STATUTORY INSTRUMENTS

2010 No. [0000]

PESTICIDES

FEES AND CHARGES

The Plant Protection Products (Fees and Charges) Regulations 2011

Made - - - -	*2011*
Laid before Parliament	*2011*
Laid before the National Assembly for Wales	*2011*
Coming into force - -	****

The Secretary of State, and the Welsh Ministers, are designated for the purposes of section 2(2) of the European Communities Act 1972(**a**) in relation to the common agricultural policy of the European Union(**b**) and measures in the veterinary and phytosanitary fields for the protection of public health(**c**).

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

The Secretary of State, in relation to England, Scotland(**e**) and Northern Ireland(**f**), and the Welsh Ministers and the Secretary of State, acting jointly in relation to Wales, make the following Regulations in exercise of the powers conferred by section 2(2) of, as read with paragraph 1A of Schedule 2 to, the European Communities Act 1972 and by section 56(1) and (2) of the Finance Act 1973.

Title, commencement and extent

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 14th June 2011.

(**a**) 1972 c. 68.
(**b**) In relation to England by S.I. 1972 No.1811 and in relation to Wales by S.I. 2010 No. 2690 by virtue of section 59 (1) of the Government of Wales Act 2006 (c. 32).
(**c**) In relation to England by S.I. 1999 No. 2027 and in relation to Wales by S.I. 2008 No. 1792.
(**d**) 1973 c. 51.
(**e**) Under section 57(1) of the Scotland Act 1998 (c.46), despite the transfer to the Scottish Ministers of functions in relation to implementing obligations under European Law in relation to devolved matters, the function of the Secretary of State in relation to implementing these obligations continues to be exercisable by the Secretary of State as regards Scotland.
(**f**) Under section 5(6) of the Northern Ireland Act 1998 (c.47).

(2) Regulation 4(2) and paragraph 5 of Schedule 1, and regulation 6 come into force on 26th November 2011.

(3) Regulation 4 and Schedules 1 and 2 do not extend to Northern Ireland.

Interpretation

2. In these Regulations—

"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(**a**);

"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(**b**);

"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 and 91/414/EEC(**c**);

"authorisation holder" means 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, unless any person has agreed, in writing, with the holder of such an authorisation or permit to be its sales representative for the authorised or permitted plant protection product and to pay the charge under these Regulations, in which case it means that person;

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

Functions of the Member State

3.—(1) The functions of the Member State in Article 74(1) of Regulation 1107/2009 are to be performed by the Secretary of State.

(2) The functions of the Member State in Article 19(1) of the Directive are to be performed by the Secretary of State.

Fees

4.—(1) The Secretary of State may charge fees for work carried out within the scope of Regulation 1107/2009 and such fees are payable in accordance with Schedule 1.

(2) The Secretary of State may charge a fee for an application for an aerial spraying approval under the Directive and such fee is payable in accordance with paragraph 5 of Schedule 1.

(3) The Secretary of State 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.

(4) The fees in these Regulations apply in relation to any activity carried out after they come into force, irrespective of when the application was made.

(5) Fees are payable by the applicant, on invoice, to the Secretary of State.

(6) The Secretary of State 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.

(7) In paragraph (6) "outstanding application" means any application for which a fee has been charged under the Plant Protection Products (Fees) Regulations 2007(**d**) or for which a fee has been charged under these Regulations.

(**a**) OJ No L 4, 6. 1. 96, p.16.
(**b**) OJ No L 70, 16.3.2005, p. 1.
(**c**) OJ No L 309, 24. 11. 2009, p. 1.
(**d**) S.I. 2007/295.

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

5. The Secretary of State may make an annual charge in respect of any costs incurred by it or on its behalf and by, or on behalf of, the Welsh Ministers, Scottish Ministers or the Northern Ireland Ministers—

(a) associated with any work carried out within the scope of Regulation 1107/2009, and

(b) arising from obligations under the MRL Regulation.

Charge in relation to the Directive

6.—(1) The Secretary of State may make an annual charge in respect of any costs incurred by it or on its behalf and by, or on behalf of, the Welsh Ministers, the Scottish Ministers or the Northern Ireland Ministers in relation to carrying out work pursuant to obligations within the scope of the Directive.

(2) The costs referred to in paragraph (1) must be treated as if they are costs referred to in regulation 5 for the purposes of the definition of "total costs incurred" in regulation 8(6).

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 the Secretary of State.

