#### STATUTORY INSTRUMENTS

# 2011 No. 2132

# PESTICIDES FEES AND CHARGES

# The Plant Protection Products (Fees and Charges) Regulations 2011

Made - - - - 25th August 2011
Laid before Parliament 2nd September 2011
Coming into force - - 24th September 2011

The Secretary of State is designated for the purposes of section 2(2) of the European Communities Act 1972(1) in relation to the common agricultural policy of the European Union(2), measures in the veterinary and phytosanitary fields for the protection of public health(3), and in relation to the environment(4).

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972 and by section 56(1) of the Finance Act 1973(5).

In accordance with section 56(1) of the Finance Act 1973 the Treasury consents to the making of these Regulations.

#### Title and commencement

- 1.—(1) These Regulations may be cited as the Plant Protection Products (Fees and Charges) Regulations 2011 and, subject to paragraph (2), come into force on 24th September 2011.
  - (2) Regulations 3(2) and 6 come into force on 26<sup>th</sup> November 2011.

<sup>(1) 1972</sup> c. 68. The power of the Secretary of State, as designated Minister, to make Regulations that (i) extend to Scotland remains exercisable by virtue of section 57(1) of the Scotland Act 1998 (c.46); (ii) extend to Northern Ireland remains exercisable by virtue of article 3(2) of the European Communities (Designation)(No 3) Order 2000 (S.I. 2000/2812), article 2(3) of the European Communities (Designation) (No 2) Order 1999 (S.I. 1999/2027) and article 2(a) of the European Communities (Designation) Order 2008 (S.I. 2008/301); and (iii) apply in Wales remains exercisable by virtue of article 6(1) of the European Communities (Designation) (No 5) Order 2010 (S.I. 2010/2690), article 5(1) of the European Communities (Designation) (No.2) Order 2008 (S.I. 2008/1792) and article 2(a) of the European Communities (Designation) Order 2008 (S.I. 2008/301).

<sup>(2)</sup> S.I. 1972/1811.

<sup>(3)</sup> S.I. 1999/2027.

<sup>(4)</sup> S.I. 2008/301.

<sup>(5) 1973</sup> c. 51.

# Interpretation

2.—(1) In these Regulations—

"authorisation holder" means the holder of a valid authorisation or permit for a plant protection product—

- (a) issued in accordance with Regulation 1107/2009, or
- (b) deemed to be issued in accordance with that Regulation,

unless there is a nominated sales representative for that plant protection product, in which case it means that person;

[F1"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;]

F2

"import tolerance" has [F3, in relation to Great Britain,] the same meaning as in the MRL Regulation;

"liability period" means the period between 1 April in any year and 31 March in the following year;

[F4"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;]

[F5":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]

[F6: MRL supplementary information requirement" means information requested by a Great Britain competent authority in accordance with Article 14(3) of the MRL Regulation;]

"nominated sales representative" means any person who has agreed in writing with the holder of a valid authorisation or permit for a plant protection product, issued in accordance with Regulation 1107/2009 or deemed to be issued in accordance with that Regulation, to be a sales representative for the authorised or permitted plant protection product and to pay the charge under these Regulations;

[F7":Northern Ireland competent authority" means the Department of Agriculture, Environment and Rural Affairs;]

[F8":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;

[F9":standalone MRL application" means an application to a Great Britain competent authority which is only for the setting, modification or deletion of a maximum residue level of an active substance;

[F104 United Kingdom 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;
- (d) in relation to Northern Ireland, the Department of Agriculture, Environment and Rural Affairs.]
- (2) Expressions used in both these Regulations and Regulation 1107/2009, other than "authorisation holder", have the same meaning in these Regulations as they have in Regulation 1107/2009.

#### **Textual Amendments**

- F1 Words in reg. 2(1) inserted (31.12.2020) by S.I. 2019/720, Sch. 1 para. 8(2A) (as inserted by The 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))
- **F2** Words in reg. 2(1) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 1 para. 8(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F3 Words in reg. 2(1) inserted (31.12.2020) by S.I. 2019/720, Sch. 1 para. 8(2B) (as inserted by The 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))
- F4 Words in reg. 2(1) inserted (31.12.2020) by S.I. 2019/720, Sch. 1 para. 8(3) (as substituted by The 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)
- F5 Words in reg. 2(1) substituted (31.12.2020) by S.I. 2019/720, Sch. 1 para. 8(3A) (as inserted by The 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))
- Words in reg. 2(1) inserted (31.12.2020) by S.I. 2019/720, reg. 1(2), Sch. 1 para. 8(4) (as amended by The 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)); 2020 c. 1, Sch. 5 para. 1(1)
- F7 Words in reg. 2(1) inserted (31.12.2020) by S.I. 2019/720, Sch. 1 para. 8(4A) (as inserted by The 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))
- **F8** Words in reg. 2(1) substituted (31.12.2020) by S.I. 2019/720, **Sch. 1 para. 8(4B)** (as inserted by The 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 reg. 2(1) inserted (31.12.2020) by S.I. 2019/720, reg. 1(2), Sch. 1 para. 8(5) (as amended by The 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)); 2020 c. 1, Sch. 5 para. 1(1)
- **F10** Words in reg. 2(1) substituted (1.3.2019) by The Pesticides and Fertilisers (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/306), regs. 1(3), **7(2)** (with reg. 8)

# [F11Functions in Article 74(1) of Regulation 1107/2009: Northern Ireland]

**3.**—(1) The functions <sup>F12</sup>... referred to in Article 74(1) of Regulation 1107/2009 are to be performed by the [F13]Northern Ireland competent authority].

