

S.I. No. 141 of 2001

**EUROPEAN COMMUNITIES (AUTHORIZATION, PLACING ON THE MARKET,
USE AND CONTROL OF PLANT PROTECTION PRODUCTS) (AMENDMENT) (No. 2)
REGULATIONS, 2001**

I, Joe Walsh, Minister for Agriculture, Food and Rural Development, in exercise of the powers conferred on me by section 3 of the European Communities Act, 1972 (No. 27 of 1972), for the purpose of giving further effect to Council Directive No 91/414/EEC of 15 July 1991¹, hereby make the following Regulations:

1. (1) These Regulations may be cited as the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) (No. 2) Regulations, 2001.
- (2) The European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 1994 to 2001 and these Regulations may be cited together as the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 1994 to 2001 and shall be construed together as one.
- (3) These Regulations shall come into operation on the first day of May 2001.

Interpretation

- 2 (1) In these Regulations -

"the principal Regulations" means the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 1994 to 2001;
- (2) In these Regulations, unless otherwise indicated -
 - (a) a reference to a Regulation is a reference to a Regulation of these Regulations,
 - (b) a reference to a paragraph or subparagraph is a reference to a paragraph or subparagraph of the provision in which the reference occurs,
 - (c) a reference to a Schedule is a reference to a Schedule of the Principal Regulations as amended by these Regulations.
- (3) A word or expression that is used in the Directive of 1991 or in any Commission Directive or Regulation of the European Communities mentioned in

¹ O.J. No. L230/1 19/8/1991

these Regulations has, unless the contrary intention appears, the meaning in these Regulations that it has in the Directive or Regulation concerned.

Amendments

3 Regulation 36 of the Principal Regulations is hereby revoked and is replaced by the following:

“36 (1) The consideration of every application for the authorization of a plant protection product, for the renewal or modification of an authorization granted, for an extension in the field of use of an authorized plant protection product, for the renewal of an extension granted, for the authorization of a plant protection product for trials purposes, for the renewal or variation in the conditions or restrictions of such an authorization, for a trials permit, for the renewal or variation in the conditions or restrictions of a trials permit, for the inclusion of an active substance in Annex I, or for the modification of the conditions or restrictions associated with any such inclusion, shall be subject to the payment of the following fees at the times specified, that is to say -

(a) in the case of an application for authorization of a plant protection product in accordance with Regulation 13, 15, or 18, the fee, or fees as appropriate, set out in column (2) of Part 1 of the Thirteenth Schedule, payable to the Minister in respect of the evaluation of the dossiers set out in column (1) of the said Part 1;

(b) in the case of an application for -

(i) inclusion of an active substance in Annex I in accordance with Articles 5 and 6 or 8.2 of the Directive,

(ii) the renewal of the inclusion of an active substance in Annex I in accordance with Article 5 of the Directive, or

(iii) a modification of the conditions or restrictions associated with any such inclusion,

the fee, or fees as appropriate, set out in column (2) of Part 2 of the Thirteenth Schedule, payable to the Minister in respect of the evaluation of the dossiers set out in column (1) of the said Part 2;

(c) in the case of an application for the renewal of an authorization in accordance with Regulation 19 (1), the fee, or fees as appropriate, set out in column (2) of Part 1 of the Thirteenth Schedule, payable to the Minister in respect of the evaluation of the dossiers set out in column (1) of the said Part 1;

(d) in the case of an application for the modification of an authorization in accordance with Regulation 19 (4), the fee, or fees as appropriate, set out in column (2) of Part 3 of the Thirteenth Schedule, payable to the Minister in

respect of the each such modification in relation to a category set out in column (1) of the said Part 3;

