2003 No. 660

PESTICIDES
FEES AND CHARGES

The Plant Protection Products (Fees) Regulations 2003

Made - - - - -	*10th March 2003*
Laid before Parliament	*11th March 2003*
Coming into force - -	*1st April 2003*

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 makes the following Regulations:

Title, commencement, extent and interpretation

1.—(1) These Regulations may be cited as the Plant Protection Products (Fees) Regulations 2003, come into force on 1st April 2003 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 an application under the 1995 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.

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 in accordance with this regulation to the relevant authority.

(**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 amending instrument listed is Commission Directive 2002/81/EC (OJ No. L276, 12.10.02, p.28)
(**e**) S.I. 1995/887 as amended by S.I. 1997/7, 1997/2499, 1999/3430, and as regards England and Wales, by S.I. 2002/2874. As regards Scotland S.I. 1995/887 has also been amended by S.S.I. 2001/161, 2001/454, 2002/117, 2002/279 and 2002/537 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.

(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 1995 Regulations,

(b) a person making a request to the relevant authority 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

(c) a person covered by Note F 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 of 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 relevant authority 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 relevant authority, and that authority 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 on demand in writing sent to the person from whom it is due.

(7) In any proceedings relating to an application under these Regulations, a certificate of the relevant authority 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 these Regulations come into force.

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

Revocation of previous Regulations

4. The Plant Protection Products (Fees) Regulations 2001(**a**) and the Plant Protection Products (Fees) (Amendment) Regulations 2002(**b**), are revoked, and so is regulation 3 of the Plant Protection Products (Payments) Regulations 2001(**c**).

Whitty
Parliamentary Under-Secretary,
10th March 2003 Department for Environment, Food and Rural Affairs

(**a**) S.I. 2001/2477 as amended by S.I. 2001/3898 and 2002/2733.
(**b**) S.I. 2002/2733.
(**c**) S.I. 2001/3898.

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 Experimental application (Note 3)	£30,
(b)	an Administrative application (Note 4)	£70 (Note A)
(c)	a Fast application (Note 5)	£1,060 (Note B)
(d)	a Parallel import application (Note 6)	£710 (Note A) (Note B)
(e)	a Mutual Recognition application (Note 7)	£1,060 (Note B)
(f)	an Experimental application (Note 8)	£1,060 (Note B)
(g)	an Off-label application (Note 9)	£470 (Note B)
(h)	a Normal application (Note 10)	£1,750 (Note B)
(i)	a Departmental application (Note 11)	£7,185 (Note B)
(3)	Examination of a routine additional matter (Note 12) in an Administrative application (Note 4)	£30 per matter
(4)	Further examination (Note 13) comprising—	
(a)	Examination in any application which is not an Administrative or Administrative Experimental (Notes 3 and 4) application of any of the following:	
(i)	label check	£425
(ii)	product/active chemistry data (Note 14)	£425
(iii)	crop safety data (minor) (Note 15)	£425
(iv)	parallel import verification (Note 16)	£200
(v)	text without data supporting a new approval or a change to the conditions of an approval in each of the following specialist areas (Note 17):	
	(aa) product/active chemistry (Note 14)	£350 (Note C)
	(bb) toxicology (Note 18)	£350 (Note C)
	(cc) operator exposure (Note 19)	£350 (Note C)
	(dd) residues/consumer exposure (Note 20)	£350 (Note C)
	(ee) fate and behaviour in the environment (Note 21)	£350 (Note C)
	(ff) ecotoxicology (Note 22)	£350 (Note C)
	(gg) crop safety and effectiveness (Notes 15 and 23)	£350 (Note C)
(b)	Applicable to Normal (Note 10), Experimental (Note 8) and Departmental (Note 11) applications:	
(i)	data relating to residues/consumer exposure (Note 20)	£750 (Note C)
(ii)	toxicology data (Note 18)	£750 (Note C)
(iii)	data relating to operator exposure (Note 19)	£750 (Note C)
(iv)	data relating to ecotoxicology (Note 22)	£750 (Note C)
(v)	data relating to fate and behaviour in the environment (Note 21)	£750 (Note C)
(vi)	effectiveness data (Note 23)	£750 (Note C)
(vii)	crop safety data (major) (Note 15)	£750 (Note C)
B	In Annex I application cases (Note 24)—	
(1)	Preliminary examination (Note 2) of an initial application	£5,000
(2)	Subsequent examination of an initial application comprising—	

Item	*Type of examination*	*Amount*
(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 (Note 25) 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(NoteD)
(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 (Note 26) comprising—	
(a)	preliminary examination (Note 2), processing and evaluation where application contains 10% or less of a full data package (Note 25)	£26,000(Note E)
(b)	preliminary examination (Note 2), processing and evaluation where application contains more than 10% but less than 25% of a full data package (Note 25)	£35,000(Note E)
(c)	preliminary examination (Note 2), processing and evaluation where application contains at least 25% but less than 50% of a full data package (Note 25)	£53,000 (Note E)
(d)	preliminary examination (Note 2), processing and evaluation where application contains at least 50% but less than 75% of a full data package (Note 25)	£71,000 (Note E)
(e)	preliminary examination (Note 2), processing and evaluation where application contains 75% or more of a full data package (Note 25)	£90,000 (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 E)
(4)	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 (Note F)
C	Preliminary examination 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	£1,500 (Note B)
(2)	in connection with the application and inspection for renewed recognition of the test facility	£1,500 (Note B)
(3)	for each re-inspection following an inspection under item C (1) or (2)	£1,125

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 Experimental applications and Off-label applications) in order to notify an applicant whether his application can proceed further.