F14(2)																

#### **Textual Amendments**

- F11 Reg. 3 heading substituted (31.12.2020) by S.I. 2019/720, Sch. 1 para. 9(a) (as substituted by The 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)
- F12 Words in reg. 3(1) omitted (31.12.2020) by S.I. 2019/720, Sch. 1 para. 9(b)(i) (as substituted by The 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)
- F13 Words in reg. 3(1) substituted (31.12.2020) by S.I. 2019/720, Sch. 1 para. 9(b)(ii) (as substituted by The 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)
- F14 Reg. 3(2) omitted (31.12.2020) by S.I. 2019/720, Sch. 1 para. 9(c) (as substituted by The 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)

#### **Fees**

- **4.**—(1) A United Kingdom 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—
  - (a) authorisation of plant protection products;

F15(h)																

(c) official recognition of a test facility or organisation,

and such fees are payable in accordance with [F16 paragraphs 1 and 3 respectively of] Schedule 1.

- [F17(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.]
- (2) A [F18Great Britain] competent authority may charge fees for applications for import tolerances [F19] and standalone MRL applications] under Article 7 of the MRL Regulation and such fees are payable in accordance with Schedule 2.
- [F20(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.]
- (3) The fees in these Regulations apply in relation to any activity carried out after they come into force, provided no invoice has been issued under the Plant Protection Product (Fees) Regulations 2007(6) or the Plant Protection Products (Fees) Regulations (Northern Ireland) 2004(7) in relation to that work.

- (4) Fees are payable by the applicant, on invoice, to [F21the relevant] competent authority.
- (5) [F22The relevant] competent authority is under no obligation to process or to issue a decision in respect of an outstanding application if there are outstanding fees in relation to it.
- (6) In paragraph (5), "outstanding application" means any application for which a fee has been charged under the Plant Protection Products (Fees) Regulations 2007, the Plant Protection Products (Fees) Regulations (Northern Ireland) 2004 or under these Regulations.
  - (7) Any unpaid fee may be recovered by [F23the relevant] competent authority as a civil debt.

#### **Textual Amendments**

- F15 Reg. 4(1)(b) omitted (31.12.2020) by S.I. 2019/720, Sch. 1 para. 10(a)(i) (as substituted by The 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)
- F16 Words in reg. 4(1) inserted (31.12.2020) by S.I. 2019/720, Sch. 1 para. 10(a)(ii) (as substituted by The 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)
- F17 Reg. 4(1A)(1B) inserted by S.I. 2019/720, Sch. 1 para. 10(b) (as substituted by The 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)
- F18 Words in reg. 4(2) substituted (31.12.2020) by S.I. 2019/720, Sch. 1 para. 10(c)(i) (as substituted by The 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)
- F19 Words in reg. 4(2) inserted (31.12.2020) by S.I. 2019/720, Sch. 1 para. 10(c)(ii) (as substituted by The 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)
- **F20** Reg. 4(2A) inserted by S.I. 2019/720, **Sch. 1 para. 10(d)** (as substituted by The 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**)
- **F21** Words in reg. 4(4) substituted (31.12.2020) by S.I. 2019/720, **Sch. 1 para. 10(e)** (as substituted by The 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**)
- Words in reg. 4(5) substituted (31.12.2020) by S.I. 2019/720, Sch. 1 para. 10(f) (as substituted by The 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)
- F23 Words in reg. 4(7) substituted (31.12.2020) by S.I. 2019/720, Sch. 1 para. 10(g) (as substituted by The 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)

#### Charge in relation to Regulation 1107/2009 and the MRL Regulation

- **5.** A United Kingdom competent authority may make an annual charge in respect of any costs incurred by it, or on its behalf—
  - (a) associated with any work carried out within the scope of Regulation 1107/2009; or
  - (b) arising from obligations under the MRL Regulation,

other than for collecting and processing information, or monitoring the effect of the use of plant protection products, for which a charge has been made under section 18(2)(b) or (c) of the Food and Environment Protection Act 1985(8).

<sup>(7)</sup> S.R.(NI) 2004 No 372.

<sup>(8) 1985</sup> c.48.

# [F24Charge for work under the Plant Protection Products (Sustainable Use) Regulations 2012]

**6.** A United Kingdom competent authority may make an annual charge in respect of any costs incurred by it, or on its behalf, in relation to carrying out work pursuant to obligations [F25] under the Plant Protection Products (Sustainable Use) Regulations 2012 ].

#### **Textual Amendments**

- **F24** Reg. 6 heading substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 1 para. 11(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F25 Words in reg. 6 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), Sch. 1 para. 11(b); 2020 c. 1, Sch. 5 para. 1(1)

#### Liability to pay the charge

- 7.—(1) In respect of a given liability period a charge shall be payable by an authorisation holder, on invoice, to a United Kingdom competent authority.
- (2) A United Kingdom competent authority shall not charge for any costs under paragraph (1) in respect of which a fee is payable [F26under regulations 4(1), 4(1A) or 4(1B)] and Schedule 1, F27... regulation 4(2) and Schedule 2 [F28or regulation 4(2A) and Schedule 3].
- (3) A United Kingdom competent authority may exclude an authorisation holder from the requirement to pay a charge where that authority decides it would be uneconomical to collect that charge.
- (4) Where an authorisation holder becomes liable to pay a charge in accordance with paragraph (1) at any time during the liability period, that person will be liable to pay a charge for the whole of that liability period.
- (5) If an authorisation holder fails to pay the charge in full, the United Kingdom competent authority may suspend any or all of the authorisations or permits for plant protection products held by the authorisation holder or for which the authorisation holder is the nominated sales representative.
- (6) Any unpaid charge may be recovered by a United Kingdom competent authority as a civil debt.