(2) The Secretary of State shall not charge for any costs under paragraph (1) in respect of which a fee is payable under regulation 4(1) and (2) and Schedule 1, or regulation 4(3) and Schedule 2.

(3) The Secretary of State may exclude an authorisation holder from the requirement to pay a charge where the Secretary of State 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 Secretary of State 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.

Calculation of charge

8.—(1) The Secretary of State shall calculate the amounts which authorisation holders are liable to pay under regulation 5 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 Secretary of State will calculate the charge payable by an authorisation holder by applying a percentage to its annual turnover. The percentage must be calculated by applying the following formula—

A/B x 100%

where—

A = the total costs incurred in the liability period

B = the total annual turnover.

(4) An authorisation holder must provide the Secretary of State 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 Secretary of State considers reasonable.

(6) In this regulation—

"total costs incurred" means the costs referred to in regulation 5 excluding any costs in respect of which a fee is payable under regulation 4(1) and (2) and Schedule 1, or regulation 4(3) and Schedule 2;

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

"annual turnover" means the amounts derived from sales 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 person who has agreed, in writing, with the holder of such an authorisation or permit to be its sales representative for the authorised or permitted plant protection product and to pay the charge under these Regulations,

in the financial year ending between 1st October and 30th September the following year, the latter date being in the calendar year in which the liability period starts;

"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(**a**)

(b) The Fees for Assessment of Active Substances (Fourth Stage Review) Regulations 2005(**b**); and

(c) The Plant Protection Products (Fees) Regulations 2007(**c**).

Signature
Date

Minister for Rural Affairs, one of the Welsh Ministers

Signature

Minister of State
Date

Department for Environment, Food and Rural Affairs

(**a**) S.I. 2005/117.
(**b**) S.I. 2005/1811.
(**c**) S.I. 2007/295.

SCHEDULE 1

Regulation 4(1) and (2)

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.

Item	*Chargeable item*	*Fee(£)*
1	Administrative research and development application[1]	50
2	Extension of use application including administration, co-ordination and technical consideration	1,495 or 1,700 [2]
3	Preliminary consideration of application type listed in items 4, 5, 7 or 12 to determine whether application can proceed further	220
4	Administrative application[3][4] for a new product or change to an existing product—	
4a	one product	150
4b	each additional product[5]	50
5	Parallel trade applications—	
5a	co-ordination of application for a new product or change to an existing product involving parallel trade[6]	500
5b	parallel trade verification[7]	200
6	Evaluation of a label in any application	200
7	Co-ordination of standard technical stream applications [8] [9]	1,600
8	Evaluation of simple reasoned cases in each of the following specialist areas—	
8a	chemistry[10]	400
8b	toxicology[11]	400
8c	operator exposure[12]	400
8d	residues and consumer exposure[13]	400
8e	fate and behaviour in the environment[14]	400
8f	ecotoxicology[15]	400
8g	efficacy[16]	400
9	Evaluation of data, modelling and detailed scientific cases in each of the following specialist areas—	
9a	chemistry[10]	750
9b	toxicology[11]	750
9c	operator exposure[12]	750
9d	residues and consumer exposure[13]	750
9e	fate and behaviour in the environment[14]	1,800
9f	ecotoxicology[15]	1,800
9g	efficacy[16]	1,800
10	Withdrawal of an application for a product specified in items 2, 4, 5, 7 and 12 before any work other than preliminary consideration has been done	100

Item	*Chargeable item*	*Fee(£)*
11	Pre-submission meetings for lead a zonal re-registration and new product applications(17)	5,000
12	Lead 'zonal' applications – co-ordination and specialist evaluation expressed as a percentage of a 'standard' active substance core dossier (18)	
	<2.5%	7,500
	≥2.5% and <5%	15,000
	≥5% and <10 %	30,000
	≥10% and <25%	40,000
	≥25% and <50%	60,000
	≥50% and <75%	80,000
	≥75%	105,000

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 1st 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 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 United Kingdom 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 Secretary of State to act as lead zonal rapporteur.

(18) This is the maximum amount to be charged. The actual fee will be based on a resource estimates following receipt of the application and will be agreed with the applicant prior to acceptance at the 'sift'.

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, is in accordance with the following table.

