (insertion of Articles 23A and 23B into the PIC Regulation), in the new Article 23B that it inserts—

(a) in paragraph 1, for "paragraphs 2 to 4" substitute "paragraphs 2 and 3";

(b) omit paragraphs 4 to 7.

59. In paragraph 171 (amendment of Annex II to the PIC Regulation)—

(a) in sub-paragraphs 3(a) and (4), for "UK PIC list" substitute "GB PIC list";

(b) for sub-paragraph (6) substitute—

"(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".".

60. For paragraph 173 (amendment of Annex IV to the PIC Regulation) substitute—

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

Amendments relating to Regulation (EU) No 283/2013 (Regulation on data requirements for active substances)

61. In paragraph 176 (amendment of the Annex to the Regulation on data requirements for active substances), in both places it occurs, for "UK" substitute "GB".

Amendments relating to Regulation (EU) 284/2013 (Regulation on data requirements for PPPs)

62. In paragraph 177 (amendment of the Annex to the Regulation on data requirements for PPPs), in each place it occurs, for "UK" substitute "GB".

Amendments relating to Regulation (EU) No 354/2013 ("the Changes Regulation")

63. In paragraph 179 (amendment of Article 2 of the Changes Regulation)—

(a) for paragraph (a) substitute—

"(a) in the first subparagraph, for "Agency" substitute "competent authority";";

(b) for paragraph (b) substitute—

"(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.";";

(c) after paragraph (b) insert—

"(c) in the third subparagraph, for "Agency" substitute "competent authority".".

Amendments relating to Regulation (EU) No 414/2013 ("the Same Products Regulation")

64. For paragraph 195 (amendment of Article 1 of the Same Products Regulation) substitute—

"**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,".".

65. In paragraphs 197 (amendment of Article 3 of the Same Products Regulation), for sub-paragraphs (3) and (4) substitute—

"(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".".

Amendments relating to Regulation (EU) No 88/2014 ("the Annex I Regulation")

66. In paragraph 209 (amendment of Article 4 of the Annex I Regulation), for sub-paragraph (2) substitute—

"(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".".

67. In paragraph 210 (amendment of Article 5 of the Annex I Regulation), in sub-paragraph (3), for the words "the Scottish Ministers, the Welsh Ministers and a Northern Ireland Department" substitute "the Scottish Ministers and the Welsh Ministers".

Amendments relating to Regulation (EU) No 1062/2014 ("the Review Regulation")

68. Paragraph 214 (amendment of Article 2 of the Review Regulation) is amended as follows—

(a) in sub-paragraphs (2) and (3), in each place it occurs, for "exit day" substitute "IP completion day";

(b) for sub-paragraph (4) substitute—

"(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;";"

(c) for sub-paragraph (5) substitute—

"(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.".".

69. In paragraph 218 (amendment of Article 6 of the Review Regulation), in paragraph 2(a), in the new point (b) which that paragraph substitutes, for "exit day" substitute "IP completion day".

70. In paragraph 227 (amendment of Article 15 of the Review Regulation)—

(a) in sub-paragraphs (3) and (4), in each place it occurs, for "exit day" substitute "IP completion day";

(b) in sub-paragraph (4), in the new point (aa) which it inserts, at the end insert "or in new, authoritative guidance published by the Competent Authority".

71. In paragraph 234 (amendment of Article 22 of the Review Regulation), in the new Article 22 which that paragraph substitutes—

(a) in new paragraph 1, at the end, for "Article 89(8)" substitute "Article 89(7)";

(b) in new paragraph 3—

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

(ii) for "paragraph 10" substitute "paragraph 8";

(iii) at the end, for "paragraphs 4 to 8" substitute "paragraphs 4 to 6";

(c) omit new paragraph 4(d) (and the semicolon which precedes it);

(d) omit new paragraphs 7 and 8;

(e) re-number paragraphs 9 and 10 as 7 and 8 respectively

(f) in the paragraph renumbered as paragraph 7 (previously paragraph 9)—

(i) for "grants the derogation" substitute "exercises the derogation";

(ii) in the second place it occurs, for "Devolved Authorities" substitute "Devolved Authority".

