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STATUTORY INSTRUMENTS

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**1999 No. 1871**

**AGRICULTURE**

**The Feedingstuffs (Zootechnical Products) Regulations 1999**

*Made - - - - 29th June 1999*

*Laid before Parliament 30th June 1999*

*Coming into force*

*All regulations and Schedules except regulations 7, 8, 46, 47, 48, 72, 73 and 74 2nd August 1999*

*Regulations 7, 8, 46, 47, 48, 72, 73 and 74 1st October 1999*

The Minister of Agriculture, Fisheries and Food and the Secretary of State, being Ministers designated<sup>(1)</sup> for the purposes of section 2(2) of the European Communities Act 1972<sup>(2)</sup> in relation to the common agricultural policy of the European Community, acting jointly, in exercise of the powers conferred on them by the said section 2(2), hereby make the following Regulations:

**PART I**

**GENERAL**

**Title, commencement and revocation**

1.—(1) These Regulations may be cited as the Feedingstuffs (Zootechnical Products) Regulations 1999 and shall come into force on the following dates—

- (a) all regulations and Schedules, except for regulations 7, 8, 46, 47, 48, 72, 73 and 74, on 2nd August 1999, and
- (b) regulations 7, 8, 46, 47, 48, 72, 73 and 74 on 1st October 1999.

(2) The Feedingstuffs (Zootechnical Products) Regulations 1998<sup>(3)</sup> (“the 1998 Regulations”) are hereby revoked.

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(1) S.I. 1972/1811.  
(2) 1972 c. 68.  
(3) S.I. 1998/1047.

## General interpretation and application

### 2.—(1) In these Regulations—

“the 1968 Act” means the Medicines Act 1968<sup>(4)</sup>.

“the 1970 Act” means the Agriculture Act 1970<sup>(5)</sup>.

“additive” has the meaning given by Article 2(a) of Directive 70/524/EEC until 30th September 1999, but on and after 1st October 1999 has the meaning given by that Article as amended by Directive 96/51/EC;

“agricultural analyst” means an agricultural analyst appointed under section 67 of the 1970 Act, and includes a deputy agricultural analyst so appointed for the same area, but in Northern Ireland does not include the Chief Agricultural Analyst;

“analyst” means an agricultural analyst, or, in Great Britain, any other analyst appointed by the Minister for the purposes of these Regulations;

“animal” includes any bird, insect or fish;

“Article 6.4 purpose” means a purpose specified in Article 6.4 of Directive 70/524/EEC;

“authorised person” means a person (whether or not an officer of the enforcement authority) who is authorised by the enforcement authority, either generally or specially, to act in relation to matters arising under these Regulations;

“authorised zootechnical additive” means a BI, BII or BIII zootechnical additive, but excludes any additive deleted, by a Regulation listed in Schedule 1, from Annex B to Directive 70/524/EEC as amended by Directive 96/51/EC;

“a BI zootechnical additive” means a zootechnical additive which is covered by Chapter I of Annex B to Directive 70/524/EEC as amended by Directive 96/51/EC and complies with any applicable provisions relating to the additive covered by that Chapter;

“a BII zootechnical additive” means a zootechnical additive which is covered by Chapter II of Annex B to Directive 70/524/EEC as amended by Directive 96/51/EC and complies with any applicable provisions relating to the additive covered by that Chapter;

“a BIII zootechnical additive” means a zootechnical additive which is covered by Chapter III of Annex B to Directive 70/524/EEC as amended by Directive 96/51/EC, which complies with any applicable provisions relating to the additive covered by that Chapter and for which the period of authorisation covered by that Chapter has not expired;

“the Chief Agricultural Analyst” means the Chief Agricultural Analyst for Northern Ireland;

“a Community authorised zootechnical additive” means a zootechnical additive in respect of which a Community authorisation is in force, and which complies with the requirements relating to the additive contained in that authorisation;

“complete feedingstuff” has the meaning given by Article 2(d) of Directive 70/524/EEC;

“compound feedingstuff” has the meaning given by Article 2(g) of Directive 70/524/EEC;

“Directive 70/524/EEC concerning additives in feeding-stuffs as amended up to, but not including, the amendments effected by Directive 96/51/EC”>Directive 70/524/EEC” means Council Directive 70/524/EEC concerning additives in feeding-stuffs<sup>(6)</sup> as amended up to, but not including, the amendments effected by Directive 96/51/EC<sup>(7)</sup>;

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(4) 1968 c. 67.

(5) 1970 c. 40.

(6) OJ No. L270, 14.12.70, p. 1 (OJ/SE Vol. 18, p. 4)

(7) The next most recent amending instrument was Council Directive 96/25/EC (OJ No. L125, 23.5.96, p. 35).

“Directive 87/153/EEC” means Council Directive [87/153/EEC](#) fixing guidelines for the assessment of additives in animal nutrition<sup>(8)</sup> as amended by Commission Directives [94/40/EC](#)<sup>(9)</sup> and [95/11/EC](#)<sup>(10)</sup>;

“Directive 95/53/EC” means Council Directive [95/53/EC](#) fixing the principles governing the organisation of official inspections in the field of animal nutrition<sup>(11)</sup> (with effect from 1st October 1999 as amended by Council Directive [1999/20/EC](#)<sup>(12)</sup>);

“Directive 95/69/EC” means Council Directive [95/69/EC](#) laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector and amending Directives [70/524/EEC](#), [74/63/EEC](#), [79/373/EEC](#) and [82/471/EEC](#)<sup>(13)</sup> (with effect from 1st October 1999 as amended by Council Directive [1999/20/EC](#));

“Directive 96/51/EC” means Council Directive [96/51/EC](#) amending Directive 70/524/EEC concerning additives in feedingstuffs<sup>(14)</sup>;

“Directive 98/51/EC” means Commission Directive [98/51/EC](#) laying down certain measures for implementing Council Directive 95/69/EC laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector<sup>(15)</sup>;

“dossier” means a dossier compiled in accordance with the relevant provisions of Directive 87/153/EEC and which includes—

- (a) a monograph;
- (b) an identification note containing the information specified in Article 9o.1 of Directive 70/524/EEC as amended by Directive 96/51/EC; and
- (c) in the case of a zootechnical additive to which Article 7a of Directive 70/524/EEC, as amended by Directive 96/51/EC, applies, the documents referred to in the first and second indented paragraphs of the first paragraph of Article 7a of Directive 70/524/EEC as so amended;

“EEA Agreement” means the Agreement on the European Economic Area<sup>(16)</sup> signed at Oporto on 2nd May 1993 as adjusted by the Protocol<sup>(17)</sup> signed at Brussels on 17th March 1993;

“EEA State” means a State which is a contracting party to the EEA Agreement other than the United Kingdom;

“the enforcement authority” means—

- (a) in relation to Great Britain, the Royal Pharmaceutical Society of Great Britain, and
- (b) in relation to Northern Ireland, the Department of Agriculture for Northern Ireland;

“feedingstuff” has the meaning given by Article 2(b) of Directive 70/524/EEC;

“fish” includes shellfish;

“medicinal tests on animals” has the meaning given by section 32(6) of the 1968 Act and “animal test certificate” shall be construed in accordance with that section;

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(8) OJ No. L64, 7.3.87, p. 19.

(9) OJ No. L208, 11.8.94, p. 15.

(10) OJ No. L106, 11.5.95, p. 23.

(11) OJ No. L265, 8.11.95, p. 17.

(12) OJ No. L80, 25.3.1999, p. 20.

(13) OJ No. L332, 30.12.95, p. 15.

(14) OJ No. L235, 17.9.96, p. 39.

(15) OJ No. L208, 24.7.98, p. 43.

(16) OJ No. L1, 3.1.94, p. 3.

(17) OJ No. L1, 3.1.94, p. 572.

