SCHEDULE 1

Regulation 2(1)

AMENDMENTS TO SUBORDINATE LEGISLATION

Health and Safety (Enforcing Authority) Regulations 1998

1.—(1) The Health and Safety (Enforcing Authority) Regulations 1998 [M1] are amended as follows.

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

Commencement Information

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

Marginal Citations

M1 S.I. 1998/494, amended by S.I. 2015/21.

PROSPECTIVE

[F1]...

[F1]**2.** . . . . . .

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

Control of Substances Hazardous to Health Regulations 2002

3.—(1) The Control of Substances Hazardous to Health Regulations 2002 [M2] are amended as follows.

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

Commencement Information

I2 Sch. 1 para. 3 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M2 S.I. 2002/2677, amended by S.I. 2015/21.

Dangerous Substances and Explosive Atmospheres Regulations 2002

4.—(1) The Dangerous Substances and Explosive Atmospheres Regulations 2002 [M3] are amended as follows.

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

Commencement Information

I3 Sch. 1 para. 4 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M3 S.I. 2002/2776, amended by S.I. 2015/21.

PROSPECTIVE

F2...

F2**5.** . . . . . .

F2 Sch. 1 para. 5 and heading omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 3**

PROSPECTIVE

F3...

F3**6.** . . . . . .

F3 Sch. 1 para. 6 and heading omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 4**

Plant Protection Products (Fees and Charges) Regulations 2011

7. The Plant Protection Products (Fees and Charges) Regulations 2011 M4 are amended in accordance with paragraphs 8 to 16.

Commencement Information

I4 Sch. 1 para. 7 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M4 S.I. 2011/2132, amended by S.I. 2016/254.

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

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

[F4(2A) After the definition of "authorisation holder", insert—

""Great Britain competent authorities" means—

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

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

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

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

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

[F5""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;"**]**.

[F6(3A) For the definition of "the MRL Regulation" substitute—

""the MRL Regulation" means—

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

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

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

""MRL supplementary information requirement" means information requested **[**F7by a Great Britain competent authority**]** in accordance with Article 14(3) of the MRL Regulation;".

[F8(4A) After the definition of "nominated sales representative", insert—

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

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

""Regulation 1107/2009" means—

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

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

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

""standalone MRL application" means an application **[**F9to a Great Britain competent authority**]** which is only for the setting, modification or deletion of a maximum residue level of an active substance;".

F4 Sch. 1 para. 8(2A)(2B) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 5(2)**

F5 Words in Sch. 1 para. 8(3) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 5(3)**

F6 Sch. 1 para. 8(3A) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 5(4)**

F7 Words in Sch. 1 para. 8(4) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 5(5)**

F8 Sch. 1 para. 8(4A)(4B) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 5(6)**

F9 Words in Sch. 1 para. 8(5) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 5(7)**

Commencement Information

I5 Sch. 1 para. 8 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

[F10 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).**]**

F10 Sch. 1 para. 9 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 6**

Commencement Information

I6 Sch. 1 para. 9 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

[F11 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".**]**

F11 Sch. 1 para. 10 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 7**

Commencement Information

I7 Sch. 1 para. 10 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

11. In regulation 6—

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

(b) for "within the scope of the Directive" substitute " under the Plant Protection Products (Sustainable Use) Regulations 2012 [M5] ".

Commencement Information

I8 Sch. 1 para. 11 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M5 S.I. 2012/1657, amended by S.I. 2016/765, 2018/942.

12. In regulation 7(2)—

(a) omit "or";

[[F12](aa) for "under regulation 4(1)" substitute "under regulations 4(1), 4(1A) or 4(1B)";**]**

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

F12 Sch. 1 para. 12(aa) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 8**

Commencement Information

I9 Sch. 1 para. 12 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

[[F13]**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;".**]**

F13 Sch. 1 para. 13 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 9**

Commencement Information

I10 Sch. 1 para. 13 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

(2) In paragraph 1—

[F14(a) in the first sentence, after "product-related applications" insert "to a United Kingdom competent authority";**]**

[F15(b)**]** in the table—

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

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

(iii) in item 11 in the second column, for "for lead zonal re-registration and new product applications" substitute " to discuss potential product applications ";

(iv) omit item 12;

[F16(c)**]** in the notes following the table—

(i) omit notes (3), (5) and (6);

(ii) in note (7) for "items 1-5, 10, 11 and 12" substitute " items 1-4, 10 and 11 ";

(iii) in note (16) omit "to the United Kingdom to act as lead zonal rapporteur";

(iv) omit note (17);

(v) in note (18) for "the United Kingdom" substitute " a United Kingdom competent authority ".

