# STATUTORY INSTRUMENTS

# 1999 No. 1871

# The Feedingstuffs (Zootechnical Products) Regulations 1999

# PART IX

# MISCELLANEOUS AND SUPPLEMENTAL PROVISIONS

#### Restrictions on toxicological tests on vertebrates

**72.** No person applying, or intending to apply, for the Community authorisation of a zootechnical additive shall begin toxicological tests on vertebrates unless, before beginning the tests, he has—

- (a) carried out a check of the type specified in the first paragraph of Article 9c.6 of Directive 70/524/EEC, as amended by Directive 96/51/EC, and
- (b) otherwise complied with the requirements of the first and second paragraphs of Article 9c.6 of Directive 70/524/EEC, as amended by Directive 96/51/EC.

## Confidential information relating to zootechnical additives

**73.**—(1) Subject to paragraphs (2) and (3), no person shall publish or disclose any confidential information relating to a zootechnical additive obtained by him in the performance of functions under these Regulations and to which this regulation applies without the previous consent in writing of the person responsible for putting the additive into circulation.

(2) Nothing in paragraph (1) shall restrict the publication or disclosure of such information for the purpose of the exercise of functions under Part II of these Regulations or the disclosure of such information for the purpose of the exercise of any function, or of assisting any authority in the exercise of any function bestowed on it, in implementation of any Directive referred to in regulation 2.

(3) Nothing in paragraph (1) shall prevent the publication or disclosure of confidential information of a type specified in Article 7.2 of Directive 70/524/EEC as amended by Directive 96/51/EC.

(4) In this regulation, "confidential information" means information of the type specified in Article 7.1 of Directive 70/524/EEC as amended by Directive 96/51/EC.

#### Use of Article 9c data

**74.** No person shall use scientific data and other information of the type specified in Article 9c of Directive 70/524/EEC, as amended by Directive 96/51/EC, unless the use of the data is in accordance with Article 9c of Directive 70/524/EEC as so amended.

# Official checks and enforcement

**75.** It shall be the duty of the enforcement authority to carry out official checks and enforce these Regulations.

#### **Powers of authorised persons**

**76.**—(1) An authorised person may exercise the powers specified in this regulation for the purposes of—

- (a) carrying out any official checks, and
- (b) ascertaining whether an offence under regulation 85(a), (b) or (c) has been or is being committed.

(2) An authorised person shall have the right at all reasonable times, and on producing, if so required, some duly authenticated document showing his authority, to enter—

- (a) any premises on which he has reasonable cause to believe that a zootechnical product has been, or is being, manufactured or produced, or is being kept for the purpose of being put into circulation, placed on the market, marketed, supplied, incorporated or used, and
- (b) any premises (not being premises appearing to be used only as a dwelling) on which he has reasonable cause to believe that there is any such product which the occupier of the premises has in his possession or under his control.

(3) If a justice of the peace, on sworn information in writing, is satisfied that there is reasonable ground for entry into any such premises as are mentioned in paragraph (2), for any such purpose as is mentioned in paragraph (1), and either—

- (a) that admission to the premises has been refused, or a refusal is apprehended, and that notice of the intention to apply for a warrant has been given to the occupier; or
- (b) that an application for admission, or the giving of such a notice, would defeat the object of the entry, or that the case is one of urgency, or that the premises are unoccupied or the occupier temporarily absent,

the justice may by warrant signed by him authorise the authorised officer to enter the premises, if need be by reasonable force.

- (4) Every warrant granted under this regulation shall continue in force for a period of one month.
- (5) In the application of paragraph (3)—
  - (a) to Scotland, any reference to a justice of the peace includes a reference to the sheriff and to a magistrate, and
  - (b) to Northern Ireland, the reference to a sworn information in writing includes a reference to a sworn complaint in writing.

(6) An authorised person entering any premises by virtue of this regulation, or of a warrant issued under it, may take with him such other persons and such equipment as may appear to him to be necessary for the purposes mentioned in sub-paragraphs (a) and (b) of paragraph (1), and on leaving any unoccupied premises which he has entered by virtue of such a warrant, shall leave them as effectively secured against unauthorised entry as he found them.

