STATUTORY INSTRUMENTS

2004 No. 1159

PESTICIDES
FEES AND CHARGES

The Plant Protection Products (Fees) (Amendment) Regulations 2004

Made - - - - -	*17th April 2004*
Laid before Parliament	*21st April 2004*
Coming into force - -	*14th May 2004*

The Secretary of State for Environment, Food and Rural Affairs, being designated(**a**) for the purposes of section 2(2) of the European Communities Act 1972(**b**) in relation to the Common Agricultural Policy of the European Community, in exercise of the powers conferred upon her by that section, hereby makes the following Regulations:

Title and commencement

1. These Regulations may be cited as the Plant Protection Products (Fees) (Amendment) Regulations 2004 and come into force on 14th May 2004.

Amendment of the Plant Protection Products (Fees) Regulations 2003

2.—(1) The Plant Protection Products (Fees) Regulations 2003(**c**) shall be amended in accordance with this regulation.

(2) For paragraph (2) of regulation 1 (title, commencement, extent and interpretation) there shall be substituted:

"(2) In these Regulations—

"the 1991 Directive" means Council Directive 91/414/EEC concerning the placing of plant protection products on the market(**d**) amended as set out in the definition of "the Directive" in the 2003 Regulations;

"the 2003 Regulations" means the Plant Protection Products Regulations 2003(**e**) or the Plant Protection Products (Scotland) Regulations 2003(**f**) as appropriate;

"data" means scientific evidence submitted in support of an application under the 2003 Regulations;

"relevant authority" means the authority in Great Britain to which an application is submitted;

"the Schedule" means the Schedule to these Regulations,

and any reference in the Schedule to an identified item or an identified note refers to the item or note so identified in the Schedule.".

(**a**) S.I. 1972/1811.
(**b**) 1972 c. 68.
(**c**) S.I. 2003/660.
(**d**) OJ No. L230, 19.8.91, p.1.
(**e**) S.I. 2003/3241.
(**f**) S.S.I. 2003/579.

(3) In regulation 2 (fees), for:

(a) "the 1995 Regulations", wherever the expression appears, there shall be substituted "the 2003 Regulations";

(b) "Note F" in paragraph (2)(c) there shall be substituted "Note C".

(4) After regulation 3 (transitional provisions) the following regulation shall be added:

"**3A.**—(1) Subject to paragraph (2), the amendments made by the Plant Protection Products (Fees) (Amendment) Regulations 2004 shall not apply in respect of any application made before the amendments come into force.

(2) The amount of any fee relating to any activity carried out after these Regulations are amended by the Plant Protection Products (Fees) (Amendment) Regulations 2004, in connection with any application made before the amendments come into force, is based on the fee specified in these Regulations as amended by those Regulations.".

(5) For the Schedule there shall be substituted the Schedule to these Regulations.

Alun Michael
Minister of State
17th April 2004 Department for Environment, Food and Rural Affairs

SCHEDULE

Regulation 2(5)