- “Member State” means a member State other than the United Kingdom;
- “the MF Regulations” means the Medicated Feedingstuffs Regulations 1998<sup>(18)</sup>;
- “the Minister” means the Minister of Agriculture, Fisheries and Food;
- “official checks” means checks of the type specified in Article 21.1 of Directive 70/524/EEC, Articles 3, 4, 7 and 10 to 12, the second paragraph of Article 14, the second and third paragraphs of Article 15.2 and Article 17.1 of Directive 95/53/EC, or Article 13 of Directive 95/69/EC, or which are carried out with a view to enforcement of the provisions of Article 6 of Directive 98/51/EC;
- “personal licence” means a licence granted under section 4 of the Animals (Scientific Procedures) Act 1986<sup>(19)</sup>;
- “person responsible for putting into circulation” has the meaning given by Article 2(1) of Directive 70/524/EEC as amended by Directive 96/51/EC;
- “premixture” has the meaning given by Article 2(h) of Directive 70/524/EEC;
- “project licence” means a licence granted under section 5 of the Animals (Scientific Procedures) Act 1986;
- “putting into circulation” has the meaning given by Article 1.3(a) of Directive 95/69/EC;
- “regulated procedure” has the meaning given by section 2 of the Animals (Scientific Procedures) Act 1986;
- “retained part of the sample” means that part of the sample retained by an authorised person pursuant to regulation 77(d);
- “the Scientific Committee for Animal Nutrition” means the committee established by Commission Decision 76/791/EEC establishing a Scientific Committee for Animal Nutrition<sup>(20)</sup>;
- “supplementary feedingstuff” has the meaning given by Article 2(e) of Directive 70/524/EEC;
- “third country” means a country other than a Member State or the United Kingdom;
- “unauthorised zootechnical additive” means a zootechnical additive other than an authorised zootechnical additive;
- “zootechnical additive” means an additive belonging to one or more of the groups of additives specified in Part I of Annex C to Directive 70/524/EEC, as amended by Directive 96/51/EC;
- “zootechnical feedingstuff” means a feedingstuff that contains a zootechnical additive or zootechnical premixture;
- “zootechnical premixture” means a premixture that contains a zootechnical additive; and subject to regulation 76(13), “zootechnical product” means a zootechnical additive, a zootechnical premixture or a zootechnical feedingstuff.

(2) The expressions listed in Part 1 of Schedule 2 have the same meaning as in Directive 70/524/EEC and any other expression which is used in these Regulations and Directive 70/524/EEC, other than an expression which is listed in Part II or III of Schedule 2, shall have, insofar as the context admits, the same meaning as in that Directive.

(3) The expressions listed in Part II of Schedule 2 have the same meaning as in Directive 70/524/EEC as amended by Directive 96/51/EC.

(4) Insofar as the context admits the expressions listed in Part III of Schedule 2 have the same meaning as in Directive 95/69/EC.

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<sup>(18)</sup> S.I. 1998/1046.

<sup>(19)</sup> 1986 c. 14.

<sup>(20)</sup> OJ No. L279, 9.10.76, p. 35.

(5) In the expressions “representative established within the United Kingdom” and “representative established within a member State”, “representative” and “established within” shall have the same meanings as in the expression “representative established within the European Community” in Directive 98/51/EC.

(6) In these Regulations, unless the context otherwise requires—

- (a) any reference to a numbered regulation or to a numbered Schedule is a reference to the regulation of or the Schedule to these Regulations so numbered in these Regulations,
- (b) any reference in a regulation to a numbered paragraph is a reference to the paragraph so numbered in the regulation in which the reference occurs, and
- (c) any reference to any things done under provisions of these Regulations shall be taken to include things done under the corresponding provisions of the 1998 Regulations.

(7) These Regulations shall apply in the field of animal feeding—

- (a) until 30th September 1999, to zootechnical products to which Directive 70/524/EEC applies, and
- (b) on and after 1st October 1999, to zootechnical products to which that Directive, as amended by Directive 96/51/EC, applies.

### **Definition of “establishment” and other related definitions**

**3.** In these Regulations “establishment” has the meaning given by Article 1.3(b) of Directive 95/69/EC and—

“the applicable day” means, in relation to any Member State, the date treated by that Member State as the first date after the closure of the period allowed by it for submission of declarations to it pursuant to Article 6.3 of Directive 98/51/EC;

“Article 12 establishment” means an establishment to which Article 12 of Directive 95/69/EC applies;

“EC approved Chapter I.1 establishment” means an establishment listed on a register of approved establishments maintained by a competent authority in a Member State in implementation of Article 5 of Directive 95/69/EC as being an establishment on which a zootechnical additive may be manufactured with a view to putting it into circulation;

“EC approved Chapter I.2 establishment” means an establishment listed on a register of approved establishments maintained by a competent authority in a Member State in implementation of Article 5 of Directive 95/69/EC as being an establishment on which a zootechnical premixture may be manufactured with a view to putting it into circulation;

“EC approved Chapter I.3(M) establishment” means an establishment listed on a register of approved establishments maintained by a competent authority in a Member State in implementation of Article 5 of Directive 95/69/EC as being an establishment on which a zootechnical compound feedingstuff may be manufactured with a view to putting it into circulation;

“EC approved Chapter I.3(P) establishment” means an establishment listed on a register of approved establishments maintained by a competent authority in a Member State in implementation of Article 5 of Directive 95/69/EC as being an establishment on which a zootechnical compound feedingstuff may be produced for the exclusive requirements of the producer’s holding;

“EC approved third country Chapter I.1 establishment” means a third country establishment listed on a register of approved establishments, maintained by a competent authority in a Member State, in implementation of Article 5 of Directive 95/69/EC (as read with Directive 98/51/EC), as being an establishment as to which a zootechnical additive, manufactured

thereon, may be imported into that Member State, and which has a representative established within that Member State;

“EC approved third country Chapter I.2 establishment” means a third country establishment listed on a register of approved establishments, maintained by a competent authority in a Member State, in implementation of Article 5 of Directive 95/69/EC (as read with Directive 98/51/EC), as being an establishment as to which a zootechnical premixture, manufactured thereon, may be imported into that Member State, and which has a representative established within that Member State;

“EC approved third country Chapter I.3(M) establishment” means a third country establishment listed on a register of approved establishments, maintained by a competent authority in a Member State, in implementation of Article 5 of Directive 95/69/EC (as read with Directive 98/51/EC), as being an establishment as to which a zootechnical compound feedingstuff, manufactured thereon, may be imported into that Member State, and which has a representative established within that Member State;

“EC permitted Chapter I.1 establishment” means an establishment located in a Member State if—

- (a) a zootechnical additive was being manufactured on the establishment, with a view to putting it into circulation, on 1st April 1998, and
- (b) before 1st September 1998 an application (which is pending) in respect of the establishment was made to the competent authority in that State, in accordance with any requirements in that State for the making of such applications, to approve the establishment, pursuant to Directive 95/69/EC, as an establishment on which such an additive may be manufactured with a view to putting it into circulation;

“EC permitted Chapter I.2 establishment” means an establishment located in a Member State if—

- (a) a zootechnical premixture was being manufactured on the establishment, with a view to putting it into circulation, on 1st April 1998, and
- (b) before 1st September 1998 an application (which is pending) in respect of the establishment was made to the competent authority in that State, in accordance with any requirements in that State for the making of such applications, to approve the establishment, pursuant to Directive 95/69/EC, as an establishment on which such a premixture may be manufactured with a view to putting it into circulation;

“EC permitted Chapter I.3(M) establishment” means an establishment located in a Member State if—

- (a) a zootechnical compound feedingstuff was being manufactured on the establishment, with a view to putting it into circulation, on 1st April 1998, and
- (b) before 1st September 1998 an application (which is pending) in respect of the establishment was made to the competent authority in that State, in accordance with any requirements in that State for the making of such applications, to approve the establishment, pursuant to Directive 95/69/EC, as an establishment on which such a feedingstuff may be manufactured with a view to putting it into circulation;