(7) An authorised person entering premises by virtue of this regulation, or of a warrant issued under it, shall have the right to inspect—

- (a) any material appearing to him to be a zootechnical product;
- (b) any article appearing to him to be a container or package used or intended to be used to wrap, package or store any such product, or to be a label used or intended to be used in connection with any such product; or
- (c) any plant or equipment appearing to him to be used, or intended to be used, in connection with the manufacture or production of any zootechnical product, and any process of manufacture or production of such a product, and the means employed, at any stage in the process of manufacture or production, for testing the product after it has been subject to those processes.

(8) Subject to paragraph (9), an authorised person entering premises by virtue of this regulation, or of a warrant issued under it, shall have the right to take on those premises, and prepare, a sample of—

- (a) any material appearing to him to be a zootechnical product manufactured, produced, wrapped, packaged, stored, circulated, marketed or supplied, or intended to be circulated, marketed or supplied; or
- (b) any material appearing to him to be a zootechnical product, used, or intended to be used, for the purpose of animal feeding,

in the like manner as that prescribed-

- (i) in the case of Great Britain, in Part II of Schedule 1 to the Feeding Stuffs (Sampling and Analysis) Regulations 1999(1), or
- (ii) in the case of Northern Ireland, in Part II of Schedule 1 to the Feeding Stuffs (Sampling and Analysis) Regulations (Northern Ireland) 1999(2),

and paragraph 10 of Part II of Schedule 1 to the Regulations concerned shall have effect for the purposes of the certificate referred to in regulations 80 and 82(2)(b).

(9) For the purposes of this Part of these Regulations, the provisions of regulation 3 and Schedule 1 to the Feeding Stuffs (Sampling and Analysis) Regulations 1999 or, as the case may be, of regulation 3 and Schedule 1 to the Feeding Stuffs (Sampling and Analysis) Regulations (Northern Ireland) 1999 shall have effect as if—

- (a) for all references to "feeding stuff" or to "feeding stuffs" there were substituted references to "zootechnical product" or to "zootechnical products" respectively, and
- (b) in paragraph 1 of Part II of Schedule 1 to the Regulations concerned, the expression ", except where section 68(2)(b) of the Act applies" were omitted.

(10) An authorised person entering premises by virtue of this regulation, or of a warrant issued under it, shall have the right—

- (a) to require any person carrying on, or appearing to be carrying on, a business which consists of or includes the activities of manufacture, production, wrapping, packaging, storage, circulation, marketing, supply or use of a zootechnical product, and any person employed in connection with such a business, to produce any record (in whatever form it is held) relating to or arising out of the exercise in the course of that business of any such activity, and which is in his possession or under his control, and
- (b) to inspect and take copies of any record, or of any entry in any record, produced in pursuance of the preceding sub-paragraph.

(11) An authorised person exercising the power conferred by paragraph (10) 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, or which it appears 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 that purpose; and

<sup>(1)</sup> S.I. 1999/1663.

<sup>(2)</sup> S.R. 1999/No.

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

(12) An authorised person entering premises by virtue of this regulation, or of a warrant issued under it, shall have the right to seize and detain any product which he has reason to believe to be a zootechnical product in relation to which, or by means of which, an offence under these Regulations is being or has been committed, and any record which he has reasonable cause to believe to be a record which may be required as evidence in proceedings under these Regulations.

(13) In this regulation—

- (a) "premises" includes any land, vehicle, vessel, aircraft or hovercraft; and
- (b) "zootechnical product" has the same meaning as that given to it in regulation 2(1), but also includes any substance or material (other than a machine or implement) appearing to be used, or intended to be used, in the manufacture or production of any zootechnical product.

#### **Division of samples**

77. Where, in accordance with these Regulations, an authorised person obtains a sample, and decides to have it analysed for the purpose of ascertaining whether there is or has been any contravention of any provision of these Regulations in connection with a zootechnical product, he shall divide the sample into three parts, of as near as may be equal size and shall—

- (a) cause each part to be marked, sealed and fastened in the like manner as that prescribed—
  - (i) in the case of Great Britain, in Part III of Schedule 1 to the Feeding Stuffs (Sampling and Analysis) Regulations 1999, or
  - (ii) in the case of Northern Ireland, in Part III of Schedule 1 to the Feeding Stuffs (Sampling and Analysis) Regulations (Northern Ireland) 1999;
- (b) send one part for analysis to-
  - (i) in Great Britain, an analyst, and
  - (ii) in Northern Ireland, an agricultural analyst in Northern Ireland;
- (c) send another part to the person subject to the official check; and
- (d) retain and preserve the remaining part as an officially sealed reference sample.