#### **Textual Amendments**

- **F26** Words in reg. 7(2) substituted (31.12.2020) by S.I. 2019/720, **Sch. 1 para. 12(aa)** (as inserted by The 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**)
- **F27** Word in reg. 7(2) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 1 para. 12(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- **F28** Words in reg. 7(2) inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 1 para. 12(b)**; 2020 c. 1, Sch. 5 para. 1(1)

#### Calculation of charge

- **8.**—(1) The United Kingdom competent authorities must calculate the amounts which authorisation holders are liable to pay under regulations 5 and 6 in accordance with the following paragraphs.
- (2) Where an authorisation holder is liable to pay a charge in respect of more than one plant protection product, the authorisation holder shall be treated as one authorisation holder for the purposes of calculating the charge and collecting payments.
- (3) The United Kingdom competent authorities will calculate the charge payable by an authorisation holder by applying a percentage to the authorisation holder's annual turnover. [F29 Except where paragraphs (3A) to (3C) apply, the] percentage must be calculated by applying the following formula—

A/B x 100% = the percentage

where-

A = the total costs incurred in the liability period, and

B = the total annual turnover.

**8.**—[F30(3A) For a charge payable to the Welsh Ministers as United Kingdom competent authority in respect of the liability period ending 31st March 2019, the percentage referred to in subparagraph (3) must be calculated by applying the following formula—

 $A/B \times (31/365) \times 100\%$ =the percentage

where A and B have the meanings given in sub-paragraph (3).]

[F30(3B) Sub-paragraph (3C) applies where, for the liability period ending 31st March 2019, an authorisation holder is liable to pay a charge to both the Secretary of State and the Welsh Ministers as United Kingdom competent authorities in relation to Wales.]

[F30(3C)] Where this sub-paragraph applies—

- (a) for the charge payable to the Welsh Ministers, the percentage referred to in sub-paragraph (3) must be calculated by applying the formula set out in sub-paragraph (3A);
- (b) for the charge payable to the Secretary of State, the percentage referred to in subparagraph (3) must be calculated by applying the following formula—

$$A/B \times (334/365) \times 100\%$$
=the percentage

where A and B have the meanings given in sub-paragraph (3).]

- (4) An authorisation holder must provide a United Kingdom competent authority with evidence of its annual turnover for a given liability period on request.
- (5) If insufficient evidence of annual turnover is submitted or if no evidence is submitted by an authorisation holder, the annual turnover will be such figure as the United Kingdom competent authorities consider reasonable.
  - (6) In this regulation—

[F31" 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;]

"total annual turnover" means the annual turnover of all authorisation holders;

"annual turnover" means the amounts derived from sales in the financial year ending between 1<sup>st</sup> October and 30<sup>th</sup> September the following year, the latter date being in the calendar year in which the liability period starts by—

- (a) the holder of a valid authorisation or permit for a plant protection product issued in accordance with Regulation 1107/2009 or of a valid authorisation or permit for a plant protection product deemed to be issued in accordance with that Regulation, and
- (b) any nominated sales representative for the authorised or permitted plant protection product;

"amounts derived from sales" includes the costs of packaging, containers and labelling and excludes value added tax and returned products;

"sales" means the sales of authorised or permitted plant protection products in the United Kingdom.

#### **Textual Amendments**

- **F29** Words in reg. 8(3) substituted (1.3.2019) by The Pesticides and Fertilisers (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/306), regs. 1(3), **7(3)(a)**
- F30 Reg. 8(3A)-(3C) inserted (1.3.2019) by The Pesticides and Fertilisers (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/306), regs. 1(3), 7(3)(b)
- F31 Words in reg. 8(6) substituted (31.12.2020) by S.I. 2019/720, Sch. 1 para. 13 (as substituted by The 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)

## Revocation

- **9.** The following regulations are revoked—
  - (a) The Fees for Assessment of Active Substances (Third Stage Review) Regulations 2005(9);
  - (b) The Fees for Assessment of Active Substances (Fourth Stage Review) Regulations 2005(10); and
  - (c) The Plant Protection Products (Fees) Regulations 2007.

Signed by the authority of the Secretary of State for Environment, Food and Rural Affairs.

Henley
Parliamentary Under Secretary of State
Department for Environment, Food and Rural
Affairs

<sup>(9)</sup> S.I. 2005/117.

<sup>(10)</sup> S.I. 2005/1811.

We consent

James Duddridge Angela Watkinson Two of the Lords Commissioners of Her Majesty's Treasury

# [F32SCHEDULE 1

Regulation 4(1)

#### Fees

# **Textual Amendments**

**F32** Sch. 1 substituted (6.4.2016) by The Plant Protection Products (Fees and Charges) (Amendment) Regulations 2016 (S.I. 2016/254), regs. 1, **2(2)** 

# Fees for application and evaluation of a plant protection product for authorisation

1. Fees for product-related applications [F33 to a United Kingdom competent authority] are in accordance with the following table, and each item is charged cumulatively.

Item	Chargeable item	Fee(£)
1	Administrative research and development application <sup>(1)</sup>	52
2	Extension of use application including administration, co-ordination and technical consideration	1,768
3	Preliminary consideration of application type listed in items 4, 5, 7,12 or 13 to determine whether the application can proceed further	
4	Administrative application <sup>(2)</sup>	
	for a new product or change to an existing product—	
4a	one product	156
4b	each additional product <sup>(4)</sup>	52
5	F35	
	•••	
5a	F35	F35
	•••	
5b	F35	F35
		• • •
6	Evaluation of a label in any application	208
7	Co-ordination of standard technical stream applications (7)(8)	1,872
8	Evaluation of simple reasoned cases in each of the following specialist areas—	
8a	chemistry <sup>(9)</sup>	416
8b	toxicology <sup>(10)</sup>	416
8c	operator exposure <sup>(11)</sup>	416
8d	residues and consumer exposure <sup>(12)</sup>	416
8e	fate and behaviour in the environment <sup>(13)</sup>	416

Item	Chargeable item	Fee(£)
8f	ecotoxicology <sup>(14)</sup>	416
8g	efficacy <sup>(15)</sup>	416
9	Evaluation of data, modelling and detailed scientific cases in each of the following specialist areas—	
9a	chemistry <sup>(9)</sup>	780
9b	toxicology <sup>(10)</sup>	780
9c	operator exposure <sup>(11)</sup>	780
9d	residues and consumer exposure <sup>(12)</sup>	780
9e	fate and behaviour in the environment <sup>(13)</sup>	1,872
9f	ecotoxicology <sup>(14)</sup>	1,872
9g	efficacy <sup>(15)</sup>	1,872
10	Withdrawal of an application for a product specified in items 2, 4, 5, 7, 12 or 13 before any work other than preliminary consideration has been done	
11	Pre-submission meetings [F36 to discuss potential product applications] (16)	5,200
12	F37	
	F37	F37
	F37	F37
12		
13	Commenting on draft study protocols <sup>(18)</sup>	416

# Notes

- (1) Application for authorisation under Regulation 1107/2009 not involving evaluation of technical information or data.
- (2) Application for authorisation under Regulation 1107/2009 involving no technical consideration.