“EC permitted Chapter I.3(P) establishment” means an establishment located in a Member State if—

- (a) a zootechnical compound feedingstuff was being produced on the establishment for the exclusive requirements of the producer’s holding on 1st April 1998, and
- (b) before 1st September 1998 an application (which is pending) in respect of the establishment was made to the competent authority in that State, in accordance with any requirements in that State for the making of such applications, to approve the

establishment, pursuant to Directive 95/69/EC, as an establishment on which such a feedingstuff may be produced for the exclusive requirements of the producer's holding;

“EC permitted third country Chapter I.1 establishment” means—

- (a) before the applicable day, a third country establishment (other than an EC approved third country Chapter I.1 establishment) if a zootechnical additive was being manufactured on the establishment, with a view to putting it into circulation, on 31st December 1998, and the establishment has, at all times since that date, had a representative established within a Member State, and
- (b) on and after the applicable day, a third country establishment if—
  - (i) a zootechnical additive was being manufactured on the establishment, with a view to putting it into circulation, on 31st December 1998, and, at all times since that date, the establishment has had a representative as aforesaid, and
  - (ii) before the applicable day, a declaration (consideration of which is pending) in respect of the establishment, has been submitted to a competent authority in the Member State, in accordance with any requirements in the Member State for the submission of such declarations pursuant to Article 6.3 of Directive 98/51/EC, with a view to registration of the establishment, pursuant to that Directive, as an establishment as to which such an additive, manufactured thereon, may be imported into that Member State;

“EC permitted third country Chapter I.2 establishment” means—

- (a) before the applicable day, a third country establishment (other than an EC approved third country Chapter I.2 establishment) if a zootechnical premixture was being manufactured on the establishment, with a view to putting it into circulation, on 31st December 1998, and the establishment has, at all times since that date, had a representative established within a Member State, and
- (b) on and after the applicable day, a third country establishment if—
  - (i) a zootechnical premixture was being manufactured on the establishment, with a view to putting it into circulation, on 31st December 1998, and, at all times since that date, the establishment has had a representative as aforesaid, and
  - (ii) before the applicable day, a declaration (consideration of which is pending) in respect of the establishment, has been submitted to a competent authority in the Member State, in accordance with any requirements in the Member State for the submission of such declarations pursuant to Article 6.3 of Directive 98/51/EC, with a view to registration of the establishment, pursuant to that Directive, as an establishment as to which such a premixture, manufactured thereon, may be imported into that Member State;

“EC permitted third country Chapter I.3(M) establishment” means—

- (a) before the applicable day, a third country establishment (other than an EC approved third country Chapter I.3(M) establishment) if a zootechnical compound feedingstuff was being manufactured on the establishment, with a view to putting it into circulation, on 31st December 1998, and the establishment has, at all times since that date, had a representative established within a Member State, and
- (b) on and after the applicable day, a third country establishment if—
  - (i) a zootechnical compound feedingstuff was being manufactured on the establishment, with a view to putting it into circulation, on 31st December 1998, and, at all times since that date, the establishment has had a representative as aforesaid, and

- (ii) before the applicable day, a declaration (consideration of which is pending) in respect of the establishment, has been submitted to a competent authority in the Member State, in accordance with any requirements in the Member State for a submission of such declarations pursuant to Article 6.3 of Directive 98/51/EC, with a view to registration of the establishment, pursuant to that Directive, as an establishment as to which such a feedingstuff, manufactured thereon, may be imported into that Member State;

“specially approved manufacturing establishment” means an establishment approved pursuant to regulation 10(1)(e) as an establishment on which a zootechnical compound feedingstuff may be manufactured using a minimum proportion of 0.05% by weight of a premixture;

“third country establishment” means an establishment located in a third country;

“UK approved Chapter I.1 establishment” means an establishment approved pursuant to regulation 11 or, as the case may be, 12, as an establishment on which a zootechnical additive may be manufactured with a view to putting it into circulation;

“UK approved Chapter I.2 establishment” means an establishment approved pursuant to regulation 11 or, as the case may be, 12, as an establishment on which a zootechnical premixture may be manufactured with a view to putting it into circulation;

“UK approved Chapter I.3(M) establishment” means an establishment approved pursuant to regulation 11 or, as the case may be, 12, as an establishment on which a zootechnical compound feedingstuff may be manufactured with a view to putting it into circulation, and includes a specially approved manufacturing establishment;

“UK approved Chapter I.3(P) establishment” means an establishment approved pursuant to regulation 11 or, as the case may be, 12, as an establishment on which a zootechnical compound feedingstuff may be produced for the exclusive requirements of the producer’s holding;

“UK approved third country Chapter I.1 establishment” means a third country establishment approved pursuant to regulation 27(1)(a) or, as the case may be, 28(3), as an establishment as to which a zootechnical additive, manufactured thereon, may be imported into the United Kingdom, and which has a representative established within the United Kingdom;

“UK approved third country Chapter I.2 establishment” means a third country establishment approved pursuant to regulation 27(1)(a) or, as the case may be, 28(3), as an establishment as to which a zootechnical premixture, manufactured thereon, may be imported into the United Kingdom, and which has a representative established within the United Kingdom;

“UK approved third country Chapter I.3(M) establishment” means a third country establishment approved pursuant to regulation 27(1)(a) or, as the case may be, 28(3), as an establishment as to which a zootechnical compound feedingstuff, manufactured thereon, may be imported into the United Kingdom, and which has a representative established within the United Kingdom;

“UK permitted Chapter I.1 establishment” means an establishment located in the United Kingdom if—

- (a) a zootechnical additive was being manufactured on the establishment, with a view to putting it into circulation, on 1st April 1998, and
- (b) before 1st September 1998 an application (which is pending and complies with regulation 10(2)) was submitted in respect of the establishment under regulation 10(1) (a) (or under regulation 12(1) in relation to zootechnical additive manufacture);

“UK permitted Chapter I.2 establishment” means an establishment located in the United Kingdom if—

- (a) a zootechnical premixture was being manufactured on the establishment, with a view to putting it into circulation, on 1st April 1998, and



- (b) before 1st September 1998 an application (which is pending and complies with regulation 10(2)) was submitted in respect of the establishment under regulation 10(1) (b) (or under regulation 12(1) in relation to zootechnical premixture manufacture);

“UK permitted Chapter I.3(M) establishment” means an establishment located in the United Kingdom if—

- (a) a zootechnical compound feedingstuff was being manufactured on the establishment, with a view to putting it into circulation, on 1st April 1998, and
- (b) before 1st September 1998 an application (which is pending and complies with regulation 10(2)) was submitted in respect of the establishment under regulation 10(1) (c) (or under regulation 12(1) in relation to zootechnical compound feedingstuff manufacture); and

“UK permitted Chapter I.3(P) establishment” means an establishment located in the United Kingdom if—

- (a) a zootechnical compound feedingstuff was being produced on the establishment for the exclusive requirements of the producer’s holding on 1st April 1998, and
- (b) before 1st September 1998 an application (which is pending and complies with regulation 10(2)) was submitted in respect of the establishment under regulation 10(1)(d) (or under regulation 12(1) in relation to zootechnical compound feedingstuff production for the exclusive requirements of the producer’s holding).