#### Supply of part of sample to manufacturer

**78.** If the person who manufactured any material of which an authorised person has taken a sample is not a person to whom part of the sample is required to be sent under regulation 77, that regulation shall have effect as if, for the reference to three parts, there were substituted a reference to four parts, and the authorised person shall send the fourth part to the manufacturer, unless he does not know the manufacturer's name, or any address of his in the United Kingdom, and is unable, after making reasonable enquiries, to ascertain the name or, as the case may be, any such address, before the expiration of fourteen days from the date when the sample was taken.

#### Statement to accompany sample

**79.** There shall be sent, with the part of the sample sent pursuant to regulation 77, a statement signed by the authorised person that the sample was taken in the manner referred to in regulation 76(8).

#### Analysis by analyst

**80.** The analyst shall analyse the part of the sample sent to him under regulation 77, and send a certificate of the analysis, completed in the form set out in Schedule 4, and in accordance with the notes set out in that Schedule, to the authorised person, who shall send a copy to—

- (a) the person who was subjected to the official check concerned, and
- (b) any person to whom he has sent a part of the sample pursuant to regulation 78.

## Alternative arrangements for carrying out analyses

**81.** If the analyst to whom a sample is sent for analysis under regulation 77 determines that an effective analysis of the sample cannot be made by him or under his direction, he shall send it to another analyst or, in Northern Ireland, to another agricultural analyst in Northern Ireland, together with any documents received by him with the sample, and thereupon regulation 80 shall apply, as if the sample had originally been sent to that other analyst or, as the case may be, agricultural analyst in Northern Ireland.

#### Further analysis of samples

**82.**—(1) Where a part of a sample sent pursuant to regulation 77 has been analysed, and it is intended to institute proceedings, or proceedings have been commenced, against a person for an offence under regulation 85(a), (b) or (c), and it is intended to adduce, on behalf of the prosecution, evidence of the result of the analysis of that part of the sample, the defendant, for the purpose of obtaining a second opinion, may request the authorised person to send the retained part of the sample for analysis to—

- (a) where the sample was taken in Great Britain, the Government Chemist, and
- (b) where the sample was taken in Northern Ireland, the Chief Agricultural Analyst.

(2) Where a defendant requests the authorised person to send the retained part of the sample to the Government Chemist or, as the case may be, the Chief Agricultural Analyst, pursuant to paragraph (1), the following procedure shall (subject to paragraph (3)), be followed—

- (a) the authorised person shall—
  - (i) send the retained part of the sample for analysis to the Government Chemist or, as the case may be, the Chief Agricultural Analyst, and
  - (ii) supply the defendant with a copy of the Government Chemist's or, as the case may be, the Chief Agricultural Analyst's, certificate of analysis of that part of the sample; and
- (b) the Government Chemist or, as the case may be, the Chief Agricultural Analyst, shall analyse the part of the sample sent to him under sub-paragraph (a) above and shall send to the authorised person a certificate of the analysis, completed in the form set out in Schedule 4, and in accordance with the notes set out in that Schedule.

(3) The authorised person may in any case give notice in writing to the defendant requesting payment of a fee specified in the notice in respect of performance of the functions specified in paragraph (2)(b) and, if the fee so specified exceeds neither—

- (a) the cost of performing them, nor
- (b) the appropriate fee for the performance of any similar function under section 78 of the 1970 Act,

the authorised person may, in the absence of agreement by the defendant to pay the fee, refuse to comply with the request made under paragraph (1).

(4) In this regulation "defendant" includes a prospective defendant.

#### Default Powers of the Minister of Agriculture, Fisheries and Food

**83.** For the purposes of this Part of these Regulations, if the Minister is of opinion that, in any area within Great Britain, these Regulations have been—

- (a) insufficiently enforced or administered, or
- (b) if applicable, enforced without sufficient regard to the requirements of Directive 95/53/EC,

he may himself appoint one or more persons to exercise in that area the powers exercisable there by authorised persons; and any expenses certified by him as having been incurred by him under this regulation shall be repaid to him, on demand, by the enforcement authority.

