2001 No. 2477

PESTICIDES
FEES AND CHARGES

The Plant Protection Products (Fees) Regulations 2001

Made - - - - -	*10th July 2001*
Laid before Parliament	*11th July 2001*
Coming into force - -	*1st August 2001*

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 on her by that section and of all other powers enabling her in that behalf, makes the following Regulations:

Title, commencement, extent and interpretation

1.—(1) These Regulations may be cited as the Plant Protection Products (Fees) Regulations 2001, come into force on 1st August 2001 and extend to Great Britain.

(2) In these Regulations—

"the 1991 Directive" means Council Directive 91/414/EEC concerning the placing of plant protection products on the market(**c**) amended as listed(**d**) in the definition of 'the Directive' in the 1995 Regulations;

"the 1995 Regulations" means the Plant Protection Products Regulations 1995(**e**);

"data" means scientific evidence submitted in support of application under the 1995 Regulations;

"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.

Fees in connection with applications under the Plant Protection Products Regulations 1995

2.—(1) An applicant under regulation 4 (active substances) or 10 (extensions) of, or for an approval under, the 1995 Regulations shall pay a fee to the Secretary of State in accordance with this regulation, and so shall—

(a) a person making a request under regulation 13(7)(b) (modifications) of the 1995 Regulations, and

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(**a**) S.I. 1972/1811.
(**b**) 1972 c. 68.
(**c**) OJ No. L230, 19.8.91 p. 1 (as read with corrigenda published in OJ No. L170, 25.6.92, p. 40).
(**d**) The final amendment instrument listed is Commission Directive 2001/28/EC (OJ No. L113, 24.4.2001, p. 5).
(**e**) S.I. 1995/887 as amended by S.I. 1997/7, 1997/2499, 1999/3430, and, as regards England and Wales, 2001/1112 and 2001/2419. As regards Scotland, S.I. 1995/887 has also been amended by S.S.I. 2001/161 and 2001/202 and, as provided for in regulation 25A, arrangements have been entered into for functions to be exercised as regards Scotland, and for fees to be collected, by the Secretary of State.

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

and for the purposes of these Regulations either such person shall count as an applicant and his request as an application.

(2) The fee is the total of the amounts specified in the Table 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 Secretary of State to the applicant then the fee is the lower sum in question.

(3) Payment shall, to the extent not previously made by the applicant, be made in accordance with any invoice for the fee (or the balance) sent to the applicant by the Secretary of State, and the Secretary of State shall be under no obligation to process the application so long as there is a failure to make any such payment.

(4) 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.

(5) Any amount due under this regulation but unpaid is recoverable on demand in writing sent to the person from whom it is due.

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

Revocation of previous Regulations

3. The Plant Protection (Fees) Regulations 1995(**a**) and the Plant Protection Products (Fees) (Amendment) Regulations 1997(**b**) are revoked.

Whitty
Parliamentary Under-Secretary,
10th July 2001 Department for Environment, Food and Rural Affairs

(**a**) S.I. 1995/888, amended by S.I. 1997/884.
(**b**) S.I. 1997/884.

SCHEDULE

Regulation 2

Table of amounts payable for types of examination undertaken

Item	Type of examination	Amount
A	In approval/extension application cases (Note 1):	
(1)	Preliminary examination (Note 2)	£125
(2)	Basic examination of—	
(a)	an Administrative Only application (Note 3)	£30
(b)	an Administrative application (Note 4)	£50
(c)	a Fast application (Note 5)	£1,060 (Note A)
(d)	a Mutual Recognition application (Note 6)	£1,060 (Note A)(Note B)
(e)	an Experimental application (Note 7)	£1,085 (Note A)(Note B)
(f)	an Off-label application (Note 8)	£470 (Note A)
(g)	a Normal application (Note 9)	£1,535 (Note A)(Note B)
(h)	a Departmental application (Note 10)	£7,185 (Note A)
(3)	Examination of a routine additional matter (Note 11) in an Administrative application (Note 4)	£20 per matter
(4)	Further examination (Note 12) comprising:	
(a)	Assessment, in a Mutual Recognition application (Note 6), in relation to one or more of the following risk assessment criteria:	£300 per criterion
(i)	efficacy (Note 13)	
(ii)	operator exposure (Note 14)	
(iii)	consumer exposure (Note 15)	
(iv)	fate and behaviour in the environment (Note 16)	
(v)	ecotoxicology (Note 17)	
(b)	Label check in any application	£425
(c)	Examination in any application which is not a Mutual Recognition application (Note 6), of any of the following:	
(i)	product/active chemistry data (Note 18)	£425
(ii)	crop safety data (minor) (Note 19)	£425
(iii)	parallel import verification (Note 20)	£425
(iv)	text without data seeking to justify a new approval or a change to the conditions of an approval	£425
(v)	data relating to consumer exposure (Note 15)	£750
(vi)	toxicology data (Note 21)	£750
(vii)	data relating to operator exposure (Note 14)	£750
(viii)	data relating to ecotoxicology (Note 17)	£750
(ix)	data relating to fate and behaviour in the environment (Note 16)	£750