“UK permitted third country Chapter I.1 establishment” means—

- (a) before 1st October 1999, a third country establishment (other than a UK approved third country Chapter I.1 establishment) if a zootechnical additive was being manufactured on the establishment, with a view to putting it into circulation, on 31st December 1998, and the establishment has, at all times since that date, had a representative established within the United Kingdom, and
- (b) on and after 1st October 1999, a third country establishment if—
  - (i) a zootechnical additive was being manufactured on the establishment, with a view to putting it into circulation, on 31st December 1998, and, at all times since that date, the establishment has had a representative as aforesaid, and
  - (ii) before 1st October 1999, a declaration under (or required to be treated as under) regulation 26(1)(a), or a corresponding declaration under (or required to be treated as under) regulation 28(1), (consideration of which in either case is pending), made in compliance with (or required to be treated as made in compliance with) regulation 26(2), or, as the case may be, 28(2), and not containing a negative reply to a question specified in regulation 26(2)(g) or, as the case may be, 28(2)(g), has been submitted in respect of the establishment;

“UK permitted third country Chapter I.2 establishment” means—

- (a) before 1st October 1999, a third country establishment (other than a UK approved third country Chapter I.2 establishment) if a zootechnical premixture was being manufactured on the establishment, with a view to putting it into circulation, on 31st December 1998, and the establishment has, at all times since that date, had a representative established within the United Kingdom, and
- (b) on and after 1st October 1999, a third country establishment if—
  - (i) a zootechnical premixture was being manufactured on the establishment, with a view to putting it into circulation, on 31st December 1998, and, at all times since that date, the establishment has had a representative as aforesaid, and

- (ii) before 1st October 1999, a declaration under (or required to be treated as under) regulation 26(1)(b), or a corresponding declaration under (or required to be treated as under) regulation 28(1), (consideration of which in either case is pending), made in compliance with (or required to be treated as made in compliance with) regulation 26(2), or, as the case may be, 28(2), and not containing a negative reply to a question specified in regulation 26(2)(g) or, as the case may be, 28(2)(g), has been submitted in respect of the establishment;

“UK permitted third country Chapter I.3(M) establishment” means—

- (a) before 1st October 1999, a third country establishment (other than a UK approved third country Chapter I.3(M) establishment) if a zootechnical compound feedingstuff was being manufactured on the establishment, with a view to putting it into circulation, on 31st December 1998, and the establishment has, at all times since that date, had a representative established within the United Kingdom, and
- (b) on and after 1st October 1999, a third country establishment if—
  - (i) a zootechnical compound feedingstuff was being manufactured on the establishment, with a view to putting it into circulation, on 31st December 1998, and, at all times since that date, the establishment has had a representative as aforesaid, and
  - (ii) before 1st October 1999, a declaration under (or required to be treated as under) regulation 26(1)(c), or a corresponding declaration under (or required to be treated as under) regulation 28(1), (consideration of which in either case is pending), made in compliance with (or required to be treated as made in compliance with) regulation 26(2), or, as the case may be, 28(2), and not containing a negative reply to a question specified in regulation 26(2)(g) or, as the case may be, 28(2)(g), has been submitted in respect of the establishment.

#### **Definition of “intermediary” and other related definitions**

4. In these Regulations “intermediary” has the meaning given by Article I.3(c) of Directive 95/69/EC and—

“EC approved Chapter I.1 intermediary” means an intermediary listed on a register of approved intermediaries maintained by a competent authority in a Member State in implementation of Article 5 of Directive 95/69/EC as being an intermediary who may wrap, package, store and put into circulation a zootechnical additive;

“EC approved Chapter I.2 intermediary” means an intermediary listed on a register of approved intermediaries maintained by a competent authority in a Member State in implementation of Article 5 of Directive 95/69/EC as being an intermediary who may wrap, package, store and put into circulation a zootechnical premixture;

“EC permitted Chapter I.1 intermediary” means an intermediary whose facilities are located in a Member State and who—

- (a) was wrapping, packaging, storing or putting into circulation a zootechnical additive on 1st April 1998, and
- (b) has made an application (which is pending) to the competent authority in that State, in accordance with any requirements in that State for the making of such applications, to be approved pursuant to Directive 95/69/EC as an intermediary who may wrap, package, store and put into circulation such an additive;

“EC permitted Chapter I.2 intermediary” means an intermediary whose facilities are located in a Member State and who—

- (a) was wrapping, packaging, storing or putting into circulation a zootechnical premixture on 1st April 1998, and
- (b) has made an application (which is pending) to the competent authority in that State, in accordance with any requirements in that State for the making of such applications, to be approved pursuant to Directive 95/69/EC as an intermediary who may wrap, package, store and put into circulation such a premixture;

“UK approved Chapter I.1 intermediary” means an intermediary approved pursuant to regulation 19 or, as the case may be, 20, as an intermediary who may wrap, package, store and put into circulation a zootechnical additive;

“UK approved Chapter I.2 intermediary” means an intermediary approved pursuant to regulation 19 or, as the case may be, 20, as an intermediary who may wrap, package, store and put into circulation a zootechnical premixture;

“UK permitted Chapter I.1 intermediary” means an intermediary whose facilities are located in the United Kingdom and who—

- (a) was wrapping, packaging, storing or putting into circulation such an additive on 1st April 1998, and
- (b) has submitted an application (which is pending and complies with regulation 18(2)) under regulation 18(1)(a) (or under regulation 20(1) in relation to zootechnical additive intermediary activity); and

“UK permitted Chapter I.2 intermediary” means an intermediary whose facilities are located in the United Kingdom and who—

- (a) was wrapping, packaging, storing or putting into circulation a zootechnical premixture on 1st April 1998, and
- (b) has submitted an application (which is pending and complies with regulation 18(2)) under regulation 18(1)(b) (or under regulation 20(1) in relation to zootechnical premixture intermediary activity).

## PART II

### APPLICATIONS FOR THE COMMUNITY AUTHORISATION OF ZOOTECHNICAL ADDITIVES

#### **Transitional applications**

**5.—**(1) An eligible person who wishes the United Kingdom to act as the rapporteur in connection with an application for the Community authorisation of a BI, BII or BIII zootechnical additive may submit an application for such authorisation, accompanied by a monograph and identification note relating to the additive, to the Minister.

(2) Where documentation is submitted to the Minister pursuant to paragraph (1), he shall process this in accordance with the requirements of—

- (a) Article 9g.2 of Directive 70/524/EEC, as amended by Directive 96/51/EC, in the case of an application relating to a BI zootechnical additive;
- (b) Article 9h.2 of Directive 70/524/EEC, as amended by Directive 96/51/EC, in the case of an application relating to a BII zootechnical additive; and
- (c) Article 9i.2 of Directive 70/524/EEC, as amended by Directive 96/51/EC, in the case of an application relating to a BIII zootechnical additive.

(3) A person who applies for the Community authorisation of a BI zootechnical additive for which the United Kingdom is acting as rapporteur may submit a dossier relating to the additive to the Minister in accordance with the requirements of Article 9g.4 of Directive 70/524/EEC, as amended by Directive 96/51/EC.

(4) Where a dossier relating to a BI zootechnical additive is submitted to the Minister pursuant to paragraph (3), he shall (subject to regulation 9)—

- (a) forward it to the Commission, and
- (b) forward a copy of it to each Member State,

if he is satisfied as specified in paragraph (5).

(5) The Minister is satisfied in accordance with this paragraph if he is satisfied that—

- (a) the dossier submitted pursuant to paragraph (3) has been compiled in accordance with the applicable provisions of Directive 87/153/EEC, and
- (b) the zootechnical additive to which the dossier relates meets the conditions laid down in Article 3a of Directive 70/524/EEC as amended by Directive 96/51/EC.

(6) If, in relation to a dossier submitted pursuant to paragraph (3), the Minister is not satisfied about both of the matters specified in paragraph (5), he shall reject the dossier, or postpone taking the action specified in paragraph (4) in relation to it, until such time as he is satisfied about both of those matters.

(7) Where the Minister rejects a dossier submitted to him pursuant to paragraph (3), or postpones taking the action specified in paragraph (4) in relation to it, he shall inform the Commission and each Member State of the rejection or postponement, and shall notify them of the reasons for the rejection or postponement.