#### **Methods of Analysis**

**84.**—(1) Subject to paragraphs (2) and (3), for the purpose of determining, by means of analysis of a part of a sample taken in the course of the carrying out of official checks, whether a substance—

- (a) of a class or description listed in column 1 of Part I of Schedule 5, or
- (b) to which the method of analysis set out in Part II, or the method set out in Part III, of that Schedule, relates,

is present in that part, or what quantity or proportion of such a substance is present therein,

- (i) the provisions specified, in the case of Great Britain, in Part I of Schedule 2 to the Feeding Stuffs (Sampling and Analysis) Regulations 1999 or, in the case of Northern Ireland, in Part I of Schedule 2 to the Feeding Stuffs (Sampling and Analysis) (Northern Ireland) Regulations 1999, under the heading "GENERAL PROVISIONS", shall have effect, in the like manner as they have effect under the Regulations in question in relation to feeding stuffs;
- (ii) in relation to a substance of a class or description listed in column 1 of Part I of Schedule 5, the relevant method of analysis set out in the European Community provision in force specified in the corresponding entry in column 2 of that Part shall be used; and
- (iii) in relation to a substance to which the method of analysis set out in Part II, or the method set out in Part III, of that Schedule relates, the method applicable to that substance shall be used.

(2) Paragraph (1) shall not apply before 1st November 1999 in the case of the following substances listed in column 1 of Part I of Schedule 5—

- (a) carbadox; and
- (b) diclazuril.
- (3) After 31st October 1999, paragraph (1) shall—
  - (a) cease to apply to the following substances listed in column 1 of Part I of Schedule 5—
    - (i) ethopabate,
    - (ii) dinitolmide,
    - (iii) menadione (vitamin K3),
    - (iv) nicarbazin, and
    - (v) vitamin A;
  - (b) have effect, in the case of the substance amprolium, which is included in the list in column 1 of Part I of Schedule 5, with the substitution, for the words appearing in column 2 of that Part opposite to the entry for that substance, of the words "Part A of the Annex to Directive 1999/27/EC."(3).

<sup>(</sup>**3**) OJ No. L118, 6.5.99, p. 36.

(4) For the purpose of determining, by means of analysis as aforesaid, whether a substance other than one to which paragraph (1) applies is present in the part of a sample concerned, or what quantity or proportion of such a substance is present therein—

- (a) if there is an applicable standard of the kind referred to in the first indent of Article 18.3 of Directive 95/53/EC, analysis shall be carried out in accordance with that standard, and
- (b) if there is no such standard, it shall be carried out in accordance with any scientifically valid method the application of which does not contravene any general principle of the Treaty establishing the European Community.

#### Offences

85. It shall be an offence for a person—

- (a) without reasonable excuse, to contravene any provision of regulation 33, 35, 36, 37, 39, 41(1) or (2), 42(1), 43(1), (2) or (54), 44(1) or (2), 45, 49, 51, 52, 53, 55, 57(1), 58(1), 59(1), 60, 61, 63, 65, 66(1), 67, 68(1), 69 to 72 inclusive, 73(1) or 74;
- (b) without reasonable excuse, to fail to comply with any provision of regulation 34, 38, 40, 46, 47(1), 48, 50, 54, 56, 62 or 64;
- (c) in connection with these Regulations to make a statement which he knows to be false in a material particular, or recklessly to make a statement which is false in a material particular;
- (d) intentionally to obstruct an authorised person in the exercise of a power conferred by regulation 76; or
- (e) without reasonable excuse, to fail to comply with any requirement lawfully made of him, pursuant to regulation 76, by an authorised person.

# **Punishment of offences**

**86.**—(1) Any person who commits any of the offences set out in regulation 85(a) or (c) 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 85(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 85(d) or 85(e) shall be liable on summary conviction to a fine not exceeding level 3 on the standard scale.

## Time limit for prosecutions

**87.**—(1) Proceedings for an offence under regulation 85(b) or (c) may, subject to paragraph (2) below, be commenced within the period of six months from the date on which evidence sufficient in the opinion of the prosecutor to warrant proceedings comes to his knowledge.

(2) No such proceedings shall be commenced by virtue of this regulation more than two years after the commission of the offence.

(3) For the purpose of this regulation, a certificate signed by or on behalf of the prosecutor and stating the date on which evidence sufficient in his opinion to warrant the proceedings came to his knowledge shall be conclusive evidence of that fact.

