STATUTORY INSTRUMENTS

1998 No. 1046

The Medicated Feedingstuffs Regulations 1998

PART VIII

MISCELLANEOUS AND SUPPLEMENTAL PROVISIONS

Recovery of fees

35.—(1) Subject to paragraphs (5) to (10), the appropriate fee shall be payable by a person who makes an application of a description listed in Schedule 1.

(2) Any fee payable under paragraph (1) shall be paid at the time the application is submitted to the relevant authority.

(3) Any unpaid sum due by way of a fee payable under paragraph (1), or any part of such fee, shall be recoverable as a debt.

(4) Where any fee is payable under paragraph (1) in relation to any application the relevant authority need not process any application under these Regulations, unless the application is accompanied by the appropriate fee.

(5) Where an applicant under regulation 3, in relation to the same premises, applies on the same date (evidenced by the date on the application forms) to the enforcement authority under regulation 10 of the Feedingstuffs (Zootechnical Products) Regulations 1998(**1**) for an establishment to be approved as an establishment on which an establishment activity may be exercised, he shall be liable to pay only one fee under both these Regulations and the Feedingstuffs (Zootechnical Products) Regulations 1998 and, where the appropriate fee differs in amount from the fee payable under the Feedingstuffs (Zootechnical Products) Regulations 1998, the fee payable shall be the higher amount.

(6) An applicant under regulation 3 shall not be liable to pay the appropriate fee in relation to the manufacture of medicated feedingstuffs on premises, where he has applied to the enforcement authority under regulation 10 of the Feedingstuffs (Zootechnical Products) Regulations 1998 for approval of an establishment on the same premises as an establishment on which an establishment activity may be exercised, if he applies under regulation 3 within twelve months of his application under regulation 10 of the Feedingstuffs (Zootechnical Products) Regulations 1998 and at the date of his application under regulation 3:

(a) an on the spot verification by the enforcement authority is pending in relation to his application under regulation 10 of the Feedingstuffs (Zootechnical Products) Regulations 1998, or

(b) the enforcement authority has conducted an on the spot verification in relation to his application under regulation 10 and has granted approval pursuant to regulation 11 of the Feedingstuffs (Zootechnical Products) Regulations 1998 which has not been withdrawn.

(7) Where an applicant under regulation 3 of these Regulations, in relation to the same premises, applies on the same date (evidenced by the date on the application forms) to the relevant authority under regulation 12 of the Feedingstuffs (Zootechnical Products) Regulations 1998 for an

(**1**) S.I.1998/1047.

establishment to be approved as an establishment on which a new establishment activity may be exercised, he shall be liable to pay only one fee under both these Regulations and the Feedingstuffs (Zootechnical Products) Regulations 1998 and, where the appropriate fee differs in amount from the fee payable under the Feedingstuffs (Zootechnical Products) Regulations 1998, the fee payable shall be the higher amount.

(8) An applicant under regulation 3 shall not be liable to pay the appropriate fee in relation to the manufacture of medicated feedingstuffs on premises, where he has applied to the enforcement authority under regulation 12 of the Feedingstuffs (Zootechnical Products) Regulations 1998 for an establishment on the same premises to be approved as an establishment on which a new establishment activity may be exercised, if he applies under regulation 3 within twelve months of his application under regulation 12 of the Feedingstuffs (Zootechnical Products) Regulations 1998 and at the date of his application under regulation 3:

(a) an on the spot verification by the enforcement authority is pending in relation to his application under regulation 12 of the Feedingstuffs (Zootechnical Products) Regulations 1998, or

(b) the enforcement authority has conducted an on the spot verification in relation to his application under regulation 12 and has granted approval pursuant to regulation 12(2) of the Feedingstuffs (Zootechnical Products) Regulations 1998 which has not been withdrawn.

(9) A person who has paid a sum by way of a fee under regulation 3 of the Medicines (Medicated Animal Feedingstuffs) (No. 2) Regulations 1992(**2**) for entry or retention of premises in, or restoration of premises to, Part A or B of the Register of Manufacturers of Animal Feedingstuffs in respect of the financial year commencing 1st April 1998 shall by virtue of this provision be treated for the purposes of this regulation as having paid that sum towards payment of the appropriate fee (in respect of the financial year ending on 31st March 1999) referred to under the column headed "Applications for approvals of premises" in item 1 or 2 of Schedule 1, and shall be entitled to a refund of any surplus over that appropriate fee.