(8) If requested to do so by the Commission, the Minister shall forward a copy of all or part of a dossier relating to a BI zootechnical additive submitted to him pursuant to paragraph (3) to each member of the Scientific Committee for Animal Nutrition.

(9) In paragraph (1) “eligible person” means a person who is entitled to apply for the Community authorisation of a BI, BII or BIII zootechnical additive, as the case may be, in accordance with the provisions of—

- (a) Article 9g.2 of Directive 70/524/EEC, as amended by Directive 96/51/EC, in the case of a BI zootechnical additive;
- (b) Article 9h.2 of Directive 70/524/EEC, as amended by Directive 96/51/EC, in the case of a BII zootechnical additive; and
- (c) Article 9i.2 of Directive 70/524/EEC, as amended by Directive 96/51/EC, in the case of a BIII zootechnical additive.

### **Preliminary ordinary applications**

6.—(1) A person who, in the specified circumstances, wishes the Minister to act in accordance with the following provisions of this regulation in connection with an application for the Community authorisation of a zootechnical additive may submit an application for the Community authorisation of the additive and a dossier relating to the additive to the Minister.

(2) Where documentation is submitted to the Minister pursuant to paragraph (1), he shall—

- (a) forward it to the Commission, and
- (b) forward a copy of it to each Member State,

if he is satisfied as specified in paragraph (3) and has received the appropriate fee in accordance with paragraph (4).

(3) The Minister is satisfied in accordance with this paragraph if he is satisfied that—

- (a) the dossier submitted pursuant to paragraph (1) has been compiled in accordance with the applicable provisions of Directive 87/153/EEC, and
- (b) the zootechnical additive to which the dossier relates meets the conditions laid down in Article 3a of Directive 70/524/EEC as amended by Directive 96/51/EC.

(4) If the Minister is satisfied in accordance with paragraph (3), the Minister shall notify the person who has submitted the documentation pursuant to paragraph (1) of the Minister's intention, subject to receipt of the appropriate fee, to forward the dossier to the Commission and the other Member States in accordance with paragraph (2), and upon receipt of such notice such person shall pay the appropriate fee to the Minister and any unpaid sum shall be recoverable as a debt.

(5) If, in relation to a dossier submitted pursuant to paragraph (1), the Minister is not satisfied about both of the matters specified in paragraph (3), he shall reject the documentation or postpone taking the action specified in paragraph (2) in relation to the documentation, until such time as he is satisfied about both of those matters.

(6) Where the Minister rejects the documentation submitted to him pursuant to paragraph (1), or postpones taking the action specified in paragraph (2) in relation to it, he shall inform the person who has submitted the application pursuant to paragraph (1), the Commission and each Member State of the rejection or postponement, and shall notify them of the reasons for the rejection or postponement.

(7) If requested to do so by the Commission, the Minister shall forward a copy of all or part of a dossier relating to a zootechnical additive for which an application has been submitted to him pursuant to paragraph (1) to each member of the Scientific Committee for Animal Nutrition.

(8) For the purposes of this regulation—

(a) the “specified circumstances” apply where—

- (i) the person in question is, at the time these Regulations come into force, putting the additive in question into circulation,
- (ii) he is not an eligible person under regulation 5 in relation to that additive,
- (iii) he wishes to be able to continue putting the additive into circulation lawfully on or after 1st October 1999, and
- (iv) he submits the documentation required pursuant to paragraph (1) to the Minister and this is received by the Minister before 1st October 1999; and

(b) “the appropriate fee” means the fee specified in relation to an application under regulation 6(1) in Part I of Schedule 3.

(9) The Minister shall, subject to paragraph (10), treat any documentation submitted to him in anticipation of paragraph (1) as submitted pursuant thereto, and accordingly references in this regulation to anything submitted pursuant to that paragraph shall be taken to include anything required by this paragraph to be so treated.

(10) Paragraph (9) shall only apply where the person who has submitted the documentation in question has, following the coming into force of that paragraph, notified the Minister that he wishes the documentation to be treated as specified in that paragraph.

### **Ordinary applications**

7.—(1) A person who wishes the United Kingdom to act as the rapporteur in connection with—

- (a) an application for the Community authorisation of a zootechnical additive, or
- (b) an application for the Community authorisation of a new use of an already authorised zootechnical additive,

may submit an application for the Community authorisation of the additive or the new use of the additive, as the case may be, and a dossier relating to the additive, or the new use, as the case may be, to the Minister.

(2) Where documentation is submitted to the Minister pursuant to paragraph (1), he shall (subject to regulation 9)—

- (a) forward it to the Commission, and
- (b) forward a copy of it to each Member State,

in accordance with Article 4.3 of Directive 70/524/EEC, as amended by Directive 96/51/EC, if he is satisfied as specified in paragraph (3) below.

(3) The Minister is satisfied in accordance with this paragraph if he is satisfied that—

- (a) the dossier submitted pursuant to paragraph (1) has been compiled in accordance with the applicable provisions of Directive 87/153/EEC, and
- (b) the zootechnical additive to which the dossier relates, or the new use to which the dossier relates, as the case may be, meets the conditions laid down in Article 3a of Directive 70/524/EEC as amended by Directive 96/51/EC.

(4) If, in relation to a dossier submitted pursuant to paragraph (1), the Minister is not satisfied about both of the matters specified in paragraph (3), he shall reject the documentation, or postpone taking the action specified in paragraph (2) in relation to the documentation, until such time as he is satisfied about both of those matters.

(5) Where the Minister rejects documentation submitted to him pursuant to paragraph (1), or postpones taking the action specified in paragraph (2) in relation to it, he shall inform the Commission and each Member State of the rejection or postponement, and shall notify them of the reasons for the rejection or postponement.

(6) If requested to do so by the Commission, the Minister shall forward a copy of all or part of a dossier relating to a zootechnical additive for which an application has been submitted to him pursuant to paragraph (1) to each member of the Scientific Committee for Animal Nutrition.

### **Renewal applications**

**8.—**(1) A person who wishes the United Kingdom to act as the rapporteur in connection with an application to renew a Community authorisation relating to a zootechnical additive may submit an application to renew the Community authorisation relating to the additive and a dossier relating to the additive to the Minister.

(2) Where documentation is submitted to the Minister pursuant to paragraph (1), he shall (subject to regulation 9)—

- (a) forward it to the Commission, and
- (b) forward a copy of it to each Member State,

if he is satisfied in paragraph (3).

(3) The Minister is satisfied in accordance with this paragraph if he is satisfied that—

- (a) the dossier submitted pursuant to paragraph (1) has been compiled in accordance with the applicable provisions of Directive 87/153/EEC, and
- (b) the zootechnical additive to which the dossier relates continues to meet the conditions laid down in Article 3a of Directive 70/524/EEC as amended by Directive 96/51/EC.

(4) If, in relation to a dossier submitted pursuant to paragraph (1), the Minister is not satisfied about both of the matters specified in paragraph (3), he shall reject the documentation, or postpone taking the action specified in paragraph (2) in relation to the documentation, until such time as he is satisfied about both of those matters.

(5) Where the Minister rejects documentation submitted to him pursuant to paragraph (1), or postpones taking the action specified in paragraph (2) in relation to it, he shall inform the Commission and each Member State of the rejection or postponement, and shall notify them of the reasons for the rejection or postponement.

(6) If requested to do so by the Commission, the Minister shall forward a copy of all or part of a dossier relating to a zootechnical additive for which an application has been submitted to him pursuant to paragraph (1) to each member of the Scientific Committee for Animal Nutrition.

### **Fees**

**9.—(1)** In this regulation, “the relevant fee”, in relation to any application under regulation 5(3), 7(1)(a) or (b) or 8(1), means the fee specified opposite the application in question in Part I of Schedule 3, and it shall be payable by the person who submits a dossier to the Minister in connection with that application pursuant to the regulation concerned.

(2) Any relevant fee shall be paid at the time that the dossier is submitted to the Minister.