72. In paragraph 235 (insertion of Articles 22A to 22D of the Review Regulation), in the new Articles 22A to 22D which it inserts—

(a) in new Article 22A—

(i) in the heading, and in new paragraph 1, in each place it occurs, for "exit day" substitute "IP completion day";

(ii) in new paragraph 2, in each of subparagraphs (a) and (b)—

(aa) in the first place it occurs, for "exit day" substitute "IP completion day";

(bb) after "United Kingdom" insert "competent authority";

(cc) for "Member State" substitute "competent authority";

(dd) in the second place it occurs, for "exit day" substitute "30 March 2019";

(iii) after paragraph 2 insert—

"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).";

(b) in new Articles 22B and 22C, in each place it occurs, for "exit day" substitute "IP completion day";

(c) in new Article 22D—

(i) in the heading, and in new paragraph 1, for "exit day" substitute "IP completion day";

(ii) in new paragraph 2, for points (a) and (b), substitute—

"(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";";

(iii) after paragraph 2 insert—

"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).".

SCHEDULE 3

Regulation 9

Amendment of Schedule 3 to the 2019 Regulations

1. In Schedule 3 to the 2019 Regulations (Amendments to Annex II to the EEA Agreement), in paragraph 1—

(a) for sub-paragraphs (a) and (b) substitute—

"(a) omit point 12n (including the words from "The provisions of the Regulation" to the end);

(b) omit point 12o (including the words from "The provisions of the Regulation" to the end);"

(b) in sub-paragraph (c)—

(i) re-number paragraph (ii) as (iii);

(ii) after paragraph (i) insert—

"(ii) omit "32020 R 0011: Commission Delegated Regulation (EU) 2020/11 of 29 October 2019 (OJ L 6, 10.1.2020, p. 8)".".

SCHEDULE 4

Regulation 10

Insertion of Schedule 4 into the 2019 Regulations

After Schedule 3 to the 2019 Regulations (Amendments to Annex II to the EEA Agreement) insert—

"SCHEDULE 4

Regulation 5

Savings, transitional and consequential provision

Provision relating to Regulation (EC) No 1272/2008

1. In relation to Great Britain, a classification which, immediately before IP completion day, is set out in Table 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures is to be treated as if it were approved by the Secretary of State in accordance with Article 37A of Regulation (EC) No 1272/2008.

Provision relating to Regulation (EU) No 528/2012

2.—(1) After Article 95 of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, insert—

"**95A Transitional measures for simplified notification procedure**

1. Where, before IP completion day, a product was authorised in a country which was a Member State of the EU other than the United Kingdom in accordance with Article 26 of Regulation (EU) No 528/2012, and was placed on the market in the United Kingdom in accordance with Article 27 of Regulation (EU) No 528/2012—

(a) it is to be treated as if it were authorised by the competent authority under Article 26 of this Regulation, and

(b) the competent authority must grant an authorisation under Article 26 of this Regulation.

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

(a) the authorisation holder is not established in the United Kingdom within 12 months from IP completion day, or

(b) the authorisation holder does not supply the competent authority with relevant scientific and authorisation data by whichever is the earlier of the following—

(i) the date of any application for renewal or the date of any application for amendment of the authorisation under Article 50 of this Regulation, or

(ii) within 60 days of any request made by the competent authority to the authorisation holder.

95B Transitional measures for mutual recognition applications

1. This Article applies where—

(a) an application for mutual recognition of a national authorisation of a biocidal product was made before IP completion day in accordance with Articles 33, 34 or 39 of Regulation (EU) No 528/2012, and

(b) a decision was not made before IP completion day.

