STATUTORY INSTRUMENTS

2007 No. 295

PESTICIDES

FEES AND CHARGES

The Plant Protection Products (Fees) Regulations 2007

Made - - - -	*5th February 2007*
Laid before Parliament	*8th February 2007*
Coming into force - -	*1st March 2007*

The Secretary of State is a Minister designated(**a**) for the purposes of making Regulations under section 2(2) of the European Communities Act 1972(**b**) in relation to the common agricultural policy of the European Community.

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

The Secretary of State makes these Regulations in exercise of the powers conferred on him by section 2(2) of the European Communities Act 1972 and by section 56(1) of the Finance Act 1973.

Title and commencement

1. These Regulations may be cited as the Plant Protection Products (Fees) Regulations 2007 and come into force on 1st March 2007.

Interpretation

2. In these Regulations "the 2005 Regulations" means the Plant Protection Products Regulations 2005(**d**) or the Plant Protection Products (Scotland) Regulations 2005(**e**) as appropriate.

Fees

3.—(1) Fees for work carried out under the 2005 Regulations and work related to those Regulations are payable in accordance with the Schedule.

(2) 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.

(**a**) S. I. 1971/1811.
(**b**) 1972 c. 68.
(**c**) 1973 c.51.
(**d**) S. I. 2005/1435 to which there are amendments not relevant to these Regulations.
(**e**) S. S. I. 2005/331 to which there are amendments not relevant to these Regulations.

Revocations

4. The following are revoked—

(a) the Evaluation of Active Substances for Pesticides (Fees) Regulations 2000(**a**);

(b) the Plant Protection Products (Fees) Regulations 2003(**b**);

(c) the Evaluation of Active Substances for Pesticides (Fees)(Amendment) Regulations 2004(**c**); and

(d) the Plant Protection Products (Fees) (Amendment) Regulations 2004(**d**).

Jeff Rooker
Minister of State
22nd January 2007 Department for Environment, Food and Rural Affairs

We consent

Claire Ward
Dave Watts
5th February 2007 Two of the Lords Commissioners of Her Majesty's Treasury

SCHEDULE

Regulation 3

Fees

1. Fees are payable by the applicant, on invoice, to the Pesticides Safety Directorate(**e**).

2. The Pesticides Safety Directorate is under no obligation to process the application if there are outstanding fees in relation to it.

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

Product-related application

Item	*Chargeable item*	*Fee(£)*
1	Administrative experimental application(1)	30
2	Extension of use application(2) including administration, co-ordination and technical consideration	1,700
3	Preliminary consideration of application type listed in item 4 or 5 to determine whether application can proceed further—	
	application submitted electronically	150
	other	175

(**a**) S.I. 2000/2119.
(**b**) S.I. 2003/660.
(**c**) S. I. 2004/694.
(**d**) S.I. 2004/1159.
(**e**) The Pesticides Safety Directorate is an Executive Agency of the Department for Environment, Food and Rural Affairs.

Item	*Chargeable item*	*Fee(£)*
4	Administrative application[3][4] for a new product or change to an existing product—	
4a	one product	120
4b	each additional product[5]	40
5	Co-ordination of application for new product or change to existing product—	
5a	relating to a parallel import[6]	710
5b	requiring technical consideration by other Government departments[7]	7,185
5c	requiring data evaluation[8]	1,800
5d	requiring evaluation of technical information but not evaluation of data[8]	1,100
6	Evaluation of a label in any application	300
7	Parallel import verification[9]	200
8	Evaluation of technical information other than data in any application in each of the following specialist areas—	
8a	chemistry[10]	250
8b	toxicology[11]	250
8c	operator exposure[12]	250
8d	residues/consumer exposure[13]	250
8e	fate and behaviour in the environment[14]	250
8f	ecotoxicology[15]	250
8g	crop safety/effectiveness[16]	250
9	Evaluation of data in any application in each of the following specialist areas:	
9a	chemistry[10]	425
9b	toxicology[11]	500
9c	operator exposure[12]	750
9d	residues/consumer exposure[13]	1,000
9e	fate and behaviour in the environment[14]	1,000
9f	ecotoxicology[15]	1,000
9g	crop safety[16]	500
9h	effectiveness[16]	1,000
10	Referral of technical information under item 8, or data evaluation under item 9, to other Government departments	1,600
11	Withdrawal of an application for a product specified in item 5 before any work other than preliminary consideration has been done	100

Notes

(1) Application for approval under regulation 9 of the 2005 Regulations not involving evaluation of technical information or data.

