STATUTORY INSTRUMENTS

2003 No. 545

The Feedingstuffs (Zootechnical Products) (Amendment) Regulations 2003

Title, commencement and extent

1.—(1) These Regulations may be cited as the Feedingstuffs (Zootechnical Products) (Amendment) Regulations 2003 and, except as provided for in paragraph (2), shall come into force on 1st May 2003.

(2) Regulation 3 shall extend only to Scotland, England and Wales and shall come into force on 31st March 2003.

Amendment of the Feedingstuffs (Zootechnical Products) Regulations 1999

2.—(1) The Feedingstuffs (Zootechnical Products) Regulations 1999(**1**) shall be amended in accordance with this regulation.

(2) In regulation 2(1), for the definition of "Directive 95/53", substitute:

""Directive 95/53/EC" means Council Directive 95/53 fixing the principles governing the organisation of official inspections in the field of animal nutrition(**2**) as amended by Council Directive 1999/20/EC(**3**), Directive 2000/77/EC of the European Parliament and of the Council(**4**), and Directive 2001/46/EC of the European Parliament and of the Council(**5**);".

(3) In Schedule 1, after item 3, insert the following item:

"**4.** Commission Regulation (EC) No. 2205/2001 (OJ L 297, 15.11.2001, p. 3) amending Council Directive 70/524/EEC concerning additives in feedingstuffs as regards withdrawal of the authorisation of certain additives.".

Amendment of the Feedingstuffs (Zootechnical Products) Regulations 1999 in Scotland, England and Wales

3.—(1) The Feedingstuffs (Zootechnical Products) Regulations 1999 shall be amended in their application to Scotland, England and Wales in accordance with this regulation.

(2) In regulation 2(1), for the definition of "the MF Regulations", substitute:

""the MF Regulations" means the Medicated Feedingstuffs Regulations 1998(**6**) as amended by the Feedingstuffs (Zootechnical Products) and Medicated Feedingstuffs (Amendment) Regulations 2000(**7**), the Medicated Feedingstuffs (Amendment) (England, Scotland and Wales) Regulations 2002(**8**) and the Medicated Feedingstuffs (Amendment) (Scotland, England and Wales) Regulations 2003(**9**);".

(**1**) SI 1999/1871, as amended by SI 2000/1686 and SI 2002/696.
(**2**) OJ No. L 265, 8.11.1995, p. 17.
(**3**) OJ No. L 80, 25.3.1999, p. 20.
(**4**) OJ No. L 333, 29.12.2000, p. 81.
(**5**) OJ No. L 234, 1.9.2001, p. 55.
(**6**) SI 1998/1046.
(**7**) SI 2000/1686.
(**8**) SI 2002/697.

(3) In regulation 10(2) for "An application made under paragraph (1) shall be in writing", substitute:

"Save as provided for in paragraph (3), an application made under paragraph (1) shall be in writing.".

(4) After regulation 10(2) insert the following paragraph:

> "(3) An application made under paragraph (1)(a) need not be accompanied by particulars demonstrating that the establishment meets the applicable minimum conditions laid down in the Annex to Directive 95/69/EC if the applicant holds a valid Medicines Act licence to manufacture authorised medicated pre-mixes and he submits a copy of that licence with his application.".

(5) In regulation 11(1)(a), before "check by means of an on-the-spot verification" insert:

"except in the case of an application falling within regulation 10(3),".

(6) In regulation 11(2) for "Where the enforcement authority is satisfied that" substitute:

"Save as provided for in paragraph (3), where the enforcement authority is satisfied that".

(7) After regulation 11(2), insert the following paragraph:

> "(3) In the case of an application falling within regulation 10(3) the enforcement authority need not be satisfied that the establishment meets the applicable minimum conditions as laid down in the Annex to Directive 95/69/EC before approving the establishment in accordance with regulation 11(2), if the enforcement authority is satisfied that the applicant is an eligible person holding a valid Medicines Act licence in respect of the manufacture of authorised medicated pre-mixes.".