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

(4) The Minister need not process any application made under regulation 5(3), 7(1) or 8(1), unless the application is accompanied by the relevant fee.

## **PART III**

### **APPROVAL OF ESTABLISHMENTS LOCATED IN THE UNITED KINGDOM**

#### **Applications for the approval of establishments**

**10.—(1)** An eligible person may apply to the enforcement authority to approve an establishment as an establishment on which one or more of the following activities may be exercised—

- (a) the manufacture of a zootechnical additive with a view to putting it into circulation;
- (b) the manufacture of a zootechnical premixture with a view to putting it into circulation;
- (c) the manufacture of a zootechnical compound feedingstuff with a view to putting it into circulation;
- (d) the production of a zootechnical compound feedingstuff for the exclusive requirements of the applicant’s holding; and
- (e) the manufacture of a zootechnical compound feedingstuff using a minimum proportion of 0.05% by weight of a premixture.

**2)** An application made under paragraph (1) shall be in writing, in the English language, (or, where the establishment in respect of which the application is made is situated wholly or partly in Wales, in either that language or the Welsh language) signed by or on behalf of the applicant, and shall contain the name (or business name) and address of the applicant, shall specify each activity in relation to which the application is made, and shall be accompanied by particulars which seek to demonstrate that the establishment meets the applicable minimum conditions laid down in the Annex to Directive 95/69/EC.

#### **Approval of establishments**

**11.—(1)** Where an application is made under regulation 10 or 12, the enforcement authority shall (subject to regulation 15)—

- (a) check by means of an on the spot verification whether the establishment meets the applicable minimum conditions laid down in the Annex to Directive 95/69/EC, and
- (b) process the application in accordance with the requirements of the second paragraph of Article 4.1 or the second paragraph of Article 4.2 of Directive 95/69/EC as applicable.

(2) Where the enforcement authority is satisfied that, in respect of the relevant establishment activity, the establishment meets the applicable minimum conditions laid down in the Annex to Directive 95/69/EC, it shall approve the establishment as an establishment on which the relevant establishment activity may be exercised, and register the establishment on the register of approved establishments in accordance with Article 5.1 of Directive 95/69/EC, as read with Articles 8 and 9 of, and the Annex to, Directive 98/51/EC, as being an approved establishment on which the relevant establishment activity may be exercised.

### **Amendment of approvals**

**12.**—(1) An eligible person may apply to the enforcement authority to approve an approved establishment as an establishment on which a further establishment activity (“the new establishment activity”) may be exercised—

- (a) in addition to an establishment activity in respect of which the establishment is already approved, or
- (b) instead of that activity.

**2)** Where an application complying with regulation 10(2) 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 establishment meets the applicable minimum conditions laid down in the Annex to Directive 95/69/EC.

(3) Where, pursuant to paragraph (2), the enforcement authority amends an approval relating to an approved establishment, it shall update the register of approved establishments to show all the establishment activities that may be exercised on the approved establishment.

### **Withdrawal of approvals**

**13.**—(1) The enforcement authority shall withdraw an approval relating to the exercise of an establishment activity on an approved establishment if it is satisfied that the exercise of that activity on the establishment has ceased.

(2) The enforcement authority shall withdraw an approval relating to the exercise of an establishment activity on an approved establishment if, following the procedure in regulation 14, it is not satisfied that the person exercising the relevant activity on the establishment is complying with the duties imposed on him by regulations 34, 50, 62 or 64 as the case may be.

(3) Where, pursuant to paragraph (1) or (2), the enforcement authority withdraws an approval relating to the exercise of an establishment activity on an approved establishment, it shall update the register of approved establishments—

- (a) to show any remaining establishment activity that may continue to be exercised on the approved establishment, or
- (b) by removing the establishment from the register where, as a result of withdrawing the approval relating to the exercise of the relevant establishment activity, the establishment is no longer approved as an establishment on which an establishment activity of any sort may be exercised.



### **Procedure relating to the withdrawal of approvals**

**14.**—(1) Where the enforcement authority proposes to withdraw an approval relating to the exercise of an establishment activity on an approved establishment because it is not satisfied that the person exercising the activity on the establishment is complying with the duties imposed on him by regulation 34, 50, 62 or 64, as the case may be, the enforcement authority shall not withdraw the approval unless—

- (a) it serves a notice complying with the requirements of paragraph (2) on that person (“the recipient of the notice”), and
  - (b) it is not satisfied, after the time for compliance with the notice has expired, that the recipient of the notice has complied with the requirements specified in the notice.
- (2) A notice served by the enforcement authority under paragraph (1) shall—
- (a) state that it proposes to withdraw the approval of the establishment relating to the relevant establishment activity because it is not satisfied that the recipient of the notice is complying with the duties imposed on him by regulation 34, 50, 62 or 64 as the case may be;
  - (b) specify—
    - (i) the essential conditions that the enforcement authority is not satisfied that the recipient of the notice is complying with; and
    - (ii) the requirements that the recipient of the notice must comply with in order to satisfy the enforcement authority as to compliance with those essential conditions; and
  - (c) specify that, unless it is satisfied that the recipient of the notice has complied with the requirements specified in the notice within such reasonable time as is specified in the notice, the approval of the establishment insofar as it relates to the relevant establishment activity will be withdrawn.

### **Fees**

**15.**—(1) In this regulation, “the relevant fee”, in relation to any application, means the fee specified opposite the application in question in Part II of Schedule 3, and (subject to paragraphs (5) to (11)) it shall be payable by a person who applies to the enforcement authority under regulation 10 or 12 to approve an establishment as an establishment on which an establishment activity may be exercised.

(2) Any fee payable under paragraph (1) shall be paid at the time the application is submitted to the enforcement 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 enforcement authority need not process any application under regulation 10 or 12, unless the application is accompanied by that fee.

(5) Where an eligible person applies to the enforcement authority under regulation 10 for an establishment to be approved and in his application seeks approval to exercise more than one establishment activity, such person shall be liable to pay only one fee and, where the amount of the relevant fee differs according to establishment activity, the fee payable shall be the highest.

(6) Where an eligible person applies to the enforcement authority under regulation 10 for an establishment to be approved as an establishment on which an establishment activity may be exercised and, in relation to the same establishment, applies on the same date (evidenced by the date on the application forms) under regulation 3 of the MF Regulations to the relevant authority for approval of the establishment as premises on which medicated feedingstuffs may be manufactured, he shall be liable to pay only one fee under both these Regulations and the MF Regulations and,

where the relevant fee differs in amount from the fee payable under the MF Regulations, the fee payable shall be the higher amount.

(7) An eligible person shall not be liable to pay the relevant fee where he applies to the enforcement authority under regulation 10 for an establishment to be approved as an establishment on which an establishment activity may be exercised and, in relation to the same establishment, has applied under regulation 3 of the MF Regulations for approval of the establishment as premises on which medicated feedingstuffs may be manufactured, if he applies under regulation 10 within twelve months of his application under regulation 3 of the MF Regulations and at the date of his application under regulation 10—

- (a) an inspection by the relevant authority is pending in relation to his application under regulation 3 of the MF Regulations, or
- (b) the relevant authority has conducted such inspection and has granted approval pursuant to regulation 4 of the MF Regulations which remains valid.

(8) Where an eligible person applies to the enforcement authority under regulation 12 for an establishment to be approved and in his application seeks approval to exercise more than one new establishment activity, such person shall be liable to pay only one fee and, where the amount of the relevant fee differs according to establishment activity, the fee payable shall be the highest.

(9) Subject to paragraph (10), an eligible person shall not be liable to pay the relevant fee where he applies to the enforcement authority under regulation 12 for an establishment to be approved as an establishment on which a new establishment activity may be exercised and, in relation to the same establishment, has applied under regulation 10(1)(a), (b) or (e), if he applies under regulation 12 within twelve months of his application under regulation 10 and at the date of his application under regulation 12—

- (a) an on the spot verification by the enforcement authority is pending in relation to his application under regulation 10 at the date of his application under regulation 12, or
- (b) the relevant authority has conducted an on the spot verification in relation to his application under regulation 10, and has granted approval pursuant to regulation 11 which has not been withdrawn.