Table of amounts payable for types of examination undertaken

Item		*Type of Examination*	*Amount*
A		In cases not covered by item B or C—	
(1)		Administrative experimental application[1]	£30
(2)		Off-label application[2] including administration, co-ordination and technical consideration	£470
(3)		Preliminary examination of application type listed in item A(4) or (5) to determine whether application can proceed further	£125
(4)	(a)	Administrative application[3][4]: for new product or change to a single existing product	£120
	(b)	Additional products[5] included in an administrative application[3][4]	£40
(5)		Co-ordination of application for new product or change to existing product:	
	(a)	Parallel import[6]	£710
	(b)	Mutual Recognition[7]	£1,060
	(c)	Experimental approval[8]	£1,060
	(d)	Other application[9] (involving no specialist data examination in any of items A(9)(c) to (i))	£1,060
	(e)	Other application[9] (involving specialist data examination in any of items A(9)(c) to (i))	£1,750
	(f)	Departmental application[10]	£7,185
(6)		Examination of a label in any application	£300
(7)		Parallel import verification[11]	£200
(8)		Examination of technical information other than data in any application in each of the following specialist areas:	
	(a)	Product/active chemistry[12]	£250
	(b)	Toxicology[13]	£250
	(c)	Operator exposure[14]	£250
	(d)	Residues/consumer exposure[15]	£250
	(e)	Fate and behaviour in the environment[16]	£250
	(f)	Ecotoxicology[17]	£250
	(g)	Crop safety, effectiveness or both[18]	£250
(9)		Examination of data in any application in each of the following specialist areas:	
	(a)	Product/active chemistry[12]	£425
	(b)	Crop safety, effectiveness or both (minor consideration)[18]	£425
	(c)	Toxicology[13]	£750
	(d)	Operator exposure[14]	£750
	(e)	Residues/consumer exposure[15]	£750
	(f)	Fate and behaviour in the environment[16]	£750
	(g)	Ecotoxicology[17]	£750
	(h)	Crop safety (major consideration)[18]	£750
	(i)	Effectiveness (major consideration)[18]	£750
(10)		Reference of technical information under item (8), or data under item (9), to Government Departments other than the relevant authority.	£1,475
(11)		Withdrawal processing[19]	£100
B		In Annex I application cases[20]—	
(1)		Preliminary examination[21] of an initial application	£5,000
(2)		Subsequent examination of an initial application comprising—	
	(a)	where an active substance covered by an application is neither a biocontrol agent nor a pheromone, processing and evaluation of a provisional approval where application contains a full data package[22] but does not call for other activity covered by item B(2)(b)	£95,000
	(b)	where an active substance covered by an application is neither a biocontrol agent nor a pheromone, evaluation of an Annex I application (including any provisional approval for a product where requested as part of the application) and preparation of a draft assessment report and subsequent finalisation of that report as a result of discussions with all or any of the EC Commission, the European Food Safety Authority and other Member States	£110,000[A]

Item	*Type of Examination*	*Amount*
(c)	processing and evaluation in respect of a provisional approval or evaluation of an Annex I application for an active substance that is either a biocontrol agent or pheromone (including any provisional approval for a product where requested as part of the application) and preparation of a draft assessment report and subsequent finalisation of that report as a result of discussions with all or any of the EC Commission, the European Food Safety Authority and other Member States	£40,000
(3)	Examination of a resubmitted application[23] (in respect of an active substance which is neither a biocontrol agent nor a pheromone) comprising—	
(a)	preliminary examination[21], processing and evaluation where application contains 10% or less of a full data package[22]	£26,000[B]
(b)	preliminary examination[21], processing and evaluation where application contains more than 10% but less than 25% of a full data package[22]	£35,000[B]
(c)	preliminary examination[21], processing and evaluation where application contains at least 25% but less than 50% of a full data package[22]	£53,000[B]
(d)	preliminary examination[21], processing and evaluation where application contains at least 50% but less than 75% of a full data package[22]	£71,000[B]
(e)	preliminary examination[21], processing and evaluation where application contains 75% or more of a full data package[22]	£90,000[B]
(4)	Examination of a resubmitted application[23] comprising preliminary examination[21], processing and evaluation in respect of an active substance which is either a biocontrol agent or pheromone	£20,000[B]
(5)	Evaluation and scientific review to assist another Member State regulatory authority with their evaluation of a new active substance for inclusion on Annex I	£10,000[C]
C	Preliminary examination and evaluation of an application for the official recognition of a test facility or organisation[24]—	
(1)	in connection with the application and inspection for initial official recognition of the test facility	£1,500[D]
(2)	in connection with the application and inspection for renewed recognition of the test facility	£1,500[D]
(3)	for each re-inspection following an inspection under item C(1) or (2)	£1,125

Notes (Numbered)

[1] Application for approval under regulation 9 of the 2003 Regulations not involving examination of technical information or data ("technical consideration").

[2] Application for extension of approved use under regulation 10 or modification of such under regulation 13(7) of the 2003 Regulations which involves technical consideration but not consultation of Government Departments other than the relevant authority.

[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 2003 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 2003 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 11, or modification of such under regulation 13(7), of the 2003 Regulations, involving technical consideration.

[8] Application for approval under regulation 9, or modification of such under regulation 13(7), of the 2003 Regulations, which involves technical consideration but not consultation of Government Departments other than the relevant authority.