[F17(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

(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.

Item	*Chargeable item*	*Fee(£)*
	(b) parallel trade verification[(2)]	208
	(c) parallel trade permit for personal use	156”.**]**

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

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

(3) In paragraph 2—

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

[[F18](b) in the first sentence—

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

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

(c) in the table—

(i) in the heading before item 1, for “or synergist” substitute “ , synergist or basic substance ”;

(ii) omit item 2;

(iii) in item 3 for the words in the second column substitute “ Co-ordination of scientific advice and public consultation and finalising the draft assessment report ”;

(iv) in items 7 and 10, for the words in the second column substitute “ Co-ordination of scientific advice and public consultation, and finalising the draft assessment report ”;

(v) in item 12, in the second column, after “synergist,” insert “ basic substance, ”;

(d) in the notes following the table—

(i) omit note (2);

(ii) in note (3)—

(aa) at the beginning insert “ In relation to active substances, safeners or synergists, ”;

(bb) after the first sentence insert “ In relation to basic substances, a full data package comprises the complete dossier (the information referred to in Article 23(3) of Regulation 1107/2009) to support one or more uses of the basic substance. ”;

(cc) in the second sentence after “the product” insert “ or basic substance ”;

(iii) in note (4)—

(aa) omit paragraph (c);

(bb) in paragraph (d) at the beginning insert “ in relation to active substances, safeners or synergists, ”;

(cc) omit paragraph (e);

(dd) in paragraphs (f) and (g), at the beginning insert “ in relation to active substances, safeners or synergists, ”;

(ee) after paragraph (g) insert—

“(h) in relation to basic substances, resubmissions (for example where the previous application for approval under Regulation 1107/2009 has been unsuccessful and a new application is made in an attempt to address all the concerns raised from that earlier submission);

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

(iv) for the final sentence substitute—

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

[F19(3A) In paragraph 3, after "organisation" insert "by a United Kingdom competent authority".**]**

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

F14 Sch. 1 para. 14(2)(a) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 10(2)(b)**

F15 Sch. 1 para. 14(2)(a) renumbered as Sch. 1 para. 14(2)(b) (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 10(2)(a)**

F16 Sch. 1 para. 14(2)(b) renumbered as Sch. 1 para. 14(2)(c) (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 10(2)(a)**

F17 Sch. 1 para. 14(2A) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 10(3)**

F18 Sch. 1 para. 14(3)(b) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 10(4)**

F19 Sch. 1 para. 14(3A) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 10(5)**

Commencement Information

I11 Sch. 1 para. 14 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

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

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

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

(5) In that paragraph—

[F20(a) in the first sentence, for the words from the start to "product-related applications" substitute "Fees chargeable by a Great Britain competent authority for import tolerances";**]**

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

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

(c) in the notes following the table—

(i) for note (1) substitute—

"(1) This category is mainly for active substances not currently approved in respect of the part of **[**F21Great Britain**]** to which the application relates. In certain cases it may also include active substances still being reviewed if toxicological endpoints have not yet been agreed and accepted in respect of that part of **[**F21Great Britain**]**.";

(ii) in note (2)—

(aa) for "plant protection products" substitute " active substances ";

(bb) for "at a European level" substitute " and accepted in respect of the part of **[**F22Great Britain**]** to which the application relates ";

(iii) in note (3)—

(aa) for "plant protection products" substitute " active substances ";

(bb) for "at European level" substitute " and accepted in respect of the part of **[**F23Great Britain**]** to which the application relates ";

(iv) after note (3) insert—

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

(6) After that paragraph insert—

"**Fees for standalone MRL applications**

2. Fees **[**F24chargeable by a Great Britain competent authority**]** for standalone MRL applications are in accordance with the following table.