- (e) a fee of £150 shall be payable to the Minister in each case where an application is made for a minor amendment to the packaging and labelling or to the documentation, information and materials submitted in accordance with Regulation 8 (3), where it is considered that an evaluation of the risks arising for man, animals or the environment or an evaluation of the performance of the plant protection product are not involved or required;
 - (f) a fee of £1,000 shall be payable to the Minister in each case where an application is made for a permission to market in accordance with Regulation 5 (3); and
 - (g) a fee of £200 shall be payable to the Minister in each case where an application is made for an extension in field of use of an authorized plant protection product, in accordance with Regulation 16.
- (2) (a) The consideration of every application for the authorization of a plant protection product for trials purposes in accordance with the provisions of Regulation 25 shall be subject to the payment of a fee of £250 payable to the Minister.
- (b) The renewal of an authorization of a plant protection product for trials purposes in accordance with the provisions of Regulation 25 shall be subject to the payment of a fee of £50 payable to the Minister.
- (c) The variation of the conditions or restrictions of an authorization of a plant protection product for trials purposes in accordance with the provisions of Regulation 25 shall be subject to the payment of a fee of £50 payable to the Minister.
- (3) (a) The consideration of every application for a trials permit in accordance with the provisions of Regulation 26 shall be subject to the payment of a fee of £1,000 payable to the Minister.
- (b) The renewal of a trials permit in accordance with the provisions of Regulation 26 shall be subject to the payment of a fee of £250 payable to the Minister.
- (c) The variation of the conditions or restrictions of a trials permit in accordance with the provisions of Regulation 26 shall be subject to the payment of a fee of £250 payable to the Minister.
- (4) (a) Authorization, whether or not, for a provisional period, or permission to market for a plant protection product, granted in accordance with the requirements of these Regulations or clearance before 1 October 1994 in accordance with the provisions of the Regulations of 1994 shall be revoked if there is a failure to pay the annual fee set out in Part 4 of the Thirteenth Schedule, within 30 days of the annual fee falling due, but renewal of

authorization or permission to market or clearance, as appropriate, may be granted where application is made more than 30 days but not more than 60 days after the annual fee fell due, on payment to the Minister of the late annual fee set out in Part 4 of the Thirteenth Schedule.

- (b) Plant protection products notified as being on the market on or before the second of December 1985 in accordance with the provisions of the Regulations of 1994, may continue to be placed on the market and used if the annual fee set out in Part 4 of the Thirteenth Schedule has been paid to the Minister, within 30 days of the annual fee falling due. Where for a particular plant protection product, the annual fee has not been paid by the date due, the notification concerned shall be revoked, but renewal of the notification may be granted where application is made more than 30 days but not more than 60 days after the annual fee fell due, on payment to the Minister of the late annual fee set out in Part 4 of the Thirteenth Schedule.
- (c) The annual fees payable in accordance with subparagraphs (a) and (b) shall be paid by 1 September of each year.
- (d) In the case of a plant protection product already on the market for a period of a year or more prior to the calendar year for which the annual fee is payable, the Minister may reduce the level of the annual fee payable to the Minister under this paragraph for particular plant protection products, where, on the basis of an auditor's certificate furnished to him, he is satisfied that the wholesale sales of the plant protection product during the previous calendar year did not exceed -
 - (i) in the case of plant protection products for household or home garden use, £5,000, and
 - (ii) in the case of other plant protection products, £15,000.

In all such cases, the minimum fee payable for each such plant protection product shall be £50.

- (e) In the case of a plant protection product on the market for less than one year prior to the calendar year for which the annual fee is payable, the Minister may refund part of the annual fee payable in accordance with this paragraph, on a request being made to him in that behalf, where, on the basis of an auditor's certificate furnished to him, he is satisfied that the wholesale sales of the plant protection product during the year for which the annual fee was paid, did not exceed -
 - (i) in the case of plant protection products for household or home garden use, £5,000, and
 - (ii) in the case of other plant protection products, £15,000.

In all such cases, any refund made shall be such that for each such plant protection product, the minimum fee payable shall be £50.