(10) A person who has paid a sum by way of a fee under regulation 8 of the Medicines (Pharmacy and Merchants' List Order) 1992(**3**) for entry or retention of his name in, or restoration of his name to, the Register of Merchants in respect of the year commencing 1st January 1998 shall by virtue of this provision be treated for the purposes of this regulation as having paid that sum towards payment of the appropriate fee (in respect of the year ending on 31st December 1998) referred to under the column headed "Applications for approvals to retail supply as distributor" in item 1 of Schedule 1, and shall be entitled to a refund of any surplus over that appropriate fee.

(11) A fee payable under combined regulations as described in paragraphs (5) and (7) shall be treated for the purposes of paragraphs (2) to (4) as included among fees payable under paragraph (1).

Sampling checks and enforcement

36. It shall be the duty of the enforcement authority to make sampling checks in accordance with the provisions of Article 13 of the Medicated Feedingstuffs Directive and to enforce these Regulations.

Powers of authorised persons

37.—(1) An authorised person may at all reasonable times and on producing, if so required, some duly authenticated document showing his authority, exercise the powers specified in this regulation for the purposes of—

(**2**) S.I. 1992/1520; relevant amending instruments are S.I. 1994/1531, 1995/799 and 1997/638; Revoked by S.I. 1998/1048.
(**3**) S.I. 1992/33, amended by S.I. 1992/3081, 1994/599, 3142 and 3169, 1995/3193, 1996/3034 and 1997/2892 and revoked by S.I. 1998/1044.

(a) carrying out sampling checks, and

(b) ascertaining whether an offence under regulation 38 has been or is being committed.

(2) An authorised person shall have the right to enter any premises (not being premises used only as a dwelling) on which he has reasonable cause to believe that—

(a) a medicated pre-mix or intermediate product is being or has been retail supplied or is being kept there for the purpose of being retail supplied;

(b) an intermediate product or medicated feedingstuff is being or has been manufactured;

(c) a medicated feedingstuff is being or has been placed on the market, put into circulation, supplied or used or is being kept there for the purpose of being placed on the market, put into circulation, supplied or used; or

(d) a medicated feedingstuff is being or has been held.

(3) An authorised person entering any premises by virtue of this regulation may take with him such other persons and such equipment as may appear to him to be necessary.

(4) An authorised person shall have the right to inspect—

(a) any substance appearing to him to be a medicated pre-mix, an intermediate product or a medicated feedingstuff;

(b) any article appearing to him to be a container or package used or intended to be used to contain a medicated feedingstuff, or to be a label used or intended to be used in connection with the labelling of any such feedingstuff; and

(c) any plant or equipment appearing to him to be used or intended to be used in connection with the manufacture of an intermediate product or medicated feedingstuff and any process of manufacture of such a product or feedingstuff, and the means employed, at any stage in the process of manufacture, for testing the product or feedingstuff after it has been subject to those processes.

(5) An authorised person shall have the right to take a sample of—

(a) any substance appearing to him to be a medicated pre-mix and to be in the course of being, or having been, retail supplied;

(b) any substance appearing to him to be an intermediate product and to be in the course of being, or having been, manufactured or retail supplied;

(c) any substance appearing to him to be a medicated feedingstuff and to be in the course of being, or having been, manufactured, placed on the market, put into circulation, supplied or used or to be otherwise being held; and

(d) a substance appearing to him to be used or intended to be used in the manufacture of an intermediate product or medicated feedingstuff.

(6) An authorised person shall have the right—

(a) to require any person carrying on a business which consists of or includes the activities of—

(i) retail supply of a medicated pre-mix or intermediate product;

(ii) manufacture of an intermediate product or medicated feedingstuff;

(iii) placing on the market, putting into circulation, supply or use of a medicated feedingstuff,

and any person employed in connection with such a business, to produce any records relating to those activities which are in his possession or under his control, including records kept pursuant to regulations 19, 22 and 24(1)(g) and an MFS prescription, or a copy of such a prescription, and

(b) to take copies of, or of any entry in, any record, produced in pursuance of the preceding paragraph.