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

Notes

(1) This category is mainly for active substances not currently approved in respect of the part of **[**F25Great Britain**]** to which the application relates. In certain cases it may also include active substances still being reviewed if toxicological endpoints have not yet been agreed and accepted in respect of that part of **[**F25Great Britain**]**.

(2) This category is for active substances where toxicological endpoints have already been agreed and accepted in respect of the part of **[**F25Great Britain**]** to which the application relates but the residue definition has only been established for crop groups unrelated to the intended use.

(3) This category is for active substances where relevant toxicological endpoints and residue definition have already been agreed and accepted in respect of the part of **[**F25Great Britain**]** to which the application relates.

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

F20 Sch. 1 para. 15(5)(a) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 11(2)(a)**

F21 Words in Sch. 1 para. 15(5)(c)(i) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 11(2)(b)(i)**

F22 Words in Sch. 1 para. 15(5)(c)(ii)(bb) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 11(2)(b)(ii)**

F23 Words in Sch. 1 para. 15(5)(c)(iii)(bb) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 11(2)(b)(ii)**

F24 Words in Sch. 1 para. 15(6) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 11(3)(a)**

F25 Words in Sch. 1 para. 15(6) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 11(3)(b)**

Commencement Information

I12 Sch. 1 para. 15 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

16. After Schedule 2 insert—

"SCHEDULE 3

Regulation 4(2A)

Maximum residue level supplementary information fees
[[F26]chargeable by a Great Britain competent authority**]**

Fees **[**[F26]chargeable by a Great Britain competent authority**]** for the evaluation of supplementary information provided in accordance with Article 14(3) of the MRL Regulation are in accordance with the following table.

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

Notes

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

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

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

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

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

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

F26 Words in Sch. 1 para. 16 inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 12**

Commencement Information

I13 Sch. 1 para. 16 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

17. The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 [M6] are amended in accordance with paragraphs 18 to 29.

Commencement Information

I14 Sch. 1 para. 17 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M6 S.I. 2013/1506.

18. In regulation 4(1)—

(a) in the definition of "the Biocides Regulation", for "Annexes I to IV" substitute " Annexes II to IV ";

(b) omit the definition of "the Commission";

(c) in the definition of "competent authority", for "a Member State" substitute " **[**[F27]Great Britain**]** ";

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

""Devolved Authority" means—

(a) the Scottish Ministers, **[**F28or**]**

(b) the Welsh MinistersF29...

F30(c) . . . . . .;";

[F31(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;";**]**

[F32(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;".**]**

F27 Words in Sch. 1 para. 18(c) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 13(a)**

F28 Word in Sch. 1 para. 18(d) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 13(b)(i)**

F29 Word in Sch. 1 para. 18(d) omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 13(b)(ii)**

F30 Words in Sch. 1 para. 18(d) omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 13(b)(iii)**

F31 Sch. 1 para. 18(e) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 13(c)**

F32 Sch. 1 para. 18(f) inserted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 13(d)**

Commencement Information

I15 Sch. 1 para. 18 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

Commencement Information

I16 Sch. 1 para. 19 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

20. For regulation 7 substitute—

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

(a) in England, Scotland and Wales, the Great Britain Executive;

(b) in Northern Ireland, the Northern Ireland Executive.

[F33(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.**]**

[F34(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."**]**

F33 Words in Sch. 1 para. 20 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 14(a)**

F34 Words in Sch. 1 para. 20 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 14(b)**

Commencement Information

I17 Sch. 1 para. 20 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

21. In regulation 8—

(a) in paragraph (2) omit "or Member State";

(b) for paragraph (4) substitute—

"(4) The duties referred to in paragraph (3) are those contained in Articles 6(1), 7(1), 13(1) and (2)(b), 20(1), 26(1), 29(1), 31(1), 50(2), 54(1) and (2), 59(2), 62(1), 63(1), (2) and (3), 64(2), 71(3), **[**F3579**]**, 93 and 95(1) of the Biocides Regulation."