(2) Application for extension of approved use under regulation 10 or modification of such under regulation 13(7) of the 2005 Regulations which involves technical consideration but not consultation with other Government departments. This fee of £1700 does not become due until 1st April 2012 and is phased as follows—

Extension of use applications

Date of application	*Fee(£)*
Before 1st April 2008	675
From 1st April 2008 but before 1st April 2009	880
From 1st April 2009 but before 1st April 2010	1,085
From 1st April 2010 but before 1st April 2011	1,290
From 1st April 2011 but before 1st April 2012	1,495
From 1st April 2012	1,700

(3) Application for approval under regulation 5, 7, 9 or 11, or an extension of approved use under regulation 10, or modification of such under regulation 13(7), of the 2005 Regulations involving no technical consideration.

(4) Application for approval for personal use only of an imported product, materially identical to a product approved under the 2005 Regulations or the Control of Pesticides Regulations 1986(**a**) ("a UK approved product").

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

(6) Application for approval of an imported product, materially identical to a UK approved product, for uses extending beyond personal use.

(7) Application for approval under regulation 5, 7, 8 or 9, or extension of approved use under regulation 10 or modification of such under regulation 13(7), of the 2005 Regulations which involves technical consideration and consultation with other Government departments.

(8) Application for approval under regulation 5, 7, 8, 9 or 11, or modification of such under regulation 13(7), of the 2005 Regulations, which involves technical consideration but not consultation with other Government Departments.

(9) Verification that the product to be imported is materially identical to a UK approved product.

(10) Chemistry covers assessment of the technical specification of the active substance 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 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 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.

(16) Effectiveness covers the assessment of whether a product consistently controls the target pest. Crop safety covers the assessment of whether the product adversely affects the treated crops, following crops or treated produce.

(**a**) S. I. 1986/1510 as amended by S. I. 1997/188.

Inclusion in Annex I to Council Directive 91/414/EEC, or the first approval in the United Kingdom for a product with a new active substance

4.—(1) The fee for inclusion in Annex I to Council Directive 91/414/EEC (concerning the placing of plant protection products on the market(**a**)), or the first approval in the United Kingdom for a product containing a new active substance, is in accordance with the following table.

(2) In this paragraph, "new active substance" means an active substance not previously used in a product approved in the United Kingdom.

Applications to include a substance in Annex I to Council Directive 91/414/EEC, or the first approval in the United Kingdom of a product containing a new active substance [(1)]

Item	*Application*	*Fee(£)*
	Where an active substance is neither a biocontrol agent nor a pheromone	
1	Preliminary evaluation[(2)] of an application	5,000
2	Processing an application for provisional approval	35,000
3	Processing an application for the inclusion of an active substance in Annex I to Directive 91/414	35,000
4	Evaluation of a full data package[(3)]	105,000
5	Evaluation of a partial data package[(4)]: percentage of data provided—	
5a	<5%	15,000
5b	≥5% and <10 %	30,000
5c	≥10% and <25%	40,000
5d	≥25% and <50%	60,000
5e	≥50% and <75%	80,000
5f	≥75%	105,000
	Where an active substance is a biocontrol agent	
6	Evaluation of a full data package and processing an application for provisional approval[(3)]	22,500
7	Processing an application for the inclusion of an active substance in Annex I	7,500
8	Evaluation of a partial data package: percentage of data provided[(4)]	
8a	<25%	5,500
8b	≥25% and <50%	11,250
8c	≥50% and <75%	17,000
8d	≥75%	22,500
	Where an active substance is a pheromone	
9	Evaluation of a full data package and processing an application for provisional approval [(3)]	13,000
10	Processing an application for the inclusion of an active substance in Annex I	7,500
11	Evaluation of a partial data package: percentage of data provided [(4)]	
11a	<25%	3,250
11b	≥25% and <50%	6,500
11c	≥50% and <75%	9,750
11d	≥75%	13,000

(**a**) OJ No. L230, 19.8.1991, p. 1 as last amended by Commission Directive No. 2006/136/EC, OJ No. L349, 12.12.2006, p. 42.

