#### STATUTORY INSTRUMENTS

# 1995 No. 888

## **PESTICIDES**

## FEES AND CHARGES

# The Plant Protection Products (Fees) Regulations 1995

Made - - - - 23rd March 1995
Laid before Parliament 27th March 1995
Coming into force - - 17th April 1995

The Minister of Agriculture, Fisheries and Food, in exercise of the powers conferred by section 56(1) and (2) of the Finance Act 1973(1) with the consent of the Treasury, hereby makes the following Regulations:

#### Title, extent and commencement

**1.** These Regulations may be cited as the Plant Protection Products (Fees) Regulations 1995, shall apply in Great Britain and shall come into force on 17th April 1995.

#### Interpretation

- 2. In these Regulations—
  - "Annex I application" means either of the following—
  - (a) an application under regulation 4(1) of the principal Regulations for the inclusion of an active substance in Annex I; or
  - (b) an application under regulation 4(2) of the principal Regulations for a variation of the conditions subject to which an active substance is included in Annex I;
  - "biocontrol agent or pheromone application"—
  - (a) in relation to an Annex I application, means an application relating to an active substance which is a biocontrol agent or a pheromone; and
  - (b) in relation to an application for provisional approval, means an application relating to a plant protection product which includes active substances all of which are biocontrol agents or pheromones or an application the preliminary examination of which has revealed that no evaluation is required of the active substances included in it which are not biocontrol agents or pheromones;

"data" means scientific evidence submitted in support of an application for approval under regulation 5 of the principal Regulations or in compliance with a requirement or condition specified in a provisional approval;

"evaluation", in relation to an Annex I application, an application for approval under regulation 5, 7, 8, 9 or 11 of the principal Regulations or an application for extension of use under regulation 10 of the principal Regulations, means an examination of an application and the information (including data) accompanying it leading to the granting or refusal of that application or, in the event of withdrawal of an application after the evaluation starts, leading to a discontinuance of the processing of that application;

"the Ministry" means the Ministry of Agriculture, Fisheries and Food;

"preliminary examination", in relation to an Annex I application, an application under regulation 5, 7, 8, 9 or 11 of the principal Regulations or an application for extension of use under regulation 10 of the principal Regulations, means an examination of the documents included in an application to determine whether the evaluation of that application can proceed;

"principal Regulations" means the Plant Protection Products Regulations 1995(2);

"provisional approval" means an approval under regulation 7 of the principal Regulations;

"resubmitted application" means an application relating to an active substance or plant protection product made following the making of an unsuccessful application relating to the same substance or product;

"saving in costs", in relation to a resubmitted application, means the saving in costs arising because, in evaluating the application, work done on the previous unsuccessful application does not have to be repeated and, where such saving is expressed as a percentage, the reference is to the saving as a percentage of the full costs of evaluating the application which would have been incurred had it been an original application; and

"active substance", "Annex I", "approval", "approved", "the Directive", "EEA State", "plant protection product" and "substance" shall have the same meanings as in the principal Regulations.

## Prescription of fees

- **3.**—(1) Subject to paragraph (2) below, the fees specified in column 2 of the Schedule to these Regulations are hereby prescribed as the fees payable in connection with the services provided and the approvals granted by the Ministry in pursuance of the Community obligations of the United Kingdom (as regards Great Britain) under the Directive, each fee specified in column 2 of that Schedule being the fee payable in connection with the service or approval specified alongside that fee in column 1 of that Schedule.
- (2) The Ministry may, if it sees fit, perform a service or grant an approval so specified for the payment of a smaller fee than that so specified.
- (3) The Schedule to these Regulations shall have effect subject to the Notes to that Schedule which identify special cases where either no fee is payable, a reduced fee is payable or a fee which has been paid will be repaid in part.

## Payment of fees

**4.**—(1) A fee prescribed under regulation 3 above shall be paid at the same time as the application is made to the Ministry for the service or approval to which it relates but the Ministry may process an application which is not accompanied by the prescribed fee.