Item				Type of examination	Amount
			(x)	effectiveness data (Note 22)	£750
			(xi)	crop safety data (major) (Note 19)	£750
			(xii)	any other material which falls within or is related to material falling within Annex II or III of the 1991 Directive	£750
		(d)		Examination in any Departmental application (Note 10), of any matter covered by any of items A(4)(c)(iv) to (xii)	In addition to the item fee, £1,475 for each such matter
B				In Annex I application cases (Note 23):	
	(1)			Preliminary examination (Note 2) of an initial application	£4,700 (Note C)
	(2)			Subseqeunt examination of an initial application comprising—	
		(a)		processing and evaluation where application contains a full data package (Note 24)	£90,000 (Note C)
		(b)		processing and evaluation in respect of an active substance which is either a biocontrol agent or pheromone	£40,000 (Note C) (Note D)
	(3)			Examination of a resubmitted application (Note 25) comprising—	
		(a)		preliminary examination (Note 2), processing and evaluation where application contains a very small data package (Note 26)	£26,000 (Note C) (Note E)
		(b)		preliminary examination (Note 2), processing and evaluation where application contains less than 25% of a full data package (Note 24) but more than a very small data package (Note 26)	£35,000 (Note C) (Note E)
		(c)		preliminary examination (Note 2), processing and evaluation where application contains 25–50% of a full data package (Note 24)	£53,000 (Note C) (Note E)
		(d)		preliminary examination (Note 2), processing and evaluation where application contains more than 50% but less than 75% of a full data package (Note 24)	£71,000 (Note C) (Note E)
		(e)		preliminary examination (Note 2), processing and evaluation where application contains 75–100% of a full data package (Note 24)	£90,000 (Note C) (Note E)
		(f)		preliminary examination (Note 2), processing and evaluation in respect of an active substance which is either a biocontrol agent or pheromone	£20,000 (Note C) (Note D) (Note E)
C				Preliminary examination (Note 2) and evaluation of an application for the official recognition of a test facility or organisation (Note 27):	
	(1)			in connection with the application and inspection for initial official recognition of the test facility	£1,120 (Note A)

Item		Type of examination	Amount
	(2)	in connection with the application and inspection for renewed recognition of the test facility	£840 (Note A)

Notes (numbered)

1. Approval/extension applications comprise all cases not covered by item B or item C.

2. A Preliminary examination is the initial examination needed, in relation to applications other than Administrative Only applications and Off-label applications, in order to notify an applicant whether his application can proceed further.

3. An Administrative Only application is—

(a) an application to be added to the list of approval personal importers and users of a product already published as approved for import for personal use, or

(b) an Experimental application which does not call for examination of data or of technical information.

4. An Administrative application is—

(a) an application to make a change to an existing approval of a type which does not call for examination of data, label checking or detailed examination of technical information, or

(b) an application by a prospective importer for approval of a product to be imported for personal use which does not fall within Note 3.

5. A Fast application is an application under regulation 5 (standard approvals), a subsequent application (as described in Note 23) under regulation 7 (provisional approvals), or an application for a modification of either such approval under regulation 13(7)(b), of the 1995 Regulations of a type which calls for technical consideration or label checking, but not significant data examination.

6. A Mutual Recognition application is an application under regulation 11 (mutual recognition of approvals), or for modification of such an approval under regulation 13(7)(b), of the 1995 Regulations.