F38(3)																																
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(4) Where the application relates to a number of different products, this charge applies to each additional product.

F38(5)																
F38(6)																

- (7) "Standard technical stream applications" are all applications other than [F39 items 1-4, 10 and 11].
  - (8) The co-ordination of applications for new products or a change to an existing product.

- (9) Chemistry covers assessment of the technical specification of the active substance, safeners and synergists in the product and the physico-chemical properties of the product.
- (10) Toxicology covers assessment of the mammalian metabolism and toxicology of the active substance, safeners and synergists in the product and determination of the types of hazard to which the product can give rise.
- (11) Operator exposure additionally covers exposure of other persons resulting from the product use.
- (12) Consumer exposure covers exposure of consumers resulting from consumption of produce from treated crops, treated produce or products derived from either, including products from animals to which any such matter has been fed.
- (13) Fate and behaviour in the environment covers the potential environmental exposure from product use, including the identity and quantity of the active substance, metabolites, degradation products and reaction products, safeners and synergists which may be available in the soil, water or air and are of toxicological or environmental significance.
- (14) Ecotoxicology covers the assessment of the potential impact on non-target species likely to be at risk from exposure to the product, including the active substance, and toxicologically or environmentally significant metabolites, degradation products and reaction products, safeners and synergists.
- (15) Efficacy covers the assessment of whether a product consistently controls the target pest and whether the product adversely affects the treated crops, following crops or treated produce.
- (16) Pre-submission meetings may be held at the request of the applicant prior to the submission of an application <sup>F40</sup>....

(18) The fee is equivalent to a specialist case fee and relates to requests from applicants for [F42a United Kingdom competent authority] to comment on the study design in advance of the data being generated and an application being submitted. For particularly complex protocols requiring significant specialist input it may be necessary to charge a data module fee in the relevant specialist area.

#### **Textual Amendments**

- F33 Words in Sch. 1 para. 1 inserted (31.12.2020) by S.I. 2019/720, Sch. 1 para. 14(2)(a) (as inserted by The 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))
- F34 Word in Sch. 1 para. 1 Table Item 4 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), Sch. 1 para. 14(2)(b)(i) (as amended by S.I. 2020/1567, reg. 1(2), Sch. 1 para. 10(2)(a)); 2020 c. 1, Sch. 5 para. 1(1)
- F35 Sch. 1 para. 1 Table Item 5-5b omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), Sch. 1 para. 14(2)(b)(ii) (as amended by S.I. 2020/1567, reg. 1(2), Sch. 1 para. 10(2)(a)); 2020 c. 1, Sch. 5 para. 1(1)
- F36 Words in Sch. 1 para. 1 Table Item 11 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), Sch. 1 para. 14(2)(b)(iii) (as amended by S.I. 2020/1567, reg. 1(2), Sch. 1 para. 10(2)(a)); 2020 c. 1, Sch. 5 para. 1(1)
- **F37** Words in Sch. 1 para. 1 Table Item 12 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations

- 2019 (S.I. 2019/720), reg. 1(2), **Sch. 1 para. 14(2)(b)(iv)** (as amended by S.I. 2020/1567, reg. 1(2), **Sch. 1 para. 10(2)(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F38 Sch. 1 para. 1 Notes 3, 5, 6 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), Sch. 1 para. 14(2)(c)(i) (as amended by S.I. 2020/1567, reg. 1(2), Sch. 1 para. 10(2)(a)); 2020 c. 1, Sch. 5 para. 1(1)
- F39 Words in Sch. 1 para. 1 Note 7 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), Sch. 1 para. 14(2)(c)(ii) (as amended by S.I. 2020/1567, reg. 1(2), Sch. 1 para. 10(2)(a)); 2020 c. 1, Sch. 5 para. 1(1)
- F40 Words in Sch. 1 para. 1 Note 16 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), Sch. 1 para. 14(2)(c)(iii) (as amended by S.I. 2020/1567, reg. 1(2), Sch. 1 para. 10(2)(a)); 2020 c. 1, Sch. 5 para. 1(1)
- F41 Sch. 1 para. 1 Note 17 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), Sch. 1 para. 14(2)(c)(iv) (as amended by S.I. 2020/1567, reg. 1(2), Sch. 1 para. 10(2)(a)); 2020 c. 1, Sch. 5 para. 1(1)
- F42 Words in Sch. 1 para. 1 Note 18 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), Sch. 1 para. 14(2)(c)(v) (as amended by S.I. 2020/1567, reg. 1(2), Sch. 1 para. 10(2)(a)); 2020 c. 1, Sch. 5 para. 1(1)

[<sup>F43</sup>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 <sup>(1)</sup>	728
	(b) parallel trade verification <sup>(2)</sup>	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.]

#### **Textual Amendments**

F43 Sch. 1 para. 1A inserted (31.12.2020) by S.I. 2019/720, Sch. 01 para. 014(02A) (as inserted by The 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))

# Fees for application and evaluation of an active substance, safener $[^{F44}$ , synergist or basic substance]

**2.** The fees [F45chargeable by a Great Britain competent authority] for evaluation for approval, or renewal of approval, under Regulation 1107/2009 of an active substance, safener [F46, synergist or basic substance], are in accordance with the following table.