- (2) Where under paragraph (1) above the Ministry processes an application which is not accompanied by the prescribed fee, that fee shall be payable forthwith upon service upon the applicant by the Ministry of a written demand for payment and shall be recoverable as a debt due to the Crown.
- (3) Regulation 25 of the principal Regulations shall have effect in relation to the service of a written demand under paragraph (2) above as if in that regulation—
  - (a) any reference to any document required or authorised to be served under those Regulations included a reference to such a written demand, and
  - (b) any reference to the Ministers included a reference to the Ministry.

## Payment into the Consolidated Fund

**5.** Fees paid to the Ministry under these Regulations shall be paid into the Consolidated Fund.

Ministry of Agriculture, Fisheries and Food 22nd March 1995

Angela Browning Parliamentary Secretary,

We consent to the making of these Regulations.

Andrew Mitchell
Timothy Wood
Two of the Lords Commissioners of Her
Majesty's Treasury

23rd March 1995

## **SCHEDULE**

Regulation 3

## PRESCRIBED FEES

TABLETA DE TELO	
Column 1	Column 2
Description of Service or Approval	Fee
<b>1.</b> Evaluation of an Annex I application or evaluation of an application for provisional approval—	£13,400 (note (c))
(a) where the application is a biocontrol agent or pheromone application	
(b) (b) where the application is not a biocontrol agent or pheromone application	£60,000 (note (c))
<b>2.</b> Preliminary examination and evaluation of a resubmitted Annex I application or preliminary examination and evaluation of a resubmitted application for provisional approval—	£17,800 (note (c))
(1) where it appears to the Ministry that there is no saving in costs or that such saving is less than 50%—	
(a) where the application is a biocontrol agent or pheromone application	
(b) (b) where the application is not a biocontrol agent or pheromone application	£64,400 (note (c))
(2) where it appears to the Ministry that the saving in costs is not less than 50% but is less than 75% but the work which has to be done in relation to the application is significant—	£8,900 (note (c))
(a) where the application is a biocontrol agent or pheromone application	
Notes  (a) If the application is withdrawn before evaluation starts there will be refunded to the applicant an amount equal to 90% of the fee but with a minimum retention of £100.	

- (b)
- £100. To justify this reduced fee the evidence supporting the application must be the same for all products included in the application. Where an application is made for provisional approval of a plant protection product not already approved in another member State which contains an active substance not included in Annex I and that application is accompanied by an Annex I application relating to that active substance no fee is payable in relation to the first mentioned application. (c)

Column 1 Column 2 Description of Service or Approval Fee (b) where the application is not £32,200 (note (c)) a biocontrol agent or pheromone application ... ... (3) where it appears to the Ministry that the £4,450 (note (c)) saving in costs is not less than 75% but the work which has to be done in relation to the application is significant— (a) where the application is a biocontrol agent or pheromone application ...... (b) where the application is not £16,100 (note (c)) a biocontrol agent or pheromone application ... ... (4) where it appears to the Ministry that the £2,300 (note (c)) saving in costs is so great that the work which has to be done in relation to the application is not significant ...... 3. Preliminary examination and evaluation of £2,300 (note (b)) an application under regulation 5 of the principal Regulations for approval of a plant protection product which is not already approved in another EEA State-(1) where the application is accompanied by (2) where the application is not accompanied £285 (note (a)) by data-(a) where scientific examination is involved-(i) where the application relates to the intended importation into Great Britain of a plant protection product for use by the importer only and the Notes If the application is withdrawn before evaluation starts there will be refunded to the applicant an amount equal to 90% of the fee but with a minimum retention of £100. (b) To justify this reduced fee the evidence supporting the application must be the same for all products included in the application. Where an application is made for provisional approval of a plant protection product not already approved in another member State which contains an active substance not included in Annex I and that application is accompanied by an Annex I application relating to that active substance no fee is payable in relation to the first mentioned application.

