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STATUTORY INSTRUMENTS

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**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<sup>(1)</sup> in relation to the common agricultural policy of the European Union<sup>(2)</sup>, measures in the veterinary and phytosanitary fields for the protection of public health<sup>(3)</sup>, and in relation to the environment<sup>(4)</sup>.

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<sup>(5)</sup>.

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.

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(1) 1972 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).

(2) S.I. 1972/1811.

(3) S.I. 1999/2027.

(4) S.I. 2008/301.

(5) 1973 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;

“the Directive” means 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<sup>(6)</sup>;

“import tolerance” has 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;

“the MRL Regulation” means 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](#)<sup>(7)</sup>;

“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;

“Regulation 1107/2009” means 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](#)<sup>(8)</sup> and [91/414/EEC](#)<sup>(9)</sup>;

“United Kingdom competent authorities” means—

- (c) in relation to England and Wales, the Secretary of State;
- (d) in relation to Northern Ireland, the Department of Agriculture and Rural Development in Northern Ireland; and
- (e) in relation to Scotland, the Scottish Ministers.

(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.

**Functions of the Member State**

**3.—(1)** The functions of the Member State referred to in Article 74(1) of Regulation 1107/2009 are to be performed by the United Kingdom competent authorities.

(2) The functions of the Member State referred to in Article 19(1) of the Directive are to be performed by the United Kingdom competent authorities.

<sup>(6)</sup> OJ No L 4, 6. 1. 96, p.16.

<sup>(7)</sup> OJ No L 70, 16.3.2005, p. 1.

<sup>(8)</sup> OJ No. L309, 24.11.2009, p.1.

<sup>(9)</sup> OJ No L 309, 24. 11. 2009, p. 1.

## **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;
- (b) approval of active substances, safeners, synergists or basic substances; or
- (c) official recognition of a test facility or organisation,

and such fees are payable in accordance with Schedule 1.

(2) A United Kingdom competent authority may charge fees for applications for import tolerances under Article 7 of the MRL Regulation and such fees are payable in accordance with Schedule 2.

(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<sup>(10)</sup> or the Plant Protection Products (Fees) Regulations (Northern Ireland) 2004<sup>(11)</sup> in relation to that work.

(4) Fees are payable by the applicant, on invoice, to a United Kingdom competent authority.

(5) A United Kingdom 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 a United Kingdom competent authority as a civil debt.

## **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<sup>(12)</sup>.

## **Charge in relation to the Directive**

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 within the scope of the Directive.

## **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 under regulation 4(1) and Schedule 1, or regulation 4(2) and Schedule 2.

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<sup>(10)</sup> S.I. 2007/295.

<sup>(11)</sup> S.R.(NI) 2004 No 372.

<sup>(12)</sup> 1985 c.48.

(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.

### 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. The percentage must be calculated by applying the following formula—

$$A/B \times 100\% = \text{the percentage}$$

where—

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

B = the total annual turnover.

**8.—(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—

“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 regulation 4(1) and Schedule 1, or regulation 4(2) and Schedule 2;

“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.

### **Revocation**

9. The following regulations are revoked—
- (a) The Fees for Assessment of Active Substances (Third Stage Review) Regulations 2005<sup>(13)</sup>;
  - (b) The Fees for Assessment of Active Substances (Fourth Stage Review) Regulations 2005<sup>(14)</sup>; and
  - (c) The Plant Protection Products (Fees) Regulations 2007.

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

20th August 2011

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

We consent

25th August 2011

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

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(13) S.I. 2005/117.  
(14) S.I. 2005/1811.

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## SCHEDULE 1

Regulation 4(1)

## Fees

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

1. Fees for product-related applications are in accordance with the following table, and each item is charged cumulatively.

<i>Item</i>	<i>Chargeable item</i>	<i>Fee(£)</i>
1	Administrative research and development application <sup>(1)</sup>	50
2	Extension of use application including administration, co-ordination and technical consideration	1,495 or 1,700 <sup>(2)</sup>
3	Preliminary consideration of application type listed in items 4, 5, 7,12 or 13 to determine whether the application can proceed further	220
4	Administrative application <sup>(3)(4)</sup> for a new product or change to an existing product—	
4a	one product	150
4b	each additional product <sup>(5)</sup>	50
5	Parallel trade applications—	
5a	co-ordination of application for a new product or change to an existing product involving parallel trade <sup>(5)</sup>	700
5b	parallel trade verification <sup>(7)</sup>	200
6	Evaluation of a label in any application	200
7	Co-ordination of standard technical stream applications <sup>(9)(9)</sup>	1,800
8	Evaluation of simple reasoned cases in each of the following specialist areas—	
8a	chemistry <sup>(10)</sup>	400
8b	toxicology <sup>(11)</sup>	400
8c	operator exposure <sup>(12)</sup>	400
8d	residues and consumer exposure <sup>(13)</sup>	400
8e	fate and behaviour in the environment <sup>(14)</sup>	400
8f	ecotoxicology <sup>(15)</sup>	400
8g	efficacy <sup>(16)</sup>	400
9	Evaluation of data, modelling and detailed scientific cases in each of the following specialist areas—	
9a	chemistry <sup>(10)</sup>	750
9b	toxicology <sup>(11)</sup>	750

