SCHEDULE 1

AMENDMENTS TO SUBORDINATE LEGISLATION

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

(2) In paragraph 1—

[F1(a) in the first sentence, after "product-related applications" insert "to a United Kingdom competent authority";**]**

[F2(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;

[F3(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 ".

[F4(2A) After paragraph 1, insert—

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

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

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

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

(3) In paragraph 2—

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

[F5(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."

[[F6](3A) In paragraph 3, after "organisation" insert "by a United Kingdom competent authority".**]**

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

Textual Amendments

F1 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)**

F2 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)**

F3 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)**

F4 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)**

F5 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)**

F6 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

I1 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)

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, Paragraph 14.