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

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

(a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or

(b) where the applicant relies on a letter of access, whichever is the later of the following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

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

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

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

(a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or

(b) where the application relies on a letter of access, whichever is the later of the following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

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

8. Anything done before IP completion day by the United Kingdom competent authority, where the United Kingdom was either the Member State concerned or the reference Member State, is taken as having been done by the competent authority under this Regulation.

9. The resubmission of any application and data referred to in paragraph 3 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

10. The resubmission of any application and data referred to in paragraph 6 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

Article 95C Renewal of authorisations subject to mutual recognition under Regulation 492/2014

1. This Article applies where—

(a) an application for the renewal of a biocidal product authorisation subject to mutual recognition was made before IP completion day in accordance with Article 3 of Commission Delegated Regulation (EU) No 492/2014 of 7 March 2014 supplementing Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the rules for renewal of authorisations of biocidal products subject to mutual recognition, and

(b) a decision on the renewal of the authorisation was not made before IP completion day.

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

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

(a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or

(b) where the applicant relies on a letter of access, whichever is the later of the following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

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

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

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

6. The application is to be treated as having been made under Article 31 of this Regulation, and the time limits under Articles 30 and 31 apply from—

(a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or

(b) where the applicant relies on a letter of access, whichever is the later of the following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

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

8. The resubmission of any application and data referred to in paragraph 3 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

9. The resubmission of any application and data referred to in paragraph 6 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

10. Where the applicant or authorisation holder does not meet the requirements of this Article—

(a) the application must be rejected by the competent authority and Article 89(11) applies as if the application had been submitted in accordance with Article 89(9), and

(b) the authorisation must be cancelled by the competent authority and Article 52 applies.

Article 95D Transitional measure for national authorisation applications

1. This Article applies where—

(a) an application was made before IP completion day to the United Kingdom competent authority under Articles 29 or 31 of Regulation (EU) No 528/2012, and

(b) a decision was not made before IP completion day.

2. The application is to be treated as having been made under this Regulation and the time limits under Articles 29, 30 and 31 as appropriate apply from—

(a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or

(b) where the applicant relies on a letter of access, whichever is the later of the following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

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

4. Anything done before IP completion day by the United Kingdom competent authority as the receiving competent authority is taken as having been done by the competent authority under this Regulation.

5. The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

Article 95E Transitional measures simplified authorisation applications

1. This Article applies where—

(a) an application was made to the United Kingdom competent authority before IP completion day under Articles 25 or 26 of Regulation (EU) No 528/2012, and

(b) a decision was not made before IP completion day.

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

(a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or

(b) where the applicant relies on a letter of access, whichever is the later of the following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

3. In a case where an application was made but the United Kingdom competent authority was not the receiving competent authority, the application is to be treated as having been made under this Regulation and the time limits under Article 26 apply from—

(a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or

(b) where the applicant relies on a letter of access, whichever is the later of the following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

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

5. Anything done before IP completion day by the United Kingdom competent authority as the receiving competent authority is taken as having been done by the competent authority under this Regulation.

6. The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

7. The resubmission of any application and data referred to in paragraph 3 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

Article 95F Transitional measures for applications for same biocidal product authorisations

1. This Article applies where—

(a) an application was made to the United Kingdom competent authority before IP completion day under Articles 3 or 4 of Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council, and

(b) a decision was not made before IP completion day.

2. The application is to be treated as having been made under Articles 3 or 4 (as appropriate) of Regulation (EU) No 414/2013 and the time limits under those Articles are apply from—

(a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or

(b) where the applicant relies on a letter of access, whichever is the later of the following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

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

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

5. The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

Article 95G Transitional measures for Regulation (EU) No 528/2012 authorisations

1. This Article applies to authorisations granted by the United Kingdom competent authority before IP completion day under Articles 19, 26, 30, 31, 33, 34, 36, 39 or 44 of Regulation (EU) No 528/2012.

