2004 No. 372

PESTICIDES

FEES AND CHARGES

Plant Protection Products (Fees) Regulations (Northern Ireland) 2004

Made - - - - - *27th August 2004*

Coming into operation *21st October 2004*

The Department of Agriculture and Rural Development, being a Department 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 on it by the said section 2(2) and of every other power enabling it in that behalf, hereby makes the following Regulations:

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Plant Protection Products (Fees) Regulations (Northern Ireland) 2004 and shall come into operation on 21st October 2004.

(2) In these Regulations –

"1991 Directive" means Council Directive 91/414/EEC concerning the placing of plant protection products on the market(**c**) amended as set out in the definition of "the Directive" in the 2004 Regulations;

"the 2004 Regulations" means the Plant Protection Products Regulations (Northern Ireland) 2004(**d**);

"data" means scientific evidence submitted in support of an application under the 2004 Regulations; and

"the Department" means the Department of Agriculture and Rural Development.

(3) The Interpretation Act (Northern Ireland) 1954(**e**) shall apply to these Regulations as it applies to an Act of the Northern Ireland Assembly.

Fees in connection with applications under the Plant Protection Products Regulations (Northern Ireland) 2004

2.—(1) An applicant under regulation 4 (active substances) or 10 (extensions) of, or for an approval under, the 2004 Regulations shall pay a fee to the Department in accordance with this regulation.

(**a**) S.I. 2000/2812
(**b**) 1972 c. 68
(**c**) O.J. No. L230, 19.8.91 p. 1 (as read with corrigenda published in O.J. No. L170, 25.6.92, p. 40)
(**d**) S.R. 2004 No. 126
(**e**) 1954 c. 33 (N.I.)

(2) The following persons shall also pay a fee in accordance with this regulation –

(a) a person making a request under regulation 13(7)(b) (modifications) of the 2004 Regulations,

(b) a person making a request to the Department for initial or the renewed official recognition of a testing facility under paragraph 2.2 or 2.3 of Annex III to the 1991 Directive, and

(c) a person covered by Note C in the Schedule,

and for the purposes of these Regulations such persons shall be treated as applicants and their requests as applications.

(3) The fee is the total of the amounts specified within the Table set out in the Schedule, as read with the notes, for each type of examination or related activity called for by the application, but if a lower sum (following consideration of actual work involved in examining any relevant application) is notified as the fee by the Department to the applicant then the fee is the lower sum.

(4) Payment shall be made in accordance with any invoice for the fee (or the balance) sent to the applicant by the Department, and the Department shall be under no obligation to process the application so long as there is a failure to make any such payment.

(5) On completion of all examinations and related activities involved in processing the application, any difference between what has been paid and the fee shall be paid or refunded.

(6) Any amount due under this regulation but unpaid is recoverable upon a demand in writing being sent to the person from whom it is due.

(7) In any proceedings relating to an application under these Regulations, a certificate of the Department as to the amount payable in connection with the application shall be evidence of the amount in question.

Transitional provisions

3.—(1) Subject to paragraph (2) these Regulations shall not apply in respect of any application made before the date on which these Regulations come into operation.

(2) The amount of any fee relating to any activity carried out on or after the date on which these Regulations come into operation in connection with any application made before the date on which they come into operation is based on the fee specified in these Regulations.

Revocation

4.—(1) The Plant Protection Products (Fees) Regulations (Northern Ireland) 1995(**a**) and the Plant Protection Products (Fees) (Amendment) Regulations 1997(**b**) are hereby revoked.

(2) The Regulations referred to in paragraph (1) shall continue to have effect in relation to any services provided or approvals granted by the Department (within the meaning of those Regulations) before the date on which these Regulations come into operation as if these Regulations had not been made.

Sealed with the Official Seal of the Department of Agriculture and Rural Development on 27th August 2004.

(L.S.) *D. Small*

A senior officer of the Department of Agriculture and Rural Development

(**a**) S.R. 1995 No. 372
(**b**) S.R. 1997 No. 246

SCHEDULE

Regulation 2

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

Item		Type of examination	Amount
(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]
	(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]

Item		Type of examination	Amount
(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 2004 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 2004 Regulations which involves technical consideration but not consultation of Government Departments other than the Department.

(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 2004 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 Plant Protection Products Regulations 2003(**a**) and the 2004 Regulations or the Control of Pesticides Regulations 1986(**b**) and the Control of Pesticides Regulations (Northern Ireland) 1987(**c**) ("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 2004 Regulations, involving technical consideration.

(8) Application for approval under regulation 9, or modification of such under regulation 13(7), of the 2004 Regulations, which involves technical consideration but not consultation of Government Departments other than the Department.

(9) Application for approval under regulation 5, 7 or 8, or modification of such under regulation 13(7), of the 2004 Regulations, which involves technical consideration but not consultation of Government Departments other than the Department.

(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 2004 Regulations which calls for technical consideration and consultation of Government Departments other than the Department.

(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.

(**a**) S.I. 2003/3241
(**b**) S.I. 1986/1510 as amended by S.I. 1990/2487, S.I. 1994/3142 and S.I. 1997/188
(**c**) S.R. 1987 No. 414 as amended by S.R. 1991 No. 203 and S.R. 1997 No. 469

(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 2004 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 2004 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 revoke and replace the Plant Protection Products (Fees) Regulations (Northern Ireland) 1995 and its 1997 amendment covering fees to be paid to the Department of Agriculture and Rural Development in connection with examinations for approval under the Plant Protection Products Regulations (Northern Ireland) 2004. The new 2004 Regulations continue to implement Council Directive 91/414/EEC concerning the placing of plant protection products on the market, as amended, in relation to Northern Ireland.

These Regulations introduce a new fee structure largely based on a modular approach founded on component examination elements, depending on the extent of examination called for by the type of application as well as the statutory examination function involved. The fee modules (Item A in the Table within the Schedule) are categorised into a preliminary examination charge, miscellaneous application charges and charges for specialist evaluations.

This new approach is not however to be applied to fees related to applications for products containing new active substances under the Directive 91/414/EEC, (Item B in the Table within the Schedule) where each such application requires examination of a full dossier of data and other information. Resubmission of such an application for approval where an earlier application has been unsuccessful involves a tiered, tapering fee dependent on the relevant percentage of the full data package required for the unsuccessful application. Similarly the new approach is not applied to fees in respect of recognition of testing facility under the Directive (Item C in the Table).

The Regulations introduce a new £10,000 fee (item B(5)) to cover the costs of acting as a co-rapporteur Member State for a new active substance following a specific request from a person involved and responsible as a notifier of that substance under Council Directive 91/414/EEC for Annex I inclusion.

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