(8) In regulation 12(2), after "complying with regulation 10(2)" insert:

"but not falling within regulation 10(3)".

(9) After regulation 12(2), insert the following paragraph:

> "(2A) Where an application complying with regulation 10(2) and falling within regulation 10(3) is made under paragraph (1), the enforcement authority shall (subject to regulation 15) amend the approval relating to the establishment, and approve the establishment as an establishment on which the new establishment activity may be exercised, if, following the procedure in regulation 11(1), it is satisfied that, in respect of the new establishment activity, the applicant is an eligible person holding a valid Medicines Act licence in respect of the manufacture of authorised medicated pre-mixes.".

(10) In regulation 12(3) for "pursuant to paragraph (2)" substitute:

"pursuant to paragraphs (2) and (2A)".

(11) In regulation 13, after paragraph (2) insert the following paragraph:

> "(2A) The enforcement authority shall withdraw a regulation 10(3) approval if it is no longer satisfied that the licence relied upon by the applicant under regulation 10(3) is valid in respect of the manufacture of authorised medicated pre-mixes, or that the holder of the licence is an eligible person.".

(12) In regulation 14(1) after "as the case may be" insert:

"or in the case of a regulation 10(3) approval, it is not satisfied that a licence relied upon under regulation 10(3) is valid in respect of the manufacture of authorised medicated pre-mixes, and that the licence holder is an eligible person,".

(13) In regulation 14(2) before "A notice served by the enforcement authority under paragraph (1) shall—" insert:

"Except in respect of the proposed withdrawal of a regulation 10(3) approval,"

(**9**) SI 2003/752.

(14) After regulation 14(2), insert the following paragraph:

"(3) Insofar as a notice served by the enforcement authority under paragraph (1) relates to the proposed withdrawal of a regulation 10(3) approval, it shall—

(a) state that the enforcement authority proposes to withdraw the regulation 10(3) approval because it is not satisfied that the recipient of the notice is an eligible person holding a valid Medicines Act licence in respect of the manufacture of authorised medicated pre-mixes ("the regulation 10(3) criteria");

(b) specify in what respect the regulation 10(3) criteria are not met;

(c) specify the requirements that the recipient of the notice must comply with in order to satisfy the enforcement authority as to compliance with the regulation 10(3) criteria;

(d) stipulate a reasonable time by when such requirements specified on the notice shall be met; and

(e) state that, unless it is satisfied that the recipient of the notice has complied with its requirements, the regulation 10(3) approval will be withdrawn."

(15) In regulation 15(3), for "as a debt" substitute "on demand.".

(16) After regulation 15(5) insert the following paragraph:

"(5A) Where an application to the enforcement authority made by an eligible person falls within regulation 10(3), the applicant shall not be liable to pay a fee to the enforcement authority."

(17) In regulation 17:

(a) after the definition of "approved establishment" insert—

""authorised medicated premixes" has the same meaning as in the MF Regulations;";

(b) after the definition of "essential conditions" delete "and"; and

(c) after the definition for "establishment activity", insert—

""Medicines Act licence" means a licence issued pursuant to section 8(2) of the Medicines Act 1968(**10**); and

"regulation 10(3) approval" means an approval granted under regulation 11 in respect of the manufacture of a zootechnical additive with a view to putting it into circulation following an application falling within regulation 10(3).".

(18) Delete regulation 75(2) and substitute the following paragraphs—

"(2) The occupier of premises specified in Part II of Schedule 3, and intermediaries specified in Part III, shall, within 30 days of a notice from the enforcement authority requiring it, pay to that enforcement authority the annual fee covering official checks specified in Schedule 3; except that this obligation shall not apply in relation to premises approved for the manufacture of medicated premixes under the Medicines Act 1968.

(3) A fee payable under paragraph (2) or any part of such a fee shall if due and unpaid be recoverable on demand."

(19) In Schedule 3, for Parts II and III shall be substituted Parts II and III set out in the Schedule to these Regulations.

(**10**) 1968 c. 67.

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6th March 2003