Item	Application	Fee(£)
	Where an active substance, safener [F47, synergist or basic substance] is neither a biocontrol agent nor a pheromone	
1	Preliminary evaluation <sup>(1)</sup> of the admissibility of an application	5,200
2	F48	F48
3	[F49Co-ordination of scientific advice and public consultation and finalising the draft assessment report]	36,400
4	Evaluation of a full data package <sup>(3)</sup>	114,400
5	Evaluation of a partial data package <sup>(4)</sup> :	
	Band 1	7,800
	Band 2	15,600
	Band 3	31,200
	Band 4	52,000
	Band 5	72,800
	Band 6	93,600
	Band 7	114,400
	Where an active substance is a biocontrol agent	
6	Evaluation of a full data package (3)	23,400
7	[F50]Co-ordination of scientific advice and public consultation, and finalising the draft assessment report]	7,800
8	Evaluation of a partial data package <sup>(4)</sup> :	
	Band 1	5,720
	Band 2	11,700
	Band 3	17,680
	Band 4	23,400
	Where an active substance is a pheromone	
9	Evaluation of a full data package <sup>(3)</sup>	13,520
10	[F50Co-ordination of scientific advice and public consultation, and finalising the draft assessment report]	7,800

Item	Application	Fee(£)
11	Evaluation of a partial data package: (4)	
	Band 1	3,380
	Band 2	6,760
	Band 3	10,140
	Band 4	13,520

#### For all evaluations

Meeting before the submission of an application in support of a new active substance, safener, synergist, [F51] basic substance,] biocontrol agent or pheromone 5,200

#### Notes

(1) The initial eva	aluation carried	out in order t	to notify the	applicant w	hether his o	r her appl	lication
can proceed further.							

F52(2)																

- (3) [F53]In relation to active substances, safeners or synergists,] a full data package comprises the complete dossier (the information referred to in paragraphs 1 and 2 of Article 8 of Regulation 1107/2009) to support one or more representative use of one product. [F54]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.] Where a data package also contains a large number of extra study reports submitted to refine risk assessments, to characterise metabolites or to support additional uses of the product [F55] or basic substance], these studies will be treated as an additional partial data package. See also note (4).
- (4) The size of a partial data package is banded as a proportion of a full data package. The proportion is estimated on the basis of the amount of time required to evaluate the data and to conduct the necessary risk assessments. Applicants will be notified of the appropriate Band prior to an evaluation taking place. Partial data packages include one or more of the following—
  - (a) additional data over and above a 'standard' core dossier for example situations where there are significantly more metabolites, or very large novel studies to be evaluated;
  - (b) additional study submissions during evaluation required to clarify the initial dossier;

F56(	- \																																
(	C)	•	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠

(d) [F57] in relation to active substances, safeners or synergists,] data to support the extension of the approval of an active substance, safener or synergist under Regulation 1107/2009 once the initial approval period has expired or to change the conditions of approval during the approval period;

F58(e)																																
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(f) [F59in relation to active substances, safeners or synergists,] large data packages in one or more areas of the risk assessment that have been submitted in support of product related applications (e.g. re-registration and new product applications under Regulation 1107/2009) that significantly exceed the size for which the standard fees specified in the product-related application fees table (paragraph 1, items 9a-g above) are payable.

- (g) [F59in relation to active substances, safeners or synergists,] additional studies submitted to support an adverse data review.
- [F60(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.]

[F61 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.]

#### **Textual Amendments**

- **F44** Words in Sch. 1 para. 2 heading substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 1 para. 14(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F45 Words in Sch. 1 para. 2 inserted (31.12.2020) by S.I. 2019/720, Sch. 1 para. 14(3)(b)(i) (as substituted by The 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))
- F46 Words in Sch. 1 para. 2 substituted (31.12.2020) by S.I. 2019/720, Sch. 1 para. 14(3)(b)(ii) (as substituted by The 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))
- **F47** Words in Sch. 1 para. 2 Table heading substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 1 para. 14(3)(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F48 Sch. 1 para. 2 Table Item 2 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), Sch. 1 para. 14(3)(c)(ii); 2020 c. 1, Sch. 5 para. 1(1)
- **F49** Words in Sch. 1 para. 2 Table Item 3 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 1 para. 14(3)(c)(iii)**; 2020 c. 1, **Sch. 5 para. 1(1)**
- F50 Words in Sch. 1 para. 2 Table Item 7, 10 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), Sch. 1 para. 14(3)(c)(iv); 2020 c. 1, Sch. 5 para. 1(1)
- F51 Words in Sch. 1 para. 2 Table Item 12 inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), Sch. 1 para. 14(3)(c)(v); 2020 c. 1, Sch. 5 para. 1(1)
- F52 Sch. 1 para. 2 Note 2 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), Sch. 1 para. 14(3)(d)(i); 2020 c. 1, Sch. 5 para. 1(1)
- **F53** Words in Sch. 1 para. 2 Note 3 inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 1 para. 14(3)(d)(ii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)
- F54 Words in Sch. 1 para. 2 Note 3 inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), Sch. 1 para. 14(3)(d)(ii)(bb); 2020 c. 1, Sch. 5 para. 1(1)
- F55 Words in Sch. 1 para. 2 Note 3 inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), Sch. 1 para. 14(3)(d)(ii)(cc); 2020 c. 1, Sch. 5 para. 1(1)
- F56 Sch. 1 para. 2 Note 4(c) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), Sch. 1 para. 14(3)(d)(iii)(aa); 2020 c. 1, Sch. 5 para. 1(1)

- F57 Words in Sch. 1 para. 2 Note 4(d) inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), Sch. 1 para. 14(3)(d)(iii)(bb); 2020 c. 1, Sch. 5 para. 1(1)
- F58 Sch. 1 para. 2 Note 4(e) omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), Sch. 1 para. 14(3)(d)(iii)(cc); 2020 c. 1, Sch. 5 para. 1(1)
- **F59** Words in Sch. 1 para. 2 Note 4(f)(g) inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), Sch. 1 para. 14(3)(d)(iii)(dd); 2020 c. 1, Sch. 5 para. 1(1)
- **F60** Words in Sch. 1 para. 2 Note 4(h)(i) inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 1 para. 14(3)(d)(iii)(ee)**; 2020 c. 1, Sch. 5 para. 1(1)
- **F61** Words in Sch. 1 para. 2 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 1 para. 14(3)(d)(iv)**; 2020 c. 1, Sch. 5 para. 1(1)

#### Fees for official recognition of a test facility or organisation

**3.** The fees for the official recognition of a test facility or organisation [<sup>F62</sup>by a United Kingdom competent authority] are in accordance with the following table<sup>(1)</sup>.