(7) An authorised person exercising the power conferred by paragraph (6) in respect of a record held by means of a computer—

(a) shall be entitled at any reasonable time to have access to, and inspect and check the operation of, any computer and associated apparatus or material which is or has been in use in connection with the record in question;

(b) may require—

(i) the person by whom or on whose behalf the computer is or has been so used, or

(ii) any person having charge of, or otherwise concerned with the operation of, the computer, apparatus or material,

to afford the authorised person such reasonable assistance as he may require for the purpose; and

(c) may require the record, or an extract from the record, to be produced in a form in which it may be taken away.

(8) An authorised person shall have the right to seize and detain any medicated pre-mix, intermediate product or medicated feedingstuff which he has reason to believe to be a medicated pre-mix, an intermediate product or a medicated feedingstuff in relation to which, or by means of which, an offence under these Regulations is being or has been committed, and any record, including a record kept pursuant to regulations 19, 22 and 24(1)(g) and an MFS prescription, or a copy of such prescription, which he has reasonable cause to believe to be a record which may be required as evidence in proceedings under these Regulations.

Offences

38. It shall be an offence for a person—

(a) without reasonable excuse, to contravene any provision of regulation 18, 20(1) or (2), 21, 23, 24(1), 25, 26, 27(1), 28(1) or (2), 29(1) or (2), 30, 32 or 33;

(b) without reasonable excuse, to fail to comply with any provision of regulation 19, 20(3), 22, 28(3), 29(3) to (7) or 31;

(c) intentionally to obstruct an authorised person in the exercise of a power conferred by regulation 37; or

(d) without reasonable excuse, to fail to comply with any requirement made of him, pursuant to regulation 37 by an authorised person.

Punishment of offences

39.—(1) Any person who commits any of the offences set out in regulation 38(a) shall be liable—

(a) on summary conviction, to a fine not exceeding the statutory maximum; and

(b) on conviction on indictment, to a fine.

(2) Any person who commits any of the offences set out in regulation 38(b) shall be liable on summary conviction to a fine not exceeding level 5 on the standard scale.

(3) Any person who commits any of the offences set out in regulation 38(c) or 38(d) shall be liable on summary conviction to a fine not exceeding level 3 on the standard scale.

Offences by bodies corporate and Scottish partnerships

40.—(1) Where a body corporate is guilty of an offence under these Regulations, and that offence is proved to have been committed with the consent or connivance of, or to be attributable to, any neglect on the part of—

(a) any director, manager, secretary or other similar officer of the body corporate, or

(b) any person who was purporting to act in any such capacity,

he as well as the body corporate, shall be guilty of the offence and liable to be proceeded against and punished accordingly.

(2) For the purposes of paragraph (1), "director" in relation to a body corporate whose affairs are managed by its members, means a member of the body corporate.

(3) Where a Scottish partnership is guilty of an offence under these Regulations in respect of an act or default which is shown to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, a partner in the partnership, he, as well as the partnership, shall be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Defence

41. Any person who manufactures, places on the market, puts into circulation, supplies or uses a medicated feedingstuff in accordance with a forged MFS prescription shall not be guilty of an offence under these Regulations if, having exercised all due diligence, he believes on reasonable grounds that the MFS prescription is genuine.

Service of notices

42. Any notice required to be served on a person under any provision of these Regulations may be served—

(a) by delivering it to him;

(b) by leaving it at the usual or last known place of abode or business of that person or, in a case where an address for service has been given by that person, at that address;

(c) by sending it in a prepaid registered letter, or by the recorded delivery service, addressed to that person at his usual or last-known place of abode or business or, in a case where an address for service has been given by that person, at that address; or

(d) in the case of a body corporate, by delivering it to the secretary or clerk of the body corporate at its registered or principal office or by sending it in a prepaid registered letter, or by the recorded delivery service, addressed to the secretary or clerk of that body corporate at that office.

Exclusion of the application of the Medicines Act 1968

43.—(1) Except as specified in paragraph (2), the Medicines Act 1968(**4**), and instruments made wholly or partly under that Act, shall not apply—

(a) to the retail supply of medicated pre-mixes, or intermediate products or

(b) to the activities in relation to medicated feedingstuffs regulated by Part VII of these Regulations.

(2) The provisions of sections 32 to 36 (other than section 35(8)(a)), 38 and 39 of the Medicines Act 1968, and instruments made under any of those provisions shall apply to—

(a) the retail supply of intermediate products, and

(**4**) 1968 c. 67.

(b) the activities so regulated in relation to medicated feedingstuffs being used in connection with an Article 7.2 scientific test as if paragraph (1) had not come into force.