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

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

(a) the authorisation holder is not established in the United Kingdom within 12 months after IP completion day, or

(b) the authorisation holder does not supply the competent authority with relevant scientific and authorisation data by whichever is the earlier of the following—

(i) the date of any application for renewal or for amendment of the authorisation under Article 50 of this Regulation, or

(ii) within 60 days of any request made by the competent authority to the authorisation holder.

Article 95H Transitional measures for ongoing applications for Union authorisations

1. This Article applies where—

(a) an application for Union authorisation was made before IP completion day in accordance with Articles 42, 43 or 45 of Regulation (EU) No 528/2012, and

(b) a decision was not made before IP completion day.

2. Paragraph 3 applies where, before IP completion day, the United Kingdom competent authority was the evaluating competent authority for applications for Union authorisations made under Regulation (EU) No 528/2012.

3. The application is to be treated as being made under Articles 29 or 31 of this Regulation and the time limits under Articles 29, 30 or 31 are suspended until—

(a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or

(b) where the applicant relies on a letter of access, whichever is the later of the following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

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

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

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

(a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or

(b) where the application relies on a letter of access, whichever is the later of the following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

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

8. Anything done before IP completion day by the United Kingdom competent authority as the evaluating competent authority is taken as having been done by the competent authority under this Regulation.

9. The resubmission of any application and data referred to in paragraph 3 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

10. The resubmission of any application and data referred to in paragraph 6 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

Article 95I Transitional measures for Article 95 List

1. This Article applies to the list prepared pursuant to Article 95 of Regulation (EU) No 528/2012 ("the Article 95 pre-IP completion day List") of active substances and persons having made submissions in relation to those active substances.

2. Subject to paragraph 3, from IP completion day the entries included in the Article 95 pre-IP completion day List are to be included in the list prepared pursuant to Article 95 of this Regulation ("the Article 95 List").

3. An entry on the Article 95 List must be removed if either of the following conditions are not met within 2 years from IP completion day—

(a) the person must be established in the United Kingdom;

(b) the person must provide to the competent authority any of the following—

(i) a complete dossier for the relevant active substance;

(ii) a reference to a complete active substance dossier for which all data protection periods have expired and the competent authority is able to obtain all the data;

(iii) a letter of access to a complete active substance dossier, where that dossier has been submitted to the competent authority within 2 years of IP completion day.

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

5. A period of grace in excess of 180 days may only be granted under paragraph 4 in exceptional circumstances.

6. Where a period of grace is granted in accordance with paragraph 4, and the supplier of a biocidal product does not comply with the second subparagraph of Article 95(1) during that period, the prohibition in Article 95(2) applies.

Article 95J Transitional measure for active substance applications made to the United Kingdom competent authority before 30 March 2019 and subsequently reallocated

1. This Article applies where—

(a) an application was made to the United Kingdom competent authority as evaluating competent authority before 30 March 2019 under Article 7 of Regulation (EU) No 528/2012,

(b) the competent authority had not completed its evaluation of the application before IP completion day due to the evaluation being reallocated at EU level, and

(c) a decision was not made before IP completion day.

2. An application referred to in paragraph 1 is to be treated as if it were made under Article 7 of this Regulation, and the time limits in Articles 7 and 8 are suspended until—

(a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or

(b) where the application relies on a letter of access, whichever is the later of the following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

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

(a) 30 March 2019 for active substances listed in the Annex to Commission Delegated Regulation (EU) 2019/227, or

(b) exit day for other substances.

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

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

6. The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

Article 95K Transitional measure for active substance applications made before IP completion day pursuant to Article 93 where the United Kingdom competent authority was not the evaluating competent authority

1. This Article applies where—

(a) an application to approve an active substance was made before IP completion day under Article 7 of Regulation (EU) No 528/2012 and in compliance with point (a) of Article 93,

(b) the United Kingdom competent authority was not the evaluating competent authority, and

(c) a decision was not made before IP completion day.