Column 1 Column 2

Description of Service or Approval Fee

product differs from another product already approved under regulation 5 of the principal Regulations in form only and not in substance .......

- (ii) any other case ... ... £620 (note (a))
  - (b) (b) where no scientific examination £285 (note (a)) is involved—
    - (i) where the application relates to one product only ... ...
- (ii) for each further product included in the £10 (note (b)) same application ... ...
- **4.** Preliminary examination of an Annex 1 £4,400 (note (c)) application or of an application for provisional approval (not being in either case a resubmitted application) ... ...
- **5.** Notification to an applicant following a £100 preliminary examination that the application (an Annex I application or an application for any approval under the principal Regulations) was incomplete ... ...
- **6.** Evaluation of data submitted in £2,300 (note (a)) compliance with a requirement or condition specified in a provisional approval, on each occasion data is submitted ... ...
- 7. Extending the period of a provisional £620 approval under regulation 7(5) of the principal Regulations ... ...
- **8.** Preliminary examination and evaluation of £2,300 (note (a)) an application for an emergency approval under regulation 8 of the principal Regulations ......

#### Notes

- (a) If the application is withdrawn before evaluation starts there will be refunded to the applicant an amount equal to 90% of the fee but with a minimum retention of £100.
- (b) To justify this reduced fee the evidence supporting the application must be the same for all products included in the application.
- application. (c) Where an application is made for provisional approval of a plant protection product not already approved in another member State which contains an active substance not included in Annex I and that application is accompanied by an Annex I application relating to that active substance no fee is payable in relation to the first mentioned application.

Column 1	Column 2
Description of Service or Approval	Fee

- **9.** Preliminary examination and evaluation of £1,600 (note (a)) an application for approval of a plant protection product for trial purposes under regulation 9 of the principal Regulations—
  - (a) where the application is a first application ... ...
  - (b) (b) where the application is for £285 (note (a)) the renewal of an approval previously granted where the period for which it was granted has expired ... ...
- 10. Preliminary examination and evalution £460 (note (a)) of an application under regulation 10 of the principal Regulations for an extension of approved use of a plant protection product already approved under regulation 5 of the principal Regulations—
  - (a) where the application is a first application for the new use ... ...
  - (b) (b) where the application is for £145 (note (a)) the renewal of an extension where the period for which the extension was granted has expired ... ...
- 11. Preliminary examination and evaluation £1,600 (note (a)) of an application under regulation 11 of the principal Regulations for approval of a plant protection product, where the application relates to a plant protection product already approved in another EEA State ... ...
- **12.** Renewal under regulation 5(2) or (3) of £2,300 (note (a)) the principal Regulations of an approval granted under regulation 5 of those Regulations—

#### Notes

- (a) If the application is withdrawn before evaluation starts there will be refunded to the applicant an amount equal to 90% of the fee but with a minimum retention of £100.
- (b) To justify this reduced fee the evidence supporting the application must be the same for all products included in the application.
  (c) Where an application is made for
- (c) Where an application is made for provisional approval of a plant protection product not already approved in another member State which contains an active substance not included in Annex I and that application is accompanied by an Annex I application relating to that active substance no fee is payable in relation to the first mentioned application.

Column 1 Column 2
Description of Service or Approval Fee

- (a) where the application is accompanied by data ... ...
- (b) (b) where the application is not £620 (note (a)) accompanied by data ... ...
- 13. Modification under regulation 13(7) of £285 (note (a)) the principal Regulations of any approval granted under those Regulations or of an extension of use granted under regulation 10 of the principal Regulations—
  - (a) where the application is for one product only ......
  - (b) (b) for each further product £10 (note (b)) included in the same application ... ...

#### Notes

- (a) If the application is withdrawn before evaluation starts there will be refunded to the applicant an amount equal to 90% of the fee but with a minimum retention of £100.
- (b) To justify this reduced fee the evidence supporting the application must be the same for all products included in the application.
- application.