Item	*Application*	*Fee(£)*
	Where an active substance, safener or synergist is neither a biocontrol agent nor a pheromone	
1	Preliminary evaluation(1) of the admissibility of an application	5,000
2	Processing an application for provisional authorisation (2)	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
3a	Helping the European Food Safety Authority to evaluate the draft assessment report where the United Kingdom is not the rapporteur or co-rapporteur Member State in relation to an application for approval	5,000
4	Evaluation of a full data package(3)	105,000
5	Evaluation of a partial data package(4): percentage of data provided—	
5a	<2.5%	7,500
5b	≥2.5% and <5%	15,000
5c	≥5% and <10 %	30,000
5d	≥10% and <25%	40,000
5e	≥25% and <50%	60,000
5f	≥50% and <75%	80,000
5g	≥75%	105,000
	Where an active substance is a biocontrol agent	
6	Evaluation of a full data package (3)	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	Helping the European Food Safety Authority to evaluate the draft assessment report where the United Kingdom is not the rapporteur or co-rapporteur Member State in relation to an application for approval	1000
9	Evaluation of a partial data package: percentage of data provided(4)	
9a	<25%	5,500
9b	≥25% and <50%	11,250
9c	≥50% and <75%	17,000
9d	≥75%	22,500

Item	*Application*		*Fee(£)*
	Where an active substance is a pheromone		
10	Evaluation of a full data package(3)		13,000
11	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
12	Helping the European Food Safety Authority to evaluate the draft assessment report where the United Kingdom is not the rapporteur or co-rapporteur Member State in relation to an application for approval		1000
13	Evaluation of a partial data package: percentage of data provided(4)		
13a		<25%	3,250
13b		≥25% and <50%	6,500
13c		≥50% and <75%	9,750
13d		≥75%	13,000
	For all evaluations		
14	Meeting before the submission of an application in support of new active substance, safener, synergist, biocontrol agent or pheromone application		5,000

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 expressed as a percentage 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. Partial data packages include 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/EEC(**a**) 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;

a OJ No. L230, 19.8.1991, p.1.

(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 in 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 Secretary of State 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 fee for the official recognition of a test facility or organisation is in accordance with the following table(1).

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

Note

(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 is in accordance with the following table.

Item	*Application*	*Fee(£)*
1	Assistance with a full data package(1)	105,000
2	Assistance with a partial data package(2): percentage of data provided	
2a	<2.5%	7,500
2b	≥2.5% and <5%	15,000
2c	≥5% and <10 %	30,000
2d	≥10% and <25%	40,000
2e	≥25% and <50%	60,000
2f	≥50% and <75%	80,000
2g	≥75%	105,000

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 expressed as a percentage 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. The following are partial data packages—

(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 Secretary of State 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.

Fee for application for approval of aerial application of pesticides

5. The fee for an application for an aerial spraying approval under the Directive is £156.

SCHEDULE 2

Regulation 4(3)

Import tolerance fee

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

Item	*Category*	*Fee(£)*
1	Full Human health description[(1)]	£15,600
2	Metabolism and residues evaluation[(2)]	£6,500
3	Residues evaluation[(3)]	£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 pesticides where relevant toxicological endpoints and residue definitions have already been agreed at a European level.

EXPLANATORY NOTE

(This note is not part of the Order)

These Regulations set fees, chargeable by the Secretary of State—

(a) for work carried out within the scope of Regulation 1107/2009 which relates to the approval of active substances, safeners and synergists, and the authorisation of plant protection products,
(b)for applications for aerial spraying, and
(c) for applications for import tolerances.

These Regulations also provides for an annual charge to be paid by authorisations holders for costs incurred by or on behalf of the Secretary of State or by or on behalf of the Welsh Ministers, the Scottish Ministers or the Northern Ireland Ministers in relation to the carrying out of work within the scope of Regulation 1107/2009, work arising from the obligations under the MRL Regulation and, after 26th 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.

These Regulations revoke—

(a) The Fees for Assessment of Active Substances (Third Stage Review) Regulation 2005(**a**)

(b) The Fees for Assessment of Active Substances (Fourth Stage Review) Regulation 2005(**b**).

(c) the Plant Protection Products (Fees) Regulations 2007(**c**).

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. Copies of both documents have been placed in the library of each House of Parliament and are available on DEFRA's website (ww.defra.gov.uk). A copy of the regulatory impact assessment is also annexed to the Explanatory Memorandum which is available alongside the instrument on the legislation website (http://www.legislation.gov.uk/).

(**a**) S.I. 2005/117.
(**b**) S.I. 2005/1811.
(**c**) S.I. 2007/295.