STATUTORY INSTRUMENTS

1994 No. 1531

The Medicines (Medicated Animal Feeding Stuffs) (Amendment) Regulations 1994

Title and commencement

1. These Regulations may be cited as the Medicines (Medicated Animal Feeding Stuffs) (Amendment) Regulations 1994 and shall come into force on 1st July 1994.

Amendment

- **2.** The Medicines (Medicated Animal Feeding Stuffs) (No. 2) Regulations 1992(1) shall be amended in accordance with the following regulations.
- **3.** For regulation 3 (Register of manufacturers of animal feeding stuffs) there shall be substituted the following regulation:

"Register of manufacturers of animal feeding stuffs

- **3.**—(1) For the purposes of these Regulations the registrar and the Department shall each continue to keep a Register comprising parts A and B, each being a list of persons entitled in the course of a business carried on by them—
 - (a) as to Part A—
 - (i) to incorporate medicinal products in any animal feeding stuff on premises in respect of which their names are entered in that Part of the Register,
 - (ii) to store on those premises any animal feeding stuff in which they have incorporated medicinal products, and
 - (iii) to place on the market such animal feeding stuffs; and
 - (b) as to Part B—
 - (i) to incorporate medicinal products in any animal feeding stuff on premises in respect of which their names are entered in that Part of the Register at a rate of at least 2 kilograms per tonne, or to incorporate such products in any animal feeding stuff by way of mobile mixing equipment at that rate,
 - (ii) to store on premises in respect of which their names are entered in that Part of the Register any animal feeding stuff in which they have incorporated medicinal products, and
 - (iii) to place on the market such animal feeding stuffs.
 - (2) Where a person carrying on a business—
 - (a) elsewhere than in Northern Ireland, applies in writing to the registrar, or
 - (b) in Northern Ireland, applies in writing to the Department,

for his name to be entered in Part A or Part B of the Register in respect of any premises on which any medicinal product is to be incorporated in an animal feeding stuff by him in the course of that business or, in the case of a person using mobile mixing equipment, in respect of the premises where that equipment is normally kept, the registrar or the Department as the case may be shall, subject to paragraphs (3) and (4) below, enter his name in Part A or Part B of the Register in respect of those premises.

- (3) The registrar or the Department shall refuse to enter in the Register the name of any person in respect of any premises unless that person has paid the appropriate fee and has given a written undertaking that he will comply with the relevant Code of Practice.
- (4) The registrar with the approval of the Minister, or the Department, may refuse to enter in the Register the name of any person in respect of any premises if, in the opinion of the registrar or the Department (as the case may be), that person cannot demonstrate that he has taken all reasonable steps to ensure that he will comply with the provisions of the relevant Code of Practice.
- (5) A person whose name is entered in the Register in respect of any premises shall, in order to retain his name in the Register in respect of those premises in any year subsequent to the year in which his name is first entered in it, in the month of July in 1994, and thereafter in the month of April in any subsequent year, make a written application to the registrar or the Department (as the case may be) for his name to be retained in the Register in respect of those premises.
- (6) The registrar or the Department shall refuse to retain in the Register in any year subsequent to the year in which his name is first entered in it the name of any person in respect of any premises unless that person has, on or before 31st July in 1994, and thereafter on or before 30th April in any subsequent year, paid the appropriate fee.
- (7) A person whose name is removed from the Register in respect of any premises by reason only that he failed either to make proper application for the retention of his name or to pay the appropriate fee in accordance with paragraphs (5) and (6) above respectively, may, in order to restore his name to the Register in respect of those premises, make a written application, within 11 months of the expiry of the registration, for his name to be restored to the Register in respect of those premises.
- (8) The registrar or the Department shall refuse to restore to the Register the name of any person in respect of any premises unless that person, having made proper application in accordance with paragraph (7) above, has paid the appropriate fee.
- (9) The registrar with the approval of the Minister, or the Department, may refuse to retain in or to restore to, or may remove from, the Register the name of any person in respect of any premises if, in the opinion of the registrar or the Department (as the case may be), that person has failed to comply with any of the provisions of the relevant Code of Practice.
- (10) The registrar or the Department may remove from the Register the name of any person entered in it in respect of any premises, at the request of that person.
- (11) The registrar and the Department, on or before 1st October every year, shall each supply to the Minister a copy of the Register, certified to be a true copy of it as at a date specified in the certificate, not being later than 1st September in the year in question, and shall at monthly intervals supply to the Minister copies of amendments made to the Register in each month following the date specified in the certificate.
 - (12) In this regulation—