(10) Where an eligible person applies to the enforcement authority under regulation 12 for an establishment to be approved as an establishment on which a new establishment activity may be exercised and, in relation to the same establishment, applies on the same date (evidenced by the date on the application forms) under regulation 3 of the MF Regulations to the relevant authority for approval of the establishment as premises on which medicated feedingstuffs may be manufactured, he shall be liable to pay only one fee under both these Regulations and the MF Regulations and, where the relevant fee differs in amount from the fee payable under the MF Regulations, the fee payable shall be the higher amount.

(11) An eligible person shall not be liable to pay the relevant fee where he applies to the enforcement authority under regulation 12 for an establishment to be approved as an establishment on which a new establishment activity may be exercised and, in relation to the same establishment and establishment activity, has applied under regulation 3 of the MF Regulations for approval of the establishment as premises on which medicated feedingstuffs may be manufactured, if he applies under regulation 12 within twelve months of his application under regulation 3 of the MF Regulations and at the date of his application under regulation 12—

- (a) an inspection by the relevant authority is pending in relation to his application under regulation 3 of the MF Regulations, or
- (b) the relevant authority has conducted such inspection and has granted approval pursuant to regulation 4 of the MF Regulations which remains valid.

(12) A fee payable under combined regulations as described in paragraphs (6) and (10) shall, as well as a fee payable by reference to paragraph (5) or (8), be treated for the purposes of paragraphs (2) to (4) as included among fees payable under paragraph (1).

### **Publication of the national list of approved establishments**

**16.** The enforcement authority shall provide the Minister in writing, on demand being made by him, such information as is available to it and which will assist the Minister to comply with the requirements of Article 6.1 of Directive 95/69/EC relating to the publication of the national list of approved establishments, as read with Article 13.3 and 13.4 of Directive 70/524/EEC as amended by Directive 96/51/EC.

### **Interpretation of Part III**

**17.** In this Part—

“the applicable minimum conditions laid down in the Annex to Directive 95/69/EC” means the minimum conditions laid down in—

- (a) Chapter I.1(b) of the Annex to Directive 95/69/EC in the case of an application to approve an establishment, other than an Article 12 establishment, as an establishment on which the activity specified in regulation 10(1)(a) may be exercised;
- (b) points 4, 5, 6.2 and 7 of Chapter I.1(b) of the Annex to Directive 95/69/EC in the case of an application to approve an Article 12 establishment as an establishment on which the activity specified in regulation 10(1)(a) may be exercised;
- (c) Chapter I.2(b) of the Annex to Directive 95/69/EC in the case of an application to approve an establishment as an establishment on which the activity specified in regulation 10(1)(b) or (e) may be exercised;
- (d) Chapter I.3(b) of the Annex to Directive 95/69/EC in the case of an application to approve an establishment as an establishment on which the activity specified in regulation 10(1)(c) may be exercised; and
- (e) with the exception of the requirements set out in point 7, Chapter I.3(b) of the Annex to Directive 95/69/EC, in the case of an application to approve an establishment as an establishment on which the activity specified in regulation 10(1)(d) may be exercised;

“approved establishment” means an establishment approved by the enforcement authority as an establishment on which an establishment activity may be exercised;

“eligible person” means a person who is entitled to apply to the enforcement authority in accordance with the first paragraph of Article 4.1 of Directive 95/69/EC or the first paragraph of Article 4.2 of that Directive for an establishment to be approved as an establishment on which an establishment activity may be exercised;

“essential conditions” means the essential conditions in—

- (a) Chapter I.1(b) of the Annex to Directive 95/69/EC in the case of the exercise of the establishment activity specified in regulation 10(1)(a);
- (b) Chapter I.2(b) of the Annex to Directive 95/69/EC in the case of the exercise of the establishment activity specified in regulation 10(1)(b) or (e);
- (c) Chapter I.3(b) of the Annex to Directive 95/69/EC in the case of the exercise of the establishment activity specified in regulation 10(1)(c);
- (d) with the exception of the requirements set out in point 7, Chapter I.3(b) of the Annex to Directive 95/69/EC in the case of the exercise of the establishment activity specified in regulation 10(1)(d); and

“establishment activity” means an activity specified in sub-paragraph (a), (b), (c), (d) or (e) of regulation 10(1).

## PART IV

### APPROVAL OF INTERMEDIARIES

#### Applications for the approval of intermediaries

**18.**—(1) An eligible person may apply to the enforcement authority to be approved as an intermediary who may—

- (a) wrap, package, store or put into circulation any zootechnical additive; or
- (b) wrap, package, store or put into circulation any zootechnical premixture.

(2) An application made under paragraph (1) shall be in writing, in the English language, (or, where the facilities in respect of which the application is made are situated wholly or partly in Wales, in either that language or the Welsh language) signed by or on behalf of the applicant, and shall contain name (or business name) and address of the applicant, shall specify each activity in relation to which the application is made, and shall be accompanied by particulars which demonstrate that the applicant meets the applicable minimum conditions laid down in the Annex to Directive 95/69/EC.

#### Approval of intermediaries

**19.**—(1) Where an application is made under regulation 18 and is accompanied by the relevant fee, the enforcement authority shall (subject to paragraph (2) and regulation 23)—

- (a) check by means of an on the spot verification whether the applicant meets the applicable minimum conditions laid down in the Annex to Directive 95/69/EC, and
- (b) process the application in accordance with the requirements of the second paragraph of Article 4.1 or the second paragraph of Article 4.2 of Directive 95/69/EC as applicable.

(2) The obligation imposed on the enforcement authority by paragraph (1)(a) shall not apply if the person who has applied to be approved as an intermediary has lodged a declaration of the type specified in the second paragraph of Article 5.1 of Directive 95/69/EC with the enforcement authority.

- (3) Where the enforcement authority is satisfied that the applicant meets the applicable minimum conditions laid down in the Annex to Directive 95/69/EC, it shall—

- (a) approve the applicant as an intermediary who may exercise the relevant intermediary activity, and
- (b) register the applicant on the register of approved intermediaries in accordance with Article 5.1 of Directive 95/69/EC, as read with Articles 8 and 9 of, and the Annex to, Directive 98/51/EC, as being an approved intermediary who may exercise that activity.

#### Amendments of approvals

**20.**—(1) An eligible person may apply to the enforcement authority to be approved as an approved intermediary who may exercise a further intermediary activity (“the new intermediary activity”)—

- (a) in addition to an intermediary activity which he is already approved to exercise, or
- (b) instead of that activity.

(2) Where an application, complying with regulation 18(2), is made under paragraph (1), the enforcement authority shall (subject to regulation 23) amend the approval relating to the intermediary, and approve him as an intermediary who may exercise the new intermediary activity, if the enforcement authority is satisfied that, in respect of the new intermediary activity, the applicant meets the applicable minimum conditions laid down in the Annex to Directive 95/69/EC.

(3) Where, pursuant to paragraph (2), the enforcement authority amends an approval relating to an approved intermediary, it shall update the register of approved intermediaries to show all the intermediary activities that may be exercised by the intermediary.

### **Withdrawal of approvals**

**21.**—(1) The enforcement authority shall withdraw an approval relating to the exercise of an intermediary activity by an approved intermediary if the enforcement authority is satisfied that the intermediary has ceased exercising that activity.

(2) The enforcement authority shall withdraw an approval relating to the exercise of an intermediary activity by an approved intermediary if, following the procedure in regulation 22, it is not satisfied that the intermediary is complying with the duties imposed on him by regulation 38, 40, 54 or 56 as the case may be.

