STATUTORY INSTRUMENTS

2016 No. 254

PESTICIDES
FEES AND CHARGES

The Plant Protection Products (Fees and Charges) (Amendment) Regulations 2016

Made - - - -	*2nd March 2016*
Laid before Parliament	*7th March 2016*
Coming into force - -	*6th April 2016*

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.

Citation and commencement

1. These Regulations may be cited as the Plant Protection Products (Fees and Charges) (Amendment) Regulations 2016 and come into force on 6th April 2016.

Amendment of the Plant Protection Products (Fees and Charges) Regulations 2011

2.—(1) The Plant Protection Products (Fees and Charges) Regulations 2011(**5**) are amended as follows.

(2) For Schedule 1, substitute—

(**1**) 1972 c.68; section 2(2) was amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 (c.51) and Part 1 of the Schedule to the European Union (Amendment) Act 2008 (c.7).
(**2**) S.I. 1972/1811.
(**3**) S.I. 1999/2027.
(**4**) S.I. 2008/301.
(**5**) S.I. 2011/2132.

"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.

Item	*Chargeable item*	*Fee(£)*
1	Administrative research and development application(1)	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	229
4	Administrative application(2)(3) for a new product or change to an existing product—	
4a	one product	156
4b	each additional product(4)	52
5	Parallel trade applications—	
5a	co-ordination of application for a new product or change to an existing product involving parallel trade(5)	728
5b	parallel trade verification(6)	208
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(9)	416
8b	toxicology(10)	416
8c	operator exposure(11)	416
8d	residues and consumer exposure(12)	416
8e	fate and behaviour in the environment(13)	416
8f	ecotoxicology(14)	416
8g	efficacy(15)	416
9	Evaluation of data, modelling and detailed scientific cases in each of the following specialist areas—	
9a	chemistry(9)	780
9b	toxicology(10)	780

Item	*Chargeable item*	*Fee(£)*
9c	operator exposure(11)	780
9d	residues and consumer exposure(12)	780
9e	fate and behaviour in the environment(13)	1,872
9f	ecotoxicology(14)	1,872
9g	efficacy(15)	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	104
11	Pre-submission meetings for lead zonal re-registration and new product applications(16)	5,200
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 (17)	
	Zonal surcharge 1	7,800
	Zonal surcharge 2	15,600
13	Commenting on draft study protocols(18)	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.

(3) Application for a parallel trade permit for personal use only.

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

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

(6) 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.

(7) "Standard technical stream applications" are all applications other than items 1-5, 10, 11 and 12.

(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 to the United Kingdom to act as lead zonal rapporteur.

(17) 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.

(18) 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(£)*
	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	5,200
2	Processing an application for provisional authorisation (2)	36,400
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	36,400
4	Evaluation of a full data package(3)	114,400
5	Evaluation of a partial data package(4):	
	Band 1	7,800
	Band 2	15,600
	Band 3	31,200
	Band 4	52,000
	Band 5	72,800

Item	*Application*	*Fee(£)*
	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	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	7,800
8	Evaluation of a partial data package[(4)]:	
	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[(3)]	13,520
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	7,800
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	
12	Meeting before the submission of an application in support of a new active substance, safener, synergist, biocontrol agent or pheromone	5,200

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 where, for example, the previous application for approval or inclusion in Annex 1 to Directive 91/414/EEC(**6**) 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 size for which the standard fees specified in the product-related application fees table (paragraph 1, items 9a-g above) are payable.

(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[(1)].

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.

(**6**) OJ No. L230, 19.8.1991, p.1.

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.

Item	*Application*	*Fee(£)*
1	Assistance with a full data package(1)	114,400
2	Assistance with a partial data package(2):	
	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

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."

(3) For Schedule 2 substitute—

"SCHEDULE 2 Regulation 4(2)

Import tolerance fee

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

Item	*Category*	*Fee(£)*
1	Full Human health description[(1)]	16,224
2	Metabolism and residues evaluation[(2)]	6,760
3	Residues evaluation[(3)]	2,028

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."

Signed by authority of the Secretary of State for Work and Pensions

Justin Tomlinson
Parliamentary Under Secretary of State,
Department for Work and Pensions

2nd March 2016

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Plant Protection Products (Fees and Charges) Regulations 2011 ("the 2011 Regulations") by substituting new Schedules 1 and 2.

These Regulations increase the fees charged in accordance with the 2011 Regulations for the evaluation of the following applications within the scope of 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, p1)—

(a) authorisation of plant protection products;

(b) approval of active substances, safeners, synergists and basic substances; and

(c) official recognition of test facilities and organisations.

These Regulations increase the fees charged in accordance with the 2011 Regulations for applications for import tolerances under Article 7 of 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.

An impact assessment of the effect that the fees introduced by these Regulations will have on the costs of business and the voluntary sector is published with the Explanatory Memorandum which is available alongside the instrument at www.legislation.gov.uk.