Item	Activity	Fee (£)	
1	Initial official recognition of the test facility	2,080	
2	Renewal of an official recognition	2,080	
3	Each re-inspection	1,560	

# Notes

(1) Article 29(3) of Regulation 1107/2009 requires that compliance with certain authorisation requirements is established by official or officially recognised tests and analyses.

#### **Textual Amendments**

**F62** Words in Sch. 1 para. 3 inserted (31.12.2020) by S.I. 2019/720, **Sch. 1 para. 14(3A)** (as inserted by The 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)**)

# Fees related to application for approval of basic substances



# **Textual Amendments**

**F63** Sch. 1 para. 4 omitted (31.12.2020) by virtue of The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 1 para. 14(4)**; 2020 c. 1, Sch. 5 para. 1(1)

# [F64SCHEDULE 2

Regulation 4(2)

# Import tolerance [F65 fees and standalone MRL application fees]

#### **Textual Amendments**

**F64** Sch. 2 substituted (6.4.2016) by The Plant Protection Products (Fees and Charges) (Amendment) Regulations 2016 (S.I. 2016/254), regs. 1, **2(3)** 

**F65** Words in Sch. 2 heading substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), **Sch. 1 para. 15(2)**; 2020 c. 1, Sch. 5 para. 1(1)

## [F66Fees for import tolerances]

[<sup>F67</sup>1]. [<sup>F68</sup>Fees chargeable by a Great Britain competent authority for import tolerances] are in accordance with the following table.

Item	Category	Fee(£)
[ <sup>F69</sup> A1	Preliminary consideration of a application to determine whether the application can proceed further	er
A2	Co-ordination of applications	1,872]
1	Full Human health description(	1) 16,224
2	Metabolism and residue evaluation <sup>(2)</sup>	es 6,760
3	Residues evaluation <sup>(3)</sup>	2,028

#### Notes

- (1) [F70This category is mainly for active substances not currently approved in respect of the part of Great Britain to which the application relates. In certain cases it may also include active substances still being reviewed if toxicological endpoints have not yet been agreed and accepted in respect of that part of Great Britain.]
- (2) This category is for [F71active substances] where toxicological endpoints have already been agreed [F72and accepted in respect of the part of Great Britain to which the application relates], but the residue definition has only been established for crop groups unrelated to the intended use or imported produce.
- (3) This category is for [F73 active substances] where relevant toxicological endpoints and residue definition have already been agreed [F74 and accepted in respect of the part of Great Britain to which the application relates].

[F75Fees for multiple import tolerances for the same active substance are calculated on a modular basis with a charge applied for each crop.]]

#### **Textual Amendments**

- F66 Sch. 2 para. 1 heading inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), Sch. 1 para. 15(3); 2020 c. 1, Sch. 5 para. 1(1)
- F67 Sch. 2 para. 1: Sch. 2 renumbered as Sch. 2 para. 1 (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), Sch. 1 para. 15(4); 2020 c. 1, Sch. 5 para. 1(1)
- F68 Words in Sch. 2 para. 1 substituted (31.12.2020) by S.I. 2019/720, Sch. 1 para. 15(5)(a) (as substituted by The 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))
- F69 Sch. 2 para. 1 Table Item A1, A2 inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), Sch. 1 para. 15(5)(b); 2020 c. 1, Sch. 5 para. 1(1)
- F70 Sch. 2 para. 1 Note 1 substituted by S.I. 2019/720, Sch. 1 para. 15(5)(c)(i) (31.12.2020) (as amended by The 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))
- F71 Words in Sch. 2 para. 1 Note 2 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), Sch. 1 para. 15(5)(c)(ii)(aa); 2020 c. 1, Sch. 5 para. 1(1)
- F72 Words in Sch. 2 para. 1 Note 2 substituted (31.12.2020) by S.I. 2019/720, reg. 1(2), Sch. 1 para. 15(5) (c)(ii)(bb) (as amended by The 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)); 2020 c. 1, Sch. 5 para. 1(1)
- F73 Words in Sch. 2 para. 1 Note 3 substituted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), Sch. 1 para. 15(5)(c)(iii)(aa); 2020 c. 1, Sch. 5 para. 1(1)
- F74 Words in Sch. 2 para. 1 Note 3 substituted (31.12.2020) by S.I. 2019/720, reg. 1(2), Sch. 1 para. 15(5) (c)(iii)(bb) (as amended by The 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)); 2020 c. 1, Sch. 5 para. 1(1)
- F75 Words in Sch. 2 para. 1 inserted (31.12.2020) by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/720), reg. 1(2), Sch. 1 para. 15(5)(c)(iv); 2020 c. 1, Sch. 5 para. 1(1)

# [F76Fees for standalone MRL applications

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

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

#### Notes

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

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

#### **Textual Amendments**

F76 Sch. 2 para. 2 inserted (31.12.2020) by S.I. 2019/720, reg. 1(2), Sch. 1 para. 15(6) (as amended by The 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)(b)); 2020 c. 1, Sch. 5 para. 1(1)

# [F77SCHEDULE 3

Regulation 4(2A)

Maximum residue level supplementary information fees chargeable by a Great Britain competent authority

#### **Textual Amendments**

F77 Sch. 3 inserted (31.12.2020) by S.I. 2019/720, reg. 1(2), Sch. 1 para. 16 (as amended by The 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); 2020 c. 1, Sch. 5 para. 1(1)

Fees 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 <sup>(1)</sup>	416
4	Analytical method <sup>(2)</sup>	416
5	Toxicology <sup>(3)</sup>	3,120

6	Metabolism and residues evaluation <sup>(4)</sup>	6,760
7	Residues evaluation <sup>(5)</sup>	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.]