  (c) Where an application is made for provisional approval of a plant protection product not already approved in another member State which contains an active substance not included in Annex I and that application is accompanied by an Annex I application relating to that active substance no fee is payable in relation to the first mentioned application.

## **EXPLANATORY NOTE**

(This note is not part of the Regulations)

These Regulations prescribe fees to be paid to the Ministry of Agriculture, Fisheries and Food in connection with services provided and approvals granted by the Ministry in pursuance of the Community obligations of the United Kingdom (as regards Great Britain) under Council Directive 91/414/EEC (OJNo. L230, 19.8.91, p.1 to be read with corrigenda published in OJ No. L170, 25.6.92, p.40) concerning the placing of plant protection products on the market ("the Directive"), as amended by Commission Directive 93/71/EEC (OJ No. L221, 31.8.93, p.27), Commission Directive 94/37/EEC (OJ No. L194, 29.7.94, p.65), and Commission Directive 94/79/EC (OJ No. L354, 31.12.94, p.16), and Council Directive 94/43/EEC (OJ No. L227, 1.9.94, p.31), and supplement the Plant Protection Products Regulations 1995 (S.I.1995/887) ("the principal Regulations"), which implement the Directive in Great Britain (regulation 3 of these Regulations).

The principal services and approvals in connection with which fees are prescribed in these Regulations are—

- (a) the preliminary examination and evaluation of an application made through the Ministry to the Commission of the European Communities under regulation 4(1) of the principal Regulations for the listing of an active substance in Annex I to the Directive, such listing being necessary to secure standard approval of any plant protection product containing that active substance under regulation 5 of the principal Regulations (items 1, 2 and 4 of the Schedule to these Regulations);
- (b) the preliminary examination and evaluation of an application under regulation 7 of the principal Regulations for the issue by the Ministry of a provisional approval of a plant protection product containing an active substance not yet listed in Annex I to the Directive (items 1, 2 and 4 of the Schedule to these Regulations);
- (c) the preliminary examination and evaluation of an application under regulation 5 of the principal Regulations for the issue by the Ministry of a standard approval of a plant protection product containing an active substance listed in Annex I to the Directive, and of an application under regulation 5(2) or (3) of the principal Regulations for the issue by the Ministry of a renewal of such a standard approval (items 3 and 12 of the Schedule to these Regulations);
- (d) the preliminary examination and evaluation of an application under regulation 8 of the principal Regulations for the issue by the Ministry of an emergency approval of a plant protection product (item 8 of the Schedule to these Regulations);
- (e) the preliminary examination and evaluation of an application under regulation 9 of the principal Regulations for the issue by the Ministry of an approval of a plant protection product for trial purposes (item 9 of the Schedule to these Regulations);
- (f) the preliminary examination and evaluation of an application under regulation 10 of the principal Regulations for the extension by the Ministry of the use of a plant protection product already approved under regulation 5 of the principal Regulations (item 10 of the Schedule to these Regulations);
- (g) the preliminary examination and evaluation of an application under regulation 11 of the principal Regulations for the issue by the Ministry of an approval of a plant protection product already approved in another EEA State (item 11 of the Schedule to these Regulations); and
- (h) the preliminary examination and evaluation of an application under regulation 13(7) of the principal Regulations for the modification by the Ministry of any approval of a plant protection product granted under the principal Regulations or of an extension of use granted under regulation 10 of those Regulations (item 13 of the Schedule to these Regulations).

The fees are set out in the Schedule to these Regulations, which must be read with the Notes thereto (regulation 3(3)). Provision is made for the payment of a smaller fee, at the Ministry's discretion (regulation 3(2)). The time at which the prescribed fees must be paid is governed by regulation 4.

A compliance cost assessment has been prepared in respect of both these Regulations and the principal Regulations. Copies of this assessment can be obtained from the Pesticides Safety Directorate of the Ministry of Agriculture, Fisheries and Food, Room 308, Mallard House, Kings Pool, 3 Peasholme Green, York YO1 2PX. A copy has been placed in the library of each House of Parliament.