[9] Application for approval under regulation 5, 7 or 8, or modification of such under regulation 13(7), of the 2003 Regulations, which involves technical consideration but not consultation of Government Departments other than the relevant authority.

(**a**) S.I. 1986/1510, amended by S.I. 1990/2487, 1994/3142, 1997/188.

(10) 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 2003 Regulations which calls for technical consideration and consultation of Government Departments other than the relevant authority.

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

(12) Product/active chemistry covers assessment of the technical specification of the active substance in the product and the physico-chemical properties of the product.

(13) 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.

(14) Operator exposure additionally covers exposure of other persons resulting from the product use.

(15) Residues/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.

(16) Fate and behaviour in the environment covers the potential environmental exposure from product use, including the identity and quantity of 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.

(17) 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.

(18) 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. Consideration is minor if it covers no more than confirmation of a finding reached previously following examination of data submitted in the course of an earlier application and extension of an approval under the 2003 Regulations to additional crop varieties; otherwise it is major.

(19) For any application under item A(5) withdrawn after preliminary examination under A(3) but before further activity in relation to the item starts.

(20) Application under regulation 4 (applications concerning active substances) or 7 (provisional approvals) of the 2003 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).

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

(22) A full data package comprises the complete dossier called for by Annex II or Annex III, or both, to the 1991 Directive, and percentages of it are based on the value of expert time called for in assessing a resubmitted application.

(23) A resubmitted application is one where a previous application for approval has been unsuccessful, and a new application is made in an attempt to address all the concerns raised from that earlier application.

(24) Annex III to the 1991 Directive 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.

Notes (Lettered)

(A) Where further information is submitted in response to requests made by the Commission pursuant to Article 6(4) of the 1991 Directive and the further information is required to be examined and evaluated in order to determine whether an active substance can be added to Annex I to that Directive, then an additional fee under item B(3), based on the size of the data package contained within that information, will become payable as if submission of that information were a resubmitted application.

(B) If the application is withdrawn after preliminary examination but before commencement of processing and evaluation, the fee in respect of the item is £5,000.

(C) The fee is payable where a person responsible for applying to another Member State for evaluation of a new active substance for inclusion in Annex I to the 1991 Directive requests the relevant authority to assist the other Member State with evaluation and scientific review.

(D) If the application is withdrawn after preliminary examination but before further activity in relation to the item starts, the fee in respect of the item is £100.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations which are made under section 2(2) of the European Communities Act 1972 amend the Plant Protection Products (Fees) Regulations 2003 (S.I. 2003/660), which set fees for the processing and examination of applications for approval for plant protection products and related works.

The Regulations alter the fees that are payable as detailed in the table of comparison with the Plant Protection Products (Fees) Regulations 2003 set out below.

The structure of Part A of the table in the Schedule to the Regulations has been amended to reflect changes to, and to clarify, the elements of the processing and examination required.

The Regulations also update the definitions for the "1991 Directive" and "data" and substitute a new definition, "the 2003 Regulations", for the "1995 Regulations" to reflect the revocation of the Plant Protection Products Regulations 1995 (S.I. 1995/887 as amended) and their re-enactment with modifications for England and Wales in the Plant Protection Products Regulations 2003 (S.I. 2003/3241) and for Scotland in the Plant Protection Products (Scotland) Regulations 2003 (S.S.I. 2003/579).

A Regulatory Impact Assessment has been prepared and placed in the library of each House of Parliament. Copies can be obtained from Pesticides Safety Directorate, Room 314, Mallard House, Kings Pool, 3 Peasholme Green, York YO1 2PX or from the website www.pesticides.gov.uk.

TABLE OF COMPARISON OF FEES SET BY S.I. 2003/660 AND NEW FEES

Item listed in Schedule	*Old Fee £*	*New Fee £*
4: Administrative application: for new product or change to existing product	70 + 30	120
Additional products with an administrative item (Old Items: A(2)(b) and A(3))	30	40
6: Examination of a label in any application (Old Item: A(4)(i))	425	300
8: Examination of technical information (not data) in any application in each of the listed specialist areas (Old Item: A(4)(v))	350	250

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