### **EXPLANATORY NOTE**

(This note is not part of the Regulations)

- 1. These Regulations provide the charging regime in relation to—
  - (a) 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 and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ No L309, 24.11.2009, p.1) ("Regulation 1107/2009");
  - (b) 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 (OJ No L70, 16.3.2005, p.1) ("the MRL Regulation"); and
  - (c) Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ No L 4, 6. 1. 96, p.16) ("the Directive").
- **2.** Regulation 1107/2009 replaces the existing scheme for approval under Council Directive 91/414/EEC concerning the placing of plant protection products on the market (OJ No L230,

- 19.8.1991, p.1), and lays down rules for the approval of active substances and the authorisation of plant protection products.
- **3.** These Regulations set fees, chargeable by the Secretary of State, the Scottish Ministers and the Department of Agriculture and Rural Development in Northern Ireland ("the United Kingdom competent authorities") for—
  - (a) work carried out within the scope of Regulation 1107/2009 which relates to evaluating applications for the authorisation of plant protection products, the approval of active substances, safeners, synergists and basic substances and official recognition of a test facility or organisation, and
  - (b) applications for import tolerances under Article 7 of the MRL Regulation.
- **4.** These Regulations also provide for an annual charge to be paid by authorisation holders for costs incurred by or on behalf of the United Kingdom competent authorities associated with any work carried out within the scope of Regulation 1107/2009 and work arising from the obligations under the MRL Regulation (other than for work charged under section 18(2)(b) or (c) of the Food and Environment Protection Act 1985) and, after 26<sup>th</sup> November 2011, work pursuant to obligations within the scope of the Directive. These Regulations also set out the consequences of failure to pay fees or charges.
  - **5.** These Regulations revoke and replace—
    - (a) The Fees for Assessment of Active Substances (Third Stage Review) Regulation 2005 (S.I. 2005/117);
    - (b) The Fees for Assessment of Active Substances (Fourth Stage Review) Regulation 2005 (S.I. 2005/1811); and
    - (c) the Plant Protection Products (Fees) Regulations 2007(S.I. 2007/295).
- **6.** A full regulatory impact assessment of the effect that this instrument will have on the costs to business and the voluntary sector has also been prepared. A copy of this document has been placed in the library of each House of Parliament and is available on DEFRA's website (www.defra.gov.uk). A copy of the regulatory impact assessment is also annexed to the Explanatory Memorandum to the Plant Protection Products Regulations 2011 and to these Regulations and is available alongside the instruments on the legislation website (http://www.legislation.gov.uk/).
- **7.** The new fees compared with those fixed by or determined under the previous fee-charging provisions are as follows:

Type of Fee	Previous Fee (£)	New Fee (£)	Percentage Increase/Decrease
Schedule 1			
1. Product related applicatio	ns		
1 Administrative research and development application	30.00	50.00	66.67%
2 Extension of use application including administration, co-ordination and technical consideration	1,495.00	1,495.00	0.00%
Extension of use application from 1 April 2012	1,495.00	1,700.00	13.71%

	Type of Fee	Previous Fee (£)	New Fee (£)	Percentage Increase/Decrease
3	Preliminary consideration of application type listed in item 4, 5, 7, 12 or 13, to determine whether the application can proceed	150.00 (electronic) or 175.00 (other)	220.00	46.67% or 25.71%
	further	1,2100 (01)		
4	Administrative application for a new product or change to an existing product,			
(a)	One product	120.00	150.00	25.00%
(b)	Each additional product	40.00	50.00	25.00%
5	Parallel trade application;			
(a)	Co-ordination of application for new product or change to existing product involving parallel trade	710.00	700.00	-1.41%
(b)	Parallel trade verification	200.00	200.00	0.00%
6	Evaluation of a label in any application.	300.00	200.00	-33.33%
7	Coordination of standard technical stream application	1,100.00 (technical)	1,800.00	45.45% or
	аррпсацоп	Oi		Oi
		1,800.00 (data evaluation)		0.00%
8	Evaluation of simple reasoned cases in each of the following specialist areas:			
(a)	Chemistry	250.00	400.00	60.00%
(b)	Toxicology	250.00	400.00	60.00%
(c)	Operator exposure	250.00	400.00	60.00%
(d)	Residues/consumer exposure	250.00	400.00	60.00%
(e)	Fate and behaviour in the environment	250.00	400.00	60.00%
(f)	Ecotoxicology	250.00	400.00	60.00%
(g)	Efficacy	250.00	400.00	60.00%
9	Evaluation of data, modelling and detailed			

	Type of Fee	Previous Fee (£)	New Fee (£)	Percentage Increase/Decrease
	scientific cases in each of the following specialist areas:			
(a)	Chemistry	425.00	750.00	76.47%
(b)	Toxicology	500.00	750.00	50.00%
(c)	Operator exposure	750.00	750.00	0.00%
(d)	Residues/consumer exposure	1,000.00	750.00	-25.00%
e)	Fate and behaviour in the environment	1,000.00	1,800.00	80.00%
<b>f</b> )	Ecotoxicology	1,000.00	1,800.00	80.00%
g)	Efficacy	1,500.00	1,800.00	20.00%
	Crop Safety (£500) and Effectiveness (£1000) previously charged separately			
1	OWithdrawal of an application for a product specified in items 2, 4, 5, 7, 12 or 13 before any work other than preliminary consideration has been done	100.00	100.00	0.00%
1	1 Pre-submission meetings for lead zone re- registration and new product applications	0.00	5,000.00	New item
1	2Zonal surcharges for lead zonal re-registration and new product applications. This fee is in addition to these described in 7 to 9 above			
	Zonal surcharge 1	0.00	7,500.00	New item
	Zonal surcharge 2	0.00	15,000.00	New item
1	3Commenting on draft study protocols	0.00	400.00	New item
Wł	Active substances related a nere an active substance, sa eromone		s neither a bioconti	ol agent nor a
-	Preliminary evaluation of an application's admissibility	5,000.00	5,000.00	0.00%

Type of Fee	Previous Fee (£)	New Fee (£)	Percentage / P
2 Processing an application for provisional authorisation	35,000.00	35,000.00	Increase/Decrease 0.00%
3 Helping the European Food Safety Authority to evaluate the draft assessment report where the United Kingdom is the rapporteur or co- rapporteur member state	35,000.00	35,000.00	0.00%
4 Evaluation of a full data package	105,000.00	110,00.00	4.76%
5 Evaluation of a partial data package:			
Band 1		7,500.00	New item
Band 2	15,000.00	15,000.00	0.00%
Band 3	30,000.00	30,000.00	0.00%
Band 4	40,000.00	50,000.00	25.00%
Band 5	60,000.00	70,000.00	16.67%
Band 6	80,000.00	90,000.00	12.50%
Band 7	105,000.00	110,000.00	4.76%
Where an active substance is	a biocontrol agent		
6 Evaluation of a full data package	22,500.00	22,500.00	0.00%
7 Helping the European Food Safety Authority to evaluate the draft assessment report where the United Kingdom is the rapporteur or co- rapporteur member State	7,500.00	7,500.00	0.00%
8 Evaluation of a partial data package:			
Band 1	5,500.00	5,500.00	0.00%
Band 2	11,250.00	11,250.00	0.00%
Band 3	17,000.00	17,000.00	0.00%
Band 4	22,500.00	22,500.00	0.00%
Where an active substance is	a pheromone		
9 Evaluation of a fill data package	13,000.00	13,000.00	0.00%

Type of Fee	Previous Fee (£)	New Fee (£)	Percentage Increase/Decrease
10Helping the European Food Safety Authority to evaluate the draft assessment report where the United Kingdom is a rapporteur or co- rapporteur member State.	7,500.00	7,500.00	0.00%
11Evaluation of a partial data package:			
Band 1	3,250.00	3,250.00	0.00%
Band 2	6,500.00	6,500.00	0.00%
Band 3	9,750.00	9,750.00	0.00%
Band 4	13,000.00	13,000.00	0.00%
For all evaluations			
the submission of an application in support of new active substance, safener or synergist, biocontrol and pheromone applications	0.00	5,000.00	New item
3. Fees for official recognition	n of a test facility or	organisation	
Initial official recognition of the test facility	1,500.00	2,000.00	33.33%
Renewal of an official recognition	1,500.00	2,000.00	33.33%
Each re-inspection	1,125.00	1,500.00	33.33%
4. Basic substance application	ns		
<ol> <li>Assistance with a full data package</li> </ol>	0.00	110,000.00	New item
2 Assistance with a partial data package:			
Band 1	0.00	7,500.00	New item
Band 2	0.00	15,000.00	New item
Band 3	0.00	30,000.00	New item
Band 4	0.00	50,000.00	New item
Band 5	0.00	70,000.00	New item
Band 6	0.00	90,000.00	New item
Band 7	0.00	110,000.00	New item
Schedule 2 Import tolerance fee			

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Changes to legislation: There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Plant Protection Products (Fees and Charges) Regulations 2011. Any changes that have already been made by the team appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Type of Fee	Previous Fee (£)	New Fee (£)	Percentage Increase/Decrease
1 Full human health evaluation	15,600.00	15,600.00	0.00%
2 Metabolism and residues evaluation	6,500.00	6,500.00	0.00%
3 Residues evaluation	1,950.00	1,950.00	0.00%

# **Changes to legislation:**

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#### Changes and effects yet to be applied to:

- Sch. 1 para. 2 words substituted by S.I. 2019/720 Sch. 1 para. 14(3)(b) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 14(3)(b) substituted immediately before IP completion day by S.I. 2020/1567, reg. 1(2), Sch. 1 para. 10(4))
- Sch. 2 para. 1 words substituted by S.I. 2019/720 Sch. 1 para. 15(5)(a) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 15(5)(a) substituted immediately before IP completion day by S.I. 2020/1567, reg. 1(2), Sch. 1 para. 11(2)(a))
- reg. 2 words substituted by S.I. 2022/1037 reg. 12(2)
- reg. 3 omitted by S.I. 2019/720 Sch. 1 para. 9 (This amendment not applied to legislation.gov.uk. Sch. 1 para. 9 substituted immediately before IP completion day by S.I. 2020/1567, reg. 1(2), Sch. 1 para. 6)
- reg. 4(2) words inserted by S.I. 2019/720 Sch. 1 para. 10(2) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 10 substituted immediately before IP completion day by S.I. 2020/1567, reg. 1(2), Sch. 1 para. 7)
- reg. 8(6) word omitted by S.I. 2019/720 Sch. 1 para. 13(a) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 13 substituted immediately before IP completion day by S.I. 2020/1567, reg. 1(2), Sch. 1 para. 9)
- reg. 8(6) words inserted by S.I. 2019/720 Sch. 1 para. 13(b)

# Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:

Whole provisions yet to be inserted into this Instrument (including any effects on those provisions):

reg. 4(2A) inserted by S.I. 2019/720 Sch. 1 para. 10(3) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 10 substituted immediately before IP completion day by S.I. 2020/1567, reg. 1(2), Sch. 1 para. 7)