- (5) In the case of a plant protection product already on the market for a period of three years or more prior to the calendar year in which the fee is payable and which is placed on the market exclusively for a specialized use or specialized uses, the fee or fees payable under subparagraphs (1) (a), (c), (d) and (f) shall be reduced by the amount specified in column (2) of Part 5A of the Thirteenth Schedule, on a request being made to the Minister in that behalf, where, on the basis of an auditor's certificate furnished to him, he is satisfied that the wholesale sales of the plant protection product during each of the three calendar years immediately prior to the year in which the fee or fees are payable, did not exceed the amounts specified in column (1) of the said part 5A.
- (6) In the case of a plant protection product on the market for a period of less than three years prior to the calendar year in which the fee is payable and which is placed on the market exclusively for a specialized use or specialized uses, the fee or fees payable under subparagraph (1) (a), (c), (d) and (f) shall be reduced by the amount specified in column (2) of Part 5B of the Thirteenth Schedule, on a request being made to the Minister in that behalf, where, on the basis of a market survey report provided to him by the applicant, he is satisfied that the potential annual wholesale sales of the plant protection product are unlikely to exceed the amounts specified in column (1) of the said part 5B. In cases, where the plant protection product has been on the market for one or two years immediately prior to the calendar year in which the fee is payable, any application made for a reduction in fees must be supported by an auditor's certificate relating to the wholesale sales of the plant protection product during each such year.
- (7) In the case of an active substance, which because of its nature and proposed uses, can be evaluated on the basis of a reduced data base, the fee payable in accordance with subparagraph (1) (b) may be reduced by the Minister on a request being made to him in that behalf.
- (8) In the case of an application for the authorization of a plant protection product for trials purposes, the fee payable under paragraph (2) may be reduced by the Minister on a request being made to him in that behalf where the potential area of use is limited to a specialised area or specialised areas of use.
- (9) A fee payable under these Regulations may be recovered by the Minister as a simple contract debt in any court of competent jurisdiction.”

- 4 The Thirteenth Schedule as set out in the Principal Regulations is hereby revoked and replaced by the following:

"THIRTEENTH SCHEDULE

PART 1

Regulations 36 (1) (a) and (c)

Fees for the consideration of applications for the authorization of plant protection products in accordance with Regulations 13, 15 and 18, and for their renewal in accordance with Regulation 19 (1)

Column (1)	Column (2)
	£
Each dossier as specified in Regulation 8 (3) (b)	4,500
Each dossier as specified in Regulation 8 (3) (a)	1,500
Each dossier as specified in Regulation 8 (6)	1,250

PART 2

Regulation 36 (1) (b)

Fees for the consideration of applications for the inclusion of an active substance in Annex I of the Directive, for the renewal of any such inclusion and for the modification of any conditions or restrictions associated with the inclusion of an active substance in Annex I

Column (1)	Column (2)
	£
Receipt, registry and completeness check	1,575
Data and information relating to identity, physical and chemical properties and methods of analysis	10,500
Toxicological and metabolism data and information	26,250
Data and information relating to residues	21,000
Data and information relating to fate and behaviour in the environment	21,000
Ecotoxicological data and information	21,000
Co-ordination of evaluation and preparation of monograph	10,500
Evaluation of further data and comments provided	50,000

PART 3

Regulation 36 (1) (d)

Fees for the consideration of applications for modification of authorization for plant protection products in accordance with Regulation 19 (4)

Column (1)	Column (2)
Category	
I	£ 1,500
II	600

"Category I" means a modification in the authorization of a plant protection product involving a major additional use, a major change in the manner of use, or a major formulation change;

"Category II" means a modification in the authorization of a plant protection product involving a minor additional use, a minor change in the manner of use, or a minor formulation change.

PART 4

Regulations 36 (4) (a), (b) and (f)

Annual Fees:	£200
Late Annual Fees:	£300

PART 5

Regulations 36 (5) and (6)

A. Reduced fees payable for plant protection products for specialized use or uses, already on the market for 3 calendar years

Column (1)	Column (2)
Wholesale sales in each of three calendar years immediately prior to the year in which the fee is payable	Percentage of the fee
	%
less than £5,000	10
£5,000 to £9,999	25
£10,000 to £19,999	50

B. Reduced fees payable for plant protection products for specialized use or uses, on the market for less than 3 calendar years

Column (1)	Column (2)
Estimated potential annual wholesale sales	Percentage of the fee
	%
less than £10,000	10
£10,000 to £19,999	25
£20,000 to £39,999	50
”	
-	

Given under my Official Seal, this 3rd day of April, 2001

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Joe Walsh
Minister for Agriculture, Food and Rural Development

Explanatory Note

(This note is not part of the instrument and does not purport to be a legal interpretation)

These Regulations, amend the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 1994 to 2001 (S.I. No. 139 of 1994, S.I. No. 200 of 1995, S.I. No. 159 of 1996, S.I. No. 290 of 1997, S.I. No. 466 of 1997, S.I. No. 182 of 1999, S.I. No. 198 of 1999, S.I. No. 356 of 1999, S.I. No. 461 of 1999, S.I. No. 366 of 2000 and S.I. No. 33 of 2001).

The amendments, specify revisions to certain application fees payable and specify that annual fees due be provided in a single payment.

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