7. An Experimental application is an application under regulation 9 (approvals for research and development), or for modification of such an approval under regulation 13(7)(b), of the 1995 Regulations which is not a Departmental application.

8. An Off-label application is an application for extension of an approved use under regulation 10, or for modification of such an extension under regulation 13(7)(b), of the 1995 Regulations of a type which calls for examination of data or detailed examination of technical information but is not a Departmental application.

9. A Normal application is—

(a) an application under regulation 8 (emergency approvals), or for modification of such an approval under regulation 13(7)(b), of the 1995 Regulations, or

(b) an application under regulation 5 (standard approvals), a subsequent application (as detailed in Note 23) under regulation 7 (provisional approvals), or an application for modification of either such approval under regulation 13(7)(b), of the 1995 Regulations of a type which calls for significant data examination,

which is not a Departmental application.

10. A Departmental application is an application under regulation 5, 8, 9 or 10 or a subsequent application (as described in Note 23) under regulation 7, of the 1995 Regulations of a type which calls for evaluation of data supplied by the applicant in relation to a risk assessment which has not been addressed in approval data to which the applicant has access.

11. A routine additional matter is a product or use change covered in the same application as a different product or different use change which calls for no additional examination.

12. Further examination is an examination in any case where the application is of a type which calls for examination by an expert on a matter covered by item A(4).

13. Efficacy refers to the effectiveness of the product in consistently controlling the target pest without adversely affecting the treated crop, following crops or treated produce.

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

15. 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 (save in relation to assessing the risk from that exposure in item A(4)(a)(v)) 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. Product/active chemistry data are data to enable assessment of the technical specification of the active substance and physico-chemical properties of the product.

19. Crop safety data are data supplied to show that the product does not adversely affect the treated crops, following crops or treated produce. The check is a minor one if only one aspect of crop safety is required to be addressed and it is required to confirm a finding deduced from other data, and otherwise it is a major one.

20. Parallel import verification is verification that a product to be imported is materially identical with a product approved under regulation 5 (standard approvals) or under regulation 7 (provisional approvals) of the 1995 Regulations.

21. Toxicology data are data used to assess the mammalian metabolism and toxicology of the active substance in the product and to determine the types of hazard to which the product can give rise.

22. Effectiveness data are data (other than crop safety data) supplied to show that a product consistently controls the target pest.

23. Annex I application cases cover applications under regulation 4 (applications concerning active substances) or 7 (provisional approvals) of the 1995 Regulations with the exception of a subsequent application (that is to say, an application under regulation 7 where there is already an approval for a product containing the active substance covered by the application and the applicant has access to data relating to the active substance covered by the approval in question).

24. A full data package comprises the total dossier called for by Annex II, 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.

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

26. A very small data package comprises data which are submitted to complete the material required to enable a full data package to be re-evaluated and which contain fewer than 10 separate studies.

27. 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. If the application is withdrawn after preliminary examination but before further activity in relation to the item starts, a fee of £100 is payable for processing the withdrawal.

B. If the application (being an application under regulation 9 (approvals for research and development) of the 1995 Regulations) is also an Administrative Only application there is no extra fee beyond the Administrative Only application fee. If the application (being of another type) is also an Administrative application there is no extra fee beyond the Administrative application fee.

C. If simultaneous applications from the same applicant cover both regulation 4 and regulation 7 of the 1995 Regulations in relation to the same active substance, no fee is payable in relation to the regulation 7 application.

D. Such processing and evaluation does not count for payment purposes as processing and evaluation of an application containing any type of data package referred to in item B(2)(a) or B(3)(a) to (e).

E. If the application is withdrawn after preliminary examination but before processing and evaluation, the fee in respect of the item is £4,700.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which extend to Great Britain, revoke and replace the Plant Protection Products (Fees) Regulations 1995 and its 1997 amendment covering fees to be paid to the Secretary of State in connection with examinations for approval under the Plant Protection Products Regulations 1995, as amended. The 1995 Regulations implement Council Directive 91/414/EEC concerning the placing of plant protection products on the market, as amended, in relation to Great Britain.

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 an initial preliminary examination charge, a basic examination charge 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 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 unsuccesful 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 a testing facility under the Directive (Item C in the Table).

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