(3) Where, pursuant to paragraphs (1) or (2), the enforcement authority withdraws an approval relating to the exercise of an intermediary activity by an approved intermediary, it shall update the register of approved intermediaries—

- (a) to show any remaining intermediary activity that the intermediary may continue to exercise, or
- (b) by removing the intermediary from the register where, as a result of withdrawing the approval relating to the exercise of the relevant intermediary activity, the intermediary is no longer approved to exercise an intermediary activity of any sort.

### **Procedure relating to the withdrawal of approvals**

**22.**—(1) Where the enforcement authority proposes to withdraw an approval relating to the exercise of an intermediary activity by an approved intermediary, because it is not satisfied that the intermediary is complying with the duties imposed on him by regulation 38, 40, 54 or 56, as the case may be, the enforcement authority shall not withdraw the approval unless—

- (a) it serves a notice complying with the requirements of paragraph (2) on the intermediary, and
  - (b) it is not satisfied, after the time for compliance with that notice has expired, that the intermediary has complied with the requirements specified in the notice.
- (2) A notice served by the enforcement authority under paragraph (1) shall—
- (a) state that it proposes to withdraw the approval relating to the intermediary's exercise of the relevant intermediary activity because it is not satisfied that the intermediary is complying with the duties imposed on him by regulation 38, 40, 54 or 56, as the case may be;
  - (b) specify—
    - (i) the essential conditions that the enforcement authority is not satisfied that the intermediary is complying with; and
    - (ii) the requirements that the intermediary must comply with in order to satisfy the enforcement authority as to compliance with those essential conditions; and
  - (c) specify that, unless it is satisfied that the intermediary has complied with the requirements specified in the notice within such reasonable time as is specified in the notice, the

intermediary's approval, insofar as it relates to the relevant intermediary activity, will be withdrawn.

## **Fees**

**23.**—(1) In this regulation, “the relevant fee” in relation to any application means the fee specified opposite the application in question in Part III of Schedule 3, and it shall be payable by a person who applies to the enforcement authority under regulation 18 or 20 to be approved as an intermediary who may exercise an intermediary activity.

(2) Any relevant fee shall be paid at the time the application is submitted to the enforcement authority.

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

(4) The enforcement authority need not process any application under regulation 18 or 20, unless the application is accompanied by the relevant fee.

## **Publication of the national list of approved intermediaries**

**24.** The enforcement authority shall provide the Minister in writing, on demand being made by him, such information as is available to it and which will assist the Minister to comply with the requirements of Article 6.1 of Directive 95/69/EC relating to the publication of the national list of approved intermediaries.

## **Interpretation of Part IV**

**25.** In this Part—

“the applicable minimum conditions laid down in the Annex to Directive 95/69/EC” means the minimum conditions laid down or referred to in—

- (a) point 7 of Chapter I.1(b) of the Annex to Directive 95/69/EC in the case of an application to approve a person as an intermediary who may exercise the intermediary activity specified in regulation 18(1)(a); and
- (b) point 7 of Chapter I.2(b) of the Annex to Directive 95/69/EC in the case of an application to approve a person as an intermediary who may exercise the intermediary activity specified in regulation 18(1)(b);

“approved intermediary” means a person approved by the enforcement authority as an intermediary who may exercise an intermediary activity;

“eligible person” means a person who is entitled to apply to the enforcement authority in accordance with the provisions of the first paragraph of Article 4.1 of Directive 95/69/EC or the first paragraph of Article 4.2 of that Directive to be approved as an intermediary who may exercise an intermediary activity;

“essential conditions” means the essential conditions contained or referred to in—

- (a) point 7 of Chapter I.1(b) of the Annex to Directive 95/69/EC in the case of the exercise of the intermediary activity specified in regulation 18(1)(a); and
- (b) point 7 of Chapter I.2(b) of the Annex to Directive 95/69/EC in the case of the exercise of the intermediary activity specified in regulation 18(1)(b); and

“intermediary activity” means an activity specified in sub-paragraph (a) or (b) of regulation 18(1).

## PART V

### APPROVAL OF ESTABLISHMENTS LOCATED IN THIRD COUNTRIES

#### **Declarations leading to the approval of establishments located in third countries**

**26.**—(1) An eligible person may submit to the Minister a declaration relating to a third country establishment on which there is being exercised, or on which it is intended to exercise, one or more of the following activities—

- (a) the manufacture of a zootechnical additive, with a view to putting it into circulation;
  - (b) the manufacture of a zootechnical premixture, with a view to putting it into circulation;
  - (c) the manufacture of a zootechnical compound feedingstuff, with a view to putting it into circulation.
- (2) A declaration submitted under paragraph (1) shall—
- (a) be in writing,
  - (b) be in the English language,
  - (c) be signed by or on behalf of the person submitting the declaration,
  - (d) contain the name (or business name) and address of that person,
  - (e) identify the establishment to which the declaration relates,
  - (f) identify the establishment activity which is being exercised or, as the case may be, it is intended to exercise, on that establishment,
  - (g) (if made by 30th September 1999) state—
    - (i) whether the establishment activity was being exercised on the establishment on 31st December 1998, and
    - (ii) if so, whether an eligible person would have been in a position to submit a declaration equivalent to one under paragraph (1) in relation to the establishment activity at a date after 30th December 1998 but before 1st May 1999, had paragraph (1) been in force at that date;
  - (h) contain a statement that the establishment complies, and an undertaking that when the establishment activity is exercised on it it will comply, with the applicable conditions, and
  - (i) contain an undertaking of the kind described in the second indent of Article 6.2 of Directive 98/51/EC.

#### **Approval of establishments located in third countries**

**27.**—(1) Where a declaration complying with regulation 26(2) is submitted under paragraph (1) of that regulation, the Minister shall—

- (a) approve the establishment as an establishment as to which any product manufactured thereon, in the course of carrying out the establishment activity to which the declaration relates, may be imported into the United Kingdom, and
  - (b) in accordance with Article 5.1 of Directive 95/69/EC, as read with Articles 8 and 9 of, and the Annex to, Directive 98/51/EC, enter the establishment on a register, which the Minister shall maintain, under an individual approval number which identifies the establishment, as an establishment approved in relation to the establishment activity concerned.
- (2) The Minister shall, for the purposes of paragraph (1), treat a declaration as submitted in anticipation of regulation 26(1) as submitted thereunder and complying with regulation 26(2) if the declaration either—

- (a) complies with all the requirements set out in regulation 26(2), or
- (b) if made after 30th December 1998 but before 1st May 1999, complies with all those requirements other than the requirement set out in regulation 26(2)(g)(ii).

### **Amendment of approvals**

**28.**—(1) An eligible person may submit to the Minister a declaration relating to an approved third country establishment on which it is intended to exercise an establishment activity (“the new establishment activity”)—

- (a) in addition to an establishment activity for the exercise of which the establishment is already approved, or
  - (b) instead of that activity.
- (2) A declaration submitted under paragraph (1) shall—
- (a) be in writing,
  - (b) be in the English language,
  - (c) be signed by or on behalf of the person submitting the declaration,
  - (d) contain the name (or business name) and address of that person,
  - (e) identify the establishment to which the declaration relates,
  - (f) identify the new establishment activity which is being exercised or, as the case may be, it is intended to exercise, on that establishment,
  - (g) (if made by 30th September 1999) state—
    - (i) whether the new establishment activity was being exercised on the establishment on 31st December 1998, and
    - (ii) if so, whether an eligible person would have been in a position to submit a declaration equivalent to one under paragraph (1) in relation to the new establishment activity at a date after 30th December 1998 but before 1st May 1999, had paragraph (1) been in force at that date;
  - (h) state under which sub-paragraph of paragraph (1) the declaration is submitted,
  - (i) contain a statement that the establishment complies, and an undertaking that when the new establishment activity is exercised on