"the appropriate fee" means the fee for the entry or retention in, or restoration to, the Register, specified in Schedule 3, and

"the relevant Code of Practice" means, in relation to entry in Part A of the Register, the Code of Practice for Category A Registered Manufacturers of Medicated Animal Feeding Stuffs, and in relation to entry in Part B of the Register, the Code of Practice for Category B Registered Manufacturers of Medicated Animal Feeding Stuffs, both published by the Ministry of Agriculture, Fisheries and Food in December 1991.".

- **4.** In regulation 6 (Restrictions on placing on the market and importation of animal feeding stuffs in which medicinal products have been incorporated)—
 - (a) in paragraph (3)—
 - (i) after the words "animal feeding stuff" where they first appear there shall be inserted the words "which has not been imported",
 - (ii) in sub-paragraph (a)(i) for the words "pursuant to Council Directive 90/167/EEC" there shall be substituted the words "and with any undertaking in respect of the relevant Code of Practice given pursuant to regulation 3(3)", and
 - (iii) in sub-paragraph (a)(ii) the words "or imported" shall be omitted;
 - (b) in paragraph (5) after the word "import" there shall be inserted the words "other than from a member State", and after the word "incorporated" there shall be inserted the words "and place such feeding stuff on the market"; and
 - (c) for paragraph (6) there shall be substituted the following paragraph:
 - "(6) No person shall import from a member State any animal feeding stuff in which a prescription only medicine has been incorporated, and place such feeding stuff on the market, unless that feeding stuff—
 - (a) complies with the provisions of Article 10.1, 1st indent, of Council Directive 90/167/EEC, and
 - (b) each imported consignment is accompanied by a certificate in the form, including the note thereto, set out Schedule 1.".
- **5.** In regulation 8 (Restrictions on placing on the market final medicated feeding stuff containing medicinal products) for paragraph (7) there shall be substituted the following paragraph:
 - "(7) No person shall, in the course of a business carried on by him, place on the market any final medicated feeding stuff in which a prescription only medicine has been incorporated unless—
 - (a) in the case of a feeding stuff which has not been imported, it has been manufactured in accordance with the provisions of these Regulations and with any undertaking given pursuant to regulation 3(3), or
 - (b) in the case of a feeding stuff which has been imported other than from a member State, it has been manufactured in accordance with the provisions of Council Directive 90/167/EEC, or
 - (c) in the case of a feeding stuff which has been imported from a member State, it complies with the provisions of Article 10.1, 1st indent, of that Council Directive."
- **6.** For regulation 9 (Restriction on use of medicated animal feeding stuffs) there shall be substituted the following regulation:

"Restriction on use of medicated animal feeding stuffs

- **9.** No person shall use any medicated animal feeding stuff in which a prescription only medicinal product has been incorporated unless—
 - (a) in the case of a feeding stuff which has not been imported, it has been manufactured in accordance with the provisions of these Regulations and with any undertaking given pursuant to regulation 3(3), or

- (b) in the case of a feeding stuff which has been imported other than from a member State, it has been manufactured in accordance with the provisions of Council Directive 90/167/EEC, or
- (c) in the case of a feeding stuff which has been imported from a member State, it complies with the provisions of Article 10.1, 1st indent, of that Council Directive."
- 7. In Schedule 2 (Veterinary Written Direction) in Note 2 at the end of Section IV, for the words "if any part of Section IV" there shall be substituted the words "If part 1 of Section IV".
 - **8.** After Schedule 2 there shall be added the Schedule set out in the Schedule to these Regulations.

In witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on

L.S.

7th June 1994.

Gillian Shephard Minister of Agriculture, Fisheries and Food

Hector Monro
Parliamentary Under Secretary of State, Scottish
Office

9th June 1994

Signed by authority of the Secretary of State for Wales

7th June 1994

Wyn Roberts
Minister of State, Welsh Office

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this

L.S.

9th day of June 1994.

P. T. Toal
Assistant Secretary

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

We consent

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

8th June 1994