2. An application referred to in paragraph 1 is to be treated as if it were made under Article 7 of this Regulation, and the time limits under Articles 7 and 8 apply from—

(a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or

(b) where the application relies on a letter of access, whichever is the later of the following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

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

4. The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

Article 95L Transitional measures for renewal of an approval of an active substance

1. This Article applies where—

(a) an application for renewal of an approval of an active substance was made before IP completion day in accordance with Article 13 of Regulation (EU) No 528/2012, and

(b) a decision was not made before IP completion day.

2. Where the United Kingdom competent authority was the evaluating competent authority before exit day, the application is to be treated as if it were made under Article 13 of this Regulation, and the time limits under Articles 13 and 14 are suspended until—

(a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or

(b) where the application relies on a letter of access, whichever is the later of the following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

3. On receipt of the resubmitted application and data by the competent authority, the time limits under Articles 13 and 14 of this Regulation apply less any time which expired between the date of acceptance of the application and data under Article 13 and 30 March 2019.

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

(a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or

(b) where the application relies on a letter of access, whichever is the later of the following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

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

6. Anything done before IP completion day by the United Kingdom competent authority as the evaluating competent authority under Regulation (EU) No 528/2012 is taken as having been done by the competent authority under this Regulation.

7. The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 90 days of IP completion day.

8. The resubmission of any application and data referred to in paragraph 4 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

Article 95M Transitional measures for ongoing applications to change or amend authorisations

1. This Article applies where—

(a) an application was made before IP completion day to the United Kingdom competent authority under Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation EU (No) 528/2012 of the European Parliament and of the Council, and

(b) a decision was not made before IP completion day.

2. An application referred to in paragraph 1 is to be treated as having been made under Regulation (EU) No 354/2013 and the time limits under that Regulation apply from—

(a) the date on which the applicant resubmits the application and any supporting data to the competent authority, or

(b) where the application relies on a letter of access, whichever is the later of the following—

(i) the applicant resubmits the application, or

(ii) the data owner resubmits the data.

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

4. For the purposes of this Article, data submitted by the applicant or the data owner for changes to authorisations issued under Commission Implementing Regulation (EU) No 414/2013 must include relevant data on the reference product.

5. The resubmission of any application and data referred to in paragraph 2 must be completed in accordance with Article 71 of this Regulation and within 180 days of IP completion day.

Article 95N Interpretation of Articles 95A to 95M

1. For the purposes of Articles 95A to 95M, the following definitions apply—

"evaluating competent authority" has the meaning given in Article 7 of Regulation (EU) No 528/2012 as it had effect immediately before IP completion day;

"Member State concerned" has the meaning given in Articles 33 and 34 of Regulation (EU) No 528/2012 as it had effect immediately before IP completion day;

"receiving competent authority" has the meaning given in Article 17 of Regulation (EU) No 528/2012 as it had effect immediately before IP completion day;

"reference Member State" has the meaning given in Articles 33 and 34 of Regulation (EU) No 528/2012 as it had effect immediately before IP completion day.".

Provision relating to critical use permits

3.—(1) This paragraph applies where—

(a) before IP completion day, the United Kingdom competent authority granted a permit under the first subparagraph of Article 55(1) of Regulation (EU) No 528/2012 for a period not exceeding 180 days, and

(b) on receipt of a reasoned request from the United Kingdom competent authority, the Commission granted an extension of that permit under the third subparagraph of Article 55(1) of Regulation (EU) No 528/2012 until IP completion day.

(2) The extension referred to in paragraph (1)(b) is to be taken as having been granted for a period of 550 days from the date when the Commission granted the extension referred to.

Provision relating to the Simplified Active Substance List

4.—(1) Any chemical which is included in Annex I to Regulation (EU) No 528/2012 immediately before IP completion day, is on IP completion day—

(a) if from categories 1 to 5 of Annex I, to be included in category A of the Simplified Active Substance List;

(b) if from category 6 of Annex I, to be included in category B of the Simplified Active Substance List;

(c) if from category 7 of Annex I, to be included in category C of the Simplified Active Substance List.

