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