Notes

(1) Application under regulation 4 or 7 of the 2005 Regulations excepting a subsequent application (i.e. an application under regulation 7 for approval of a product containing an active substance where there is already an approval for a product containing that active substance and the applicant has access to the data relating to the active substance in the approved product).

(2) The initial evaluation carried out in order to notify the applicant whether his application can proceed further.

(3) A full data package comprises the complete dossier called for by Annex II and Annex III to Council Directive 91/414/EEC to support one major 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 then 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. 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 i.e. where the previous application for approval or inclusion in Annex 1 to Directive 91/414/EEC 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 inclusion of an active substance in Annex 1 to Directive 91/414/EEC once the initial inclusion period of 10 years has expired or to change the conditions of Annex I inclusion during the inclusion period;

(e) data to support the evaluation of an active substance under the EC Regulation expected to replace Directive 91/414/EEC once the initial period of inclusion in Annex 1 of Directive 91/414/EEC has expired i.e. with no full dossier, just additional data to fill new guidance, regulations and scientific advances;

(f) joint evaluation where the Pesticides Safety Directorate will evaluate part of a core dossier and the remainder of the dossier is evaluated by the competent authorities of one or more other member States.

The official recognition of a test facility or organisation

5. The fee for the official recognition of a test facility or organisation is in accordance with the following table.

Official recognition of a test facility or organisation[(1)]

Activity	*Fee(£)*
Initial official recognition of the test facility	1,500
Renewal of an official recognition	1,500
Each re-inspection	1,125

Note

(1) Annex III to Council Directive 91/414/EEC requires that the tests and analyses of the efficacy data be conducted only by officially recognised testing facilities or organisations which are found to satisfy the requirements of the Directive following evaluation of their application and inspection of their facilities.

Fees related to Commission Regulation (EC) No. 451/2000

6.—(1) The fee for the evaluation of a dossier submitted in accordance with Article 6 of Commission Regulation (EC) No. 451/2000 (laying down the detailed rules for the implementation of the second and third stages of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC(**a**)) where the United Kingdom has been requested to act as co-rapporteur Member State under Article 8(2) of that Regulation is £10,000.

(2) The fee for work carried out by the United Kingdom in accordance with Article 8 of that Regulation—

(a) to provide the technical and scientific assistance to help a rapporteur Member State to evaluate a dossier submitted in accordance with Article 6 of that Regulation;

(b) to help the European Food Safety Authority to evaluate the rapporteur Member State's draft assessment report; and

(c) to consider the Commission's draft directive or decision under paragraph (8) of that Article,

is £5,000 in each case.

(**a**) OJ No. L55, 29.2.2000, p. 25 as last amended by Commission Regulation (EC) No. 1044/2003 OJ No. L151, 19.6.2003, p. 32.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations set fees relating to work carried out by the Pesticides Safety Directorate relating to the approval of pesticides and to the inclusion of a new active substance into Annex I to Council Directive 91/414/EEC.

They revoke—

the Evaluation of Active Substances for Pesticides (Fees) Regulations 2000;

the Plant Protection Products (Fees) Regulations 2003;

the Plant Protection Products (Fees) (Amendment) Regulations; and

the Evaluation of Active Substances for Pesticides (Fees)(Amendment) Regulations 2004.

A comparison with previous fees is on the Pesticides Safety Directorate's website at www.pesticides.gov.uk.

A full regulatory impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector is available at www.pesticides.gov.uk.

£3.00

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