(2) In Regulation (EU) No 528/2012, in Article 95(6), for "categories 1 to 5 and category 7" substitute "categories A and C".

(3) In Regulation 1062/2014—

(a) in Article 3(1), for "category 1, 2, 3, 4, 5 or 6" substitute "categories A or B";

(b) in Article 6(1)(c), for "category 1, 2, 3, 4 or 5" substitute "category A";

(c) in Article 7(2), for "category 1, 2, 3, 4, 5 or 6" substitute "categories A or B".

Provision relating to Regulation (EU) No 649/2012

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

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

(3) This paragraph applies to the following—

(a) any export notification made by an exporter under Article 8 of Regulation (EU) No 649/2012, and

(b) any explicit consent received by an exporter through the exporter's designated national authority under Article 14(6) of that Regulation.

(4) Any export notification or explicit consent to which paragraph (3) applies, which continues to be effective on or after IP completion day by virtue of Part 3 of Schedule 8 to the European Union (Withdrawal) Act 2018, is to be treated as if it were made or obtained under Regulation (EU) No 649/2012 on or after IP completion day.

(5) Any export notification or explicit consent to which paragraph (3) applies, which was processed by the Designated National Authority for Great Britain during the months leading up to IP completion day in accordance with the rules which are provided for in these Regulations, is to be treated as if it were made or obtained under Regulation (EU) No 649/2012 on or after IP completion day.

EU implementing Regulations

6. Where, as a result of these Regulations, any provision of retained direct EU legislation imposes an obligation on the Secretary of State to make regulations, that obligation is to be treated as having been met in a case where, before IP completion day, the European Commission adopted a delegated act under that provision."

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by sections 8(1) and 8C(1) of the European Union (Withdrawal) Act 2018 and the powers conferred by paragraphs 1 and 7 of Schedule 4 and paragraph 21(b) of Schedule 7 to that Act. They make provision under section 8(1) of that Act in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under section 8(2)(a), (b), (c), (d), (f) and (g) and section 8(3)(a)) arising from the withdrawal of the United Kingdom from the European Union. They make provision under section 8C(1) (in particular under section 8C(1)(c) and 8C(3)) in order to make amendments relating to the Northern Ireland Protocol. The Regulations make provision under paragraph 1 of Schedule 4 to that Act for the charging of fees by public bodies in the United Kingdom in connection with functions conferred on them as a result of amendments made by these Regulations under section 8(1) of that Act; and they make provision under paragraph 7 of Schedule 4 revoking provision for the charging of fees for the exercise of functions which are removed by amendments made under section 8(1).

These Regulations also make consequential provision in exercise of the power conferred by section 41(1) of the European Union (Withdrawal Agreement) Act 2020 to substitute a number of references to "exit day" with "IP completion day".

These Regulations make amendments to legislation in the field of chemical regulation and the regulation of genetically modified organisms. None of the changes being made alter the technical requirements and standards established by the legislation.

Part 1 covers citation and commencement.

Part 2 amends domestic subordinate legislation, namely the Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720 – "the 2019 Regulations"), which in turn amends retained EU law in the field of chemical regulation and the regulation of genetically modified organisms. Regulations 4 to 6 amend the body of the 2019 Regulations. Regulations 7 to 9, together with Schedules 1, 2 and 3, amend Schedules 1, 2 and 3 to the 2019 Regulations respectively. Schedules 1 to 3 to the 2019 Regulations amend subordinate legislation, retained direct EU legislation, and Annex II to the EEA Agreement respectively. Regulation 10 inserts a new Schedule 4 into the 2019 Regulations, as provided for in Schedule 4, to make provision for savings and transitional arrangements and some consequential amendments.

A full impact assessment has not been prepared for this instrument, as no significant impact on the private or voluntary sectors is foreseen. An Explanatory Memorandum has been published alongside these Regulations on www.legislation.gov.uk.

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