<i>Item</i>	<i>Chargeable item</i>	<i>Fee(£)</i>
9c	operator exposure <sup>(12)</sup>	750
9d	residues and consumer exposure <sup>(13)</sup>	750
9e	fate and behaviour in the environment <sup>(14)</sup>	1,800
9f	ecotoxicology <sup>(15)</sup>	1,800
9g	efficacy <sup>(16)</sup>	1,800
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	100
11	Pre-submission meetings for lead zonal re-registration and new product applications <sup>(17)</sup>	5,000
12	Zonal surcharge for lead zonal re-registration and new product applications. This fee is in addition to those described in 7 to 9 above <sup>(18)</sup>	
	Zonal surcharge 1	7,500
	Zonal surcharge 2	15,000
13	Commenting on draft study protocols <sup>(19)</sup>	400

*Notes*

- (1) Application for authorisation under Regulation 1107/2009 not involving evaluation of technical information or data.
- (2) The fee for an application for extension of authorised use received before 1<sup>st</sup> April 2012 is £1,495. The fee for an application for extension of authorised use received on or after 1st April 2012 is £1,700.
- (3) Application for authorisation under Regulation 1107/2009 involving no technical consideration.
- (4) Application for a parallel trade permit for personal use only.
- (5) Where the application relates

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- to a number of different products, this charge applies to each additional product.
- (6) Application for a parallel trade permit for other than personal use.
  - (7) Verification that the product to be traded is identical to a product authorised in the part of the United Kingdom to which the application relates in accordance with Regulation 1107/2009.
  - (8) “Standard technical stream applications” are all applications other than items 1-5, 10, 11 and 12.
  - (9) The co-ordination of applications for new products or a change to an existing product.
  - (10) 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.
  - (11) 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.
  - (12) Operator exposure additionally covers exposure of other persons resulting from the product use.
  - (13) 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.

- (14) 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.
- (15) 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.
- (16) 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.
- (17) Pre-submission meetings may be held at the request of the applicant prior to the submission of an application to the United Kingdom to act as lead zonal rapporteur.

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(18) A Zonal surcharge is applied to any new product or re-registration application for which the United Kingdom has been requested to act as the Central Zone lead Member State. This fee covers the additional co-ordination and evaluation work required to support approvals in other Member States over and above what is required in the United Kingdom. Zonal surcharge 1 is the minimum additional fee applied. Zonal Surcharge 2 is applied for any use or uses required in another Member State but not in the United Kingdom. For particularly complex protocols requiring significant specialist input it may be necessary to charge a data module fee in the relevant specialist area.

(19) The fee is equivalent to a specialist case fee and relates to requests from applicants for the United Kingdom 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.

### **Fees for application and evaluation of an active substance, safener or synergist**

2. The fees for evaluation for approval, or renewal of approval under Regulation 1107/2009 of an active substance, safener or synergist, are in accordance with the following table.

Item	Application	Fee(£)
<b>Where an active substance, safener or synergist is neither a biocontrol agent nor a pheromone</b>		
1	Preliminary evaluation <sup>(1)</sup> of the admissibility of an application	5,000
2	Processing an application for provisional authorisation <sup>(2)</sup>	35,000
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 in relation to an application for approval	35,000
4	Evaluation of a full data package <sup>(3)</sup>	110,000
5	Evaluation of a partial data package <sup>(4)</sup> :	
	Band 1	7,500
	Band 2	15,000
	Band 3	30,000
	Band 4	50,000
	Band 5	70,000
	Band 6	90,000
	Band 7	110,000
<b>Where an active substance is a biocontrol agent</b>		
6	Evaluation of a full data package <sup>(3)</sup>	22,500
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 in relation to an application for approval	7,500
8	Evaluation of a partial data package <sup>(4)</sup> :	
	Band 1	5,500
	Band 2	11,250
	Band 3	17,000
	Band 4	22,500
<b>Where an active substance is a pheromone</b>		
9	Evaluation of a full data package <sup>(3)</sup>	13,000
10	Helping the European Food Safety Authority to evaluate the draft assessment report where the United Kingdom is the rapporteur or co-rapporteur Member State in relation to an application for an approval	7,500
11	Evaluation of a partial data package <sup>(4)</sup> :	
	Band 1	3,250
	Band 2	6,500
	Band 3	9,750