F35 Word in Sch. 1 para. 21(b) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 15**

Commencement Information

I18 Sch. 1 para. 21 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

22. In regulation 13—

(a) for paragraph (1) substitute—

"(1) In this regulation, "essential use active substance" means an active substance in respect of which the Secretary of State or a Devolved Authority has granted a derogation for essential use under **[**F36Article 22 of the Review Regulation**]**.";

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

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

F36 Words in Sch. 1 para. 22(a) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 16**

Commencement Information

I19 Sch. 1 para. 22 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

[F37**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".**]**

F37 Sch. 1 para. 23 substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 17**

Commencement Information

I20 Sch. 1 para. 23 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

Commencement Information

I21 Sch. 1 para. 24 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

25. In regulation 21—

(a) for the heading, substitute " Duties on the Designated National Authority and the Secretary of State ";

(b) for "a designated national authority or the Member State" substitute " the Designated National Authority or the Secretary of State ".

Commencement Information

I22 Sch. 1 para. 25 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

26. In regulation 30(1)—

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

(b) omit sub-paragraph (b).

Commencement Information

I23 Sch. 1 para. 26 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

27. In regulation 38 omit paragraph (2).

Commencement Information

I24 Sch. 1 para. 27 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

28. In Schedule 2—

(a) in paragraph 1, in the definition of "Plant protection product", after "91/414/EEC" insert " as it had effect immediately before exit day ";

(b) after paragraph 10 insert—

"**11.** For the purposes of regulation 13 of these Regulations, essential use derogations granted by the Commission before exit day (under either Regulation 1062/2014 or its predecessor Regulation 1451/2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market) are deemed to have been granted by the Secretary of State subject to the same terms and conditions."

Commencement Information

I25 Sch. 1 para. 28 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

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

Commencement Information

I26 Sch. 1 para. 29 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

PROSPECTIVE

F38 ...

F39 **30.** . . . . . .

F38 Sch. 1 para. 30 heading omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 18**

F39 Sch. 1 paras. 30-39 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 18**

PROSPECTIVE

F39 **31.** . . . . . .

F39 Sch. 1 paras. 30-39 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 18**

PROSPECTIVE

F39 32. . . . . . .

F39 Sch. 1 paras. 30-39 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 18**

PROSPECTIVE

F39 33. . . . . . .

F39 Sch. 1 paras. 30-39 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 18**

PROSPECTIVE

F39 34. . . . . . .

F39 Sch. 1 paras. 30-39 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 18**

PROSPECTIVE

F39 35. . . . . . .

F39 Sch. 1 paras. 30-39 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 18**

PROSPECTIVE

F39 36. . . . . . .

F39 Sch. 1 paras. 30-39 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 18**

PROSPECTIVE

F39 37. . . . . . .

F39 Sch. 1 paras. 30-39 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 18**

PROSPECTIVE

F39 38. . . . . . .

F39 Sch. 1 paras. 30-39 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 18**

PROSPECTIVE

F39 39. . . . . . .

F39 Sch. 1 paras. 30-39 omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 18**

Genetically Modified Organisms (Contained Use) Regulations 2014

40.—(1) The Genetically Modified Organisms (Contained Use) Regulations 2014 [M7] are amended as follows.

(2) In regulation 3(2)—

(a) in sub-paragraph (a) omit paragraph (iii);

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

"(i) a medicinal product for veterinary use marketed in accordance with the Veterinary Medicines Regulations 2013 [M8];".

(3) After regulation 33 insert—

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

33A.—(1) Subject to paragraphs (2) and (3), these Regulations do not apply to any activity which is covered by a written consent given by a competent authority of an EEA State in

accordance with Article 15(3), 17(6) or 18(2) of Directive (EC) No 2001/18 of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms [M9].

(2) The written consent referred to in paragraph (1) must be valid immediately before **[**[F40]IP completion day**]**.

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

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

(5) The marketing authorisation referred to in paragraph (4) must be valid immediately before **[**[F40]IP completion day**]**.

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

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

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

F40 Words in Sch. 1 para. 40(3) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 19**

Commencement Information

I27 Sch. 1 para. 40 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M7 S.I. 2014/1663, amended by S.I. 2015/1637.

M8 S.I. 2013/2033, amended by S.I. 2014/599, 2018/761.

M9 OJ No. L 106, 17.04.2001, p.1.

Control of Major Accident Hazards Regulations 2015

41.—(1) The Control of Major Accident Hazards Regulations 2015 [M10] are amended as follows.