(4) A certificate stating that matter and purporting to be so signed shall be deemed to be so signed unless the contrary is proved.

(5) In relation to proceedings in Scotland, subsection (3) of section 136 of the Criminal Procedure (Scotland) Act 1995(4) (date of commencement of proceedings) shall apply for the purposes of this regulation as it applies for the purposes of that section.

#### Offences by bodies corporate and Scottish partnerships

**88.**—(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 be 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

**89.** Where a person responsible for putting a zootechnical product into circulation is charged with an offence under these Regulations in respect of a product that has been manufactured or assembled to his order by another person and which has been so manufactured or assembled so as not to comply with his order, it shall be a defence for him to prove—

- (a) that, in placing his order, a copy of the documents relating to the manufacture and assembly of the product were available, or had been provided, to that other person and the person responsible for putting the product into circulation had instructed that other person to manufacture or assemble the product in accordance with those documents,
- (b) that if that other person had complied with that instruction, no offence would have been committed, and
- (c) that the person responsible for putting the product into circulation did not know, and could not by the exercise of reasonable care have known, that those instructions had not been complied with.

# Supplementary provisions relating to sampling and analysis, prosecutions, offences and defences

**90.**—(1) Any analysis required to be made by an analyst or, as the case may be, the Government Chemist or the Chief Agricultural Analyst, may be made by any person acting under his directions.

(2) A certificate of analysis completed in accordance with these Regulations shall, in any legal proceedings, be received as evidence of the facts stated therein, if the party against whom it is to be given in evidence has been served with a copy of it not less than twenty-one days before the hearing, and has not, before the seventh day preceding the hearing, served on the other party a notice requiring the attendance of the person who made the analysis.

(3) In any legal proceedings in Scotland, a certificate of analysis received in evidence by virtue of paragraph (2) or, where the attendance of the person who made the analysis is required under

that paragraph, the evidence of that person, shall be sufficient evidence of the facts stated in the certificate.

(4) Any document purporting to be a certificate of the kind referred to in paragraphs (2) and (3) shall be deemed to be such a certificate unless the contrary is proved.

(5) Subject to paragraph (6), for the purposes of this Part of these Regulations, sections 80(1), 81 and 82 and 110 of the 1970 Act shall have effect, as if these Regulations were made under section 74A(4) of that Act.

- (6) For the purposes of paragraph (5)—
  - (a) section 82(1) of the 1970 Act shall have effect as if, for the words "any of the following provisions of this Act, namely, sections 68 (1A), (4)(b) and (c), 69(4)(c), 70(2), 71(2) (b), 73, 73A and 74A" there were substituted the words "the Feedingstuffs (Zootechnical Products) Regulations 1999", and
  - (b) section 110(1) of the 1970 Act shall have effect as if, for the words "this Act or any order or scheme made thereunder" there were substituted the words "the Feedingstuffs (Zootechnical Products) Regulations 1999".

#### Service of notices

**91.** Any certificate, notice or part of a sample, 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 application of the Medicines Act 1968**

**92.**—(1) Except as specified in paragraphs (2) and (3), the 1968 Act, and instruments made wholly or partly under that Act, shall continue not to apply to zootechnical products.

(2) The function bestowed on any committee, established under section 4 (establishment of committees) of the 1968 Act, of giving advice on veterinary medicinal products, shall include the giving of advice on zootechnical products.

(3) The provisions of sections 32 to 36 (other than section 35(8)(a)), 38 and 39 of the 1968 Act, and instruments made under any of those provisions, shall continue to apply to unauthorised zootechnical additives as if paragraph (1) had not come into force.

#### Amendment of the Feeding Stuffs (Sampling and Analysis) Regulations 1999

**93.** For regulation 3 of the Feeding Stuffs (Sampling and Analysis) Regulations 1999(**5**)(manner of taking, preparing, marking, sealing and fastening of samples) there shall be substituted the following regulation:

# "Manner of taking, preparing, marking, sealing and fastening of samples

**3.** The manner in which samples of feeding stuffs are to be taken, prepared, marked, sealed and fastened shall be as prescribed in Schedule 1, and paragraph 10 of Part II of that Schedule shall have effect for the purposes of the certificate referred to in regulation 7.".