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Item	Application	Fee (£)
	Band 4	13,000

### For all evaluations

12	Meeting before the submission of an application in support of a new active substance, safener, synergist, biocontrol agent or pheromone	5,000
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#### Notes

- (1) The initial evaluation carried out in order to notify the applicant whether his or her application can proceed further.
- (2) Application in accordance with Article 30 of Regulation 1107/2009 for a provisional authorisation in the United Kingdom (not exceeding 3 years) for a plant protection product containing a new active substance for which a decision on approval has been delayed by more than 30 months from the date of admissibility of the original application.
- (3) 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. 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, 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;
  - (c) resubmissions, for example, where the previous application for approval or inclusion in Annex 1 to Directive 91/414/EEC15 or for approval or renewal of 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;
  - (d) 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;
  - (e) data to support the evaluation of an active substance under Regulation 1107/2009 once the initial period of inclusion in Annex 1 of Directive 91/414/EEC has expired. The full dossier is not required just additional data to demonstrate compliance with any new guidance, regulations or scientific advances;
  - (f) 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 standard fees specified in the product-related application fees table (paragraph 1, items 9a-g above).
  - (g) Additional studies submitted to support an adverse data review.

A joint evaluation where the United Kingdom and one or more other Member States share the evaluation of a dossier and evaluation of scientific peer reviewed open literature on the active substance and its relevant metabolites will be treated as partial data packages.

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

3. The fees for the official recognition of a test facility or organisation are in accordance with the following table().

Item	Activity	Fee (£)
1	Initial official recognition of the test facility	2,000
2	Renewal of an official recognition	2,000
3	Each re-inspection	1,500

#### 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.

**Fees related to application for approval of basic substances**

4. The fees for work involved in assisting an applicant in preparing or submitting an application for approval of a basic substance under Article 23 of Regulation 1107/2009 are in accordance with the following table.

<i>Item</i>	<i>Application</i>	<i>Fee(£)</i>
1	Assistance with a full data package <sup>(1)</sup>	110,000
2	Assistance with a partial data package <sup>(2)</sup> :	
	Band 1	7,500
	Band 2	15,000
	Band 3	30,000
	Band 4	50,000
	Band 5	70,000
	Band 6	90,000
	Band 7	110,000

## Notes

- (1) 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, these studies will be treated as an additional partial data package. See also note (2).
- (2) The size of a partial data package is banded as a proportion of a full data package. The percentage 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;
  - (c) 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;
  - (d) data to support a change to the conditions of approval of the basic substance;
  - (e) joint evaluation where the United Kingdom and one or more other Member States share the evaluation of the dossier;

The evaluation of scientific peer reviewed open literature on the basic substance and its relevant metabolites is treated as a partial data package.

## SCHEDULE 2

Regulation 4(2)

## Import tolerance fee

Fees for product-related applications are in accordance with the following table.

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<i>Item</i>	<i>Category</i>	<i>Fee(£)</i>
1	Full Human health description <sup>(1)</sup>	15,600
2	Metabolism and residues evaluation <sup>(2)</sup>	6,500
3	Residues evaluation <sup>(3)</sup>	1,950

#### Notes

- (1) This category is mainly for plant protection products not currently authorised in any Member State. In certain cases, it may also include plant protection products still being reviewed if toxicological endpoints have not yet been agreed at a European level.
- (2) This category is for plant protection products where toxicological endpoints have already been agreed at a European level, but the residue definition has only been established for crop groups unrelated to the intended use or imported produce.
- (3) This category is for plant protection products where relevant toxicological endpoints and residue definition have already been agreed at European level.

## 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. 2005/1117);
- (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](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			

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<i>Type of Fee</i>	<i>Previous Fee (£)</i>	<i>New Fee (£)</i>	<i>Percentage Increase/Decrease</i>
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%
<b>5</b> 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%
<b>6</b> Evaluation of a label in any application.	300.00	200.00	-33.33%
<b>7</b> Coordination of standard technical stream application	1,100.00 (technical)	1,800.00	45.45%
	or		or
	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%



<i>Type of Fee</i>	<i>Previous Fee (£)</i>	<i>New Fee (£)</i>	<i>Percentage Increase/Decrease</i>
(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%
<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	35,000.00	35,000.00	0.00%

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<i>Type of Fee</i>	<i>Previous Fee (£)</i>	<i>New Fee (£)</i>	<i>Percentage Increase/Decrease</i>
the United Kingdom is the rapporteur or co-rapporteur member state			
<b>4</b> Evaluation of a full data package	105,000.00	110,00.00	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%
<b>Where an active substance is a biocontrol agent</b>			
<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 fill 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%

<i>Type of Fee</i>	<i>Previous Fee (£)</i>	<i>New Fee (£)</i>	<i>Percentage Increase/Decrease</i>
<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%
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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