(2) In regulation 2(1), in the definition of "the CLP Regulation", for "Annex VI, Part 3 Table 3.1" substitute " the **[**[F41]GB**]** mandatory classification and labelling list established under Article 38A (which for the purposes of these Regulations is deemed to be part of Regulation (EC) No. 1272/2008) ".

F41 Word in Sch. 1 para. 41(2) substituted (31.12.2020 immediately before IP completion day) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 20**

Commencement Information

I28 Sch. 1 para. 41 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M10 S.I. 2015/483.

PROSPECTIVE

F42...

F42**42.** . . . . . .

F42 Sch. 1 para. 42 and heading omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 21**

PROSPECTIVE

F43...

F43**43.** . . . . . .

F43 Sch. 1 para. 43 and heading omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 22**

PROSPECTIVE

F44...

F44**44.** . . . . . .

F44 Sch. 1 para. 44 and heading omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 23**

PROSPECTIVE

F45 ...

F45 **45.** . . . . . .

F45 Sch. 1 para. 45 and heading omitted (31.12.2020 immediately before IP completion day) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1567), reg. 1(2), **Sch. 1 para. 24**

Health and Safety and Nuclear (Fees) Regulations 2016

46.—(1) The Health and Safety and Nuclear (Fees) Regulations 2016 [M11] are amended as follows.

(2) In regulation 21—

(a) omit paragraph (1);

(b) for paragraph (2) substitute—

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

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

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

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

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

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

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

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

(3) After regulation 21 insert—

"**Fees payable for activities under the CLP Regulation**

21A.—(1) The Agency [M12] may charge fees for work it carries out within the scope of the CLP Regulation which relates to the activities listed in column 1 of Schedule 16.

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

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

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

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

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

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

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

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

(a) dividing the daily rate by 14.8 to create a half-hourly rate; and

(b) multiplying that figure by the number of half hours worked, rounded up or down to the nearest half hour.

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

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

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

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

"1 Activity	*2 Fee per person per day worked*
(a) Validation of an application for approval of an active substance	£465
(b) Evaluation of an application to approve an active substance	£465
(c) Evaluation of an application to renew an active substance approval	£465
(d) Validation of an application to amend the conditions of approval of an active substance	£465
(e) Evaluation of an application to amend the conditions of approval of an active substance	£465
(f) Work relating to a request for inclusion of an active substance in the Simplified Active Substance List made on behalf of an economic operator	£465
(g) Validation of an application to amend the conditions of inclusion of an active substance in the Simplified Active Substance List	£465
(h) Evaluation of an application to amend the conditions of inclusion of an active substance in the Simplified Active Substance List	£465
(i) Meetings with applicants and prospective applicants	£465

(j) Evaluation of an application to authorise a biocidal product under the simplified procedure	£409
(k) Validation of an application for a national authorisation of a biocidal product	£409
(l) Evaluation of an application for a national authorisation of a biocidal product	£409
(m) Evaluation of an application to renew a national authorisation of a biocidal product	£409
(n) Determination of an application to amend an existing biocidal product authorisation	£409
(o) Evaluation of an application for an emergency use permit	£409
(p) Assessment of an application to be included in the list of suppliers maintained under Article 95 of the Biocides Regulation	£465
(q) Determination of a request that information on an active substance or product is not made publicly available	£465
(r) Determination of the classification of a proposed change to an authorised product in accordance with Regulation 354/2013	£409
(s) Determination of an application to be a participant for the review of an active substance/product-type combination under Article 17 of Regulation 1062/2014	£465
(t) Assessment of technical equivalence	£465
(u) Evaluation of an application under regulation 13 of the 2013 Biocidal Products and Chemicals Regulations	£409”

(5) After Schedule 15 insert—

“SCHEDULE 16 Regulation 21A

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

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

Commencement Information

I29 Sch. 1 para. 46 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)

Marginal Citations

M11 S.I. 2016/253.

M12 The definition of Agency in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures is being amended to mean the Health and Safety Executive by amendments made elsewhere in these Regulations.

Status:
This version of this schedule contains provisions that are prospective.

Changes to legislation:
There are currently no known outstanding effects for the The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019, SCHEDULE 1.