2002 No. 697

MEDICINES

The Medicated Feedingstuffs (Amendment) (England, Scotland and Wales) Regulations 2002

Made - - - - -	*14th March 2002*
Laid before Parliament	*15th March 2002*
Coming into force - -	*31st March 2002*

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, having carried out any consultation required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council (laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(**c**)) makes the following Regulations:

Title, commencement and extent

1. These Regulations may be cited as the Medicated Feedingstuffs (Amendment) (England, Scotland and Wales) Regulations 2002; they extend to England, Scotland and Wales and come into force on 31st March 2002.

Amendment of the Medicated Feedingstuffs Regulations 1998

2.—(1) In so far as they extend to England, Scotland and Wales, the Medicated Feedingstuffs Regulations 1998(**d**) are amended in accordance with this regulation.

(2) In regulation 2(1) for the definition of "the appropriate fee" there is substituted—

""the appropriate fee" means the fee specified in Schedule 1;".

(3) Regulations 6 and 13 are revoked and so are the words "or 6" in regulations 4(4) and 7(1) and (3) and "or 13" in regulations 11(3) and 14(1).

(4) At the end of regulation 35(12) there are inserted the words "and by the Feedingstuffs (Zootechnical Products) (Amendment) (England, Scotland and Wales) Regulation 2002".

(5) The Schedule to these Regulations is substituted for Schedule 1 to those Regulations.

Whitty
Parliamentary Under Secretary of State
Department for Environment, Food and Rural Affairs

14th March 2002

(**a**) S.I. 1972/1811.
(**b**) 1972 c. 68.
(**c**) OJ No. L31, 1.2.2002. p. 1.
(**d**) S.I. 1998/1046 as amended by S.I. 2000/1686.

SCHEDULE

Regulation 2

Substituted Schedule 1

Schedule 1

Regulations 2(1) and 35(1)

Fees

Approval of premises	*Fee* £	*Previous fee*
Grant or renewal of an approval of premises to manufacture an authorised intermediate product	379	£405 for the initial approval and then £253 for annual renewal (£356 if the application for renewal was late)
Grant or renewal of an approval of premises to manufacture medicated feedingstuffs incorporating medicated pre-mixes at any concentration	379	£405 for the initial approval and then £253 for annual renewal (£356 if the application for renewal was late)
Grant or renewal of an approval of premises to manufacture medicated feedingstuffs incorporating medicated pre-mixes at a concentration of 2 kg per tonne or more only	150	£113 for the initial approval and then £71 for annual renewal (£110 if the application for renewal was late)
Grant or renewal of an approval of premises to manufacture medicated feedingstuffs incorporating medicated pre-mixes at a concentration of 2 kg per tonne or more for the manufacturer's own use	89	£113 for the initial approval and then £71 for annual renewal (£110 if the application for renewal was late)
Approval of distributors		
Approval or renewal of approval of distributors	95	£151 for the initial approval and then £90 for annual renewal (£134 if the application for renewal was late)

Note: where more than one of the above activities is carried out at one premises, only one fee is payable, which shall be the highest fee payable for any one of those activities.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicated Feedingstuffs Regulations 1998 in so far as they extend to England, Scotland and Wales. The 1998 Regulations as amended continue to implement Council Directive 90/167/EEC (OJ No. L92, 7.4.90, p.42) laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community.

They provide (at regulation 2 and the Schedule) for new fees for application for approval or renewal of—

—premises manufacturing authorised intermediate products;

—premises which manufacture medicated feedingstuffs incorporating medicated premixes; and

—distributors of medicated feedingstuffs.

The existing fee structure is changed and simplified. Previously, different fees were payable on an initial application for an approval, an application on renewal of an approval, and an application for an approval made outside the time limits in the Regulations. The new system specifies one fee for each of these applications. The previous fees are shown in the Schedule for comparison purposes.

Regulations 6 and 13 of the 1998 Regulations (which provide for late renewals) and references to them are revoked (regulation 2).

A Regulatory Impact Assessment has been prepared and has been placed in the library of each House of Parliament. Copies are available from the Veterinary Medicines Directorate, Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS.

STATUTORY INSTRUMENTS

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