3. An Administrative Experimental application is an application which would be an Experimental application but for the fact that it does not call for examination of data or of technical information.

4. An Administrative application is—

(a) an application (other than an Administrative Experimental 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.

5. A Fast application is an application under regulation 5 (standard approvals), a subsequent application 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. A subsequent application is 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.

6. A Parallel Import application is an application by a prospective importer for approval of a product to be imported for commercial use where the approval applied for relates to a product which is materially identical to a product identified in the application and already approved in the UK under the Control of Pesticides Regulations 1986(**a**) or the 1995 Regulations.

7. 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.

8. 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 but which requires examination of data or technical information.

9. 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.

10. 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 described in Note 5) 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,

that is not a Departmental application.

11. A Departmental application is an application under regulation 5, 8, 9 or 10 or a subsequent application (as described in Note 5) under regulation 7, of the 1995 Regulations of a type which calls for evaluation of data supplied by the applicant and referred to Government Departments other than the relevant authority.

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

13. 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).

14. Product/active chemistry data are data to enable assessment of the technical specification of the active substance and the physico-chemical properties of the product.

15. 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.

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

16. 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.

17. This applies where a reasoned case for technical or scientific justification for an approval or a change to the conditions of an approval is provided instead of data for consideration of matters covered by item A (4) (a) (v).

18. 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.

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

20. 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.

21. 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.

22. 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.

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

24. 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 (as described in Note 5).

25. 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.

26. 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.

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 an application which falls entirely within this description could also fall within a description of another description of application, the fee payable remains the fee for this description of application.

B. 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.

C. For any examination in a Departmental application in addition to the item fee, an additional fee £1,475 for each such matter is charged.

D. 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.

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

F. 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.

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 2001 (S.I. 2001/2477), regulation 3 of the Plant Protection Products (Payments) Regulations 2001 (S.I. 2001/3898) and the Plant Protection Products (Fees) (Amendment) Regulations 2002 (S.I. 2002/2733) covering fees to be paid to the relevant authority within Great Britain to which an application in connection with examinations for approval under the Plant Protection Products Regulations 1995 (the 1995 Regulations) is submitted. The 1995 Regulations implement Council Directive 91/414/EEC (OJ No. L230 19.8.91 p.1) concerning the placing of plant protection products on the market, as amended, in relation to Great Britain.

These Regulations alter fees that are payable as detailed (where the provisions are parallel) in the table of comparison with the Plant Protection Products (Fees) Regulations 2001 set out below. The fees introduced by S.I. 2002/2733 remain unaltered with the exception of a reduction in fee for parallel import verification (item A (4)(a)(iv)).

The structure of the Table within the Schedule of these Regulations is similar to the Table that is being replaced in S.I. 2001/2477. However under item A the previous distinction made between Mutual recognition and other applications in relation to further examination has been removed. In addition, provision has been introduced for item A(4)(a)(v) applicants to pay a £350 fee per specialism based on evaluation work carried out following submission of a reasoned case instead of actual data.

These Regulations introduce a change from the existing fee Regulations (S.I. 2001/2477) with regard to the treatment of particular Annex I application cases (item B of the Table in the Schedule) where the distinction is now drawn between those applications that only involve the evaluation of a provisional approval under regulation 7 of the 1995 Regulations (item B (2) (a)) and those applications which additionally include an evaluation of the active substance for the purpose of including that substance on the Annex I to the 1991 Directive (item B (2) (b)).

The Regulations also introduce a new £10,000 fee (item B (4)) 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.

TABLE OF COMPARISON OF OLD (IN S.I. 2002/2733) AND NEW FEES

	£ OLD	£ NEW
Administrative (item A (2) (b)),	50	70
Experimental (item A (2) (e) (old) and A (2) (f) (new)),	1085	1060
Normal (item A (2) (g) (old) and A (2) (h) (new)),	1535	1750
Examination of a routine additional matter in an Administrative application. For each product and task (item A (3)),	20	30
Parallel import verification (item A (4) (c) (iii) (old) and A (4) (a) (iv) (new)),	300	200
Preliminary examination of an initial Annex I application (item B (1)),	4,700	5,000
Processing an evaluation of a Provisional approval where the application contains a full data package (item B (2) (a)),	90,000	95,000
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 (item B (2) (b)),	90,000	110,000

These new fees have been the subject of a consultation with interested persons.

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