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## 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

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in the library of each House of Parliament and is available on DEFRA's website ([www.defra.gov.uk](http://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:

<i>Type of Fee</i>	<i>Previous Fee (£)</i>	<i>New Fee (£)</i>	<i>Percentage Increase/Decrease</i>
<b>Schedule 1</b>			
<b>1. Product related applications</b>			
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%
3 Preliminary consideration of application type listed in item 4, 5, 7, 12 or 13, to determine whether the application can proceed further	150.00 (electronic) or 175.00 (other)	220.00	46.67% or 25.71%
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) or	1,800.00	45.45% or

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	1,800.00 (data evaluation)		0.00%
<b>8</b> 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%
<b>9</b> Evaluation of data, modelling and detailed 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%
(f) 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			
<b>10</b> 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	100.00	100.00	0.00%

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Type of Fee	Previous Fee (£)	New Fee (£)	Percentage Increase/Decrease
<b>11</b> Pre-submission meetings for lead zone re-registration and new product applications	0.00	5,000.00	New item
<b>12</b> Zonal 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
<b>13</b> Commenting on draft study protocols	0.00	400.00	New item
<b>2. Active substances related applications</b>			
<b>Where an active substance, safener or synergist is neither a biocontrol agent nor a pheromone</b>			
<b>1</b> Preliminary evaluation of an application's admissibility	5,000.00	5,000.00	0.00%
<b>2</b> Processing an application for provisional authorisation	35,000.00	35,000.00	0.00%
<b>3</b> 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%
<b>4</b> Evaluation of a full data package	105,000.00	110,000.00	4.76%
<b>5</b> 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**

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Type of Fee	Previous Fee (£)	New Fee (£)	Percentage Increase/Decrease
<b>6</b> Evaluation of a full data package	22,500.00	22,500.00	0.00%
<b>7</b> 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%
<b>8</b> 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%
<b>Where an active substance is a pheromone</b>			
<b>9</b> Evaluation of a full data package	13,000.00	13,000.00	0.00%
<b>10</b> Helping 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%
<b>11</b> Evaluation 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%
<b>For all evaluations</b>			
<b>12</b> Meeting before 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
<b>3. Fees for official recognition of a test facility or organisation</b>			
Initial official recognition of the test facility	1,500.00	2,000.00	33.33%

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<i>Type of Fee</i>	<i>Previous Fee (£)</i>	<i>New Fee (£)</i>	<i>Percentage Increase/Decrease</i>
Renewal of an official recognition	1,500.00	2,000.00	33.33%
Each re-inspection	1,125.00	1,500.00	33.33%
<b>4. Basic substance applications</b>			
<b>1</b> Assistance with a full data package	0.00	110,000.00	New item
<b>2</b> 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
<b>Schedule 2</b>			
<b>Import tolerance fee</b>			
<b>1</b> Full human health evaluation	15,600.00	15,600.00	0.00%
<b>2</b> Metabolism and residues evaluation	6,500.00	6,500.00	0.00%
<b>3</b> Residues evaluation	1,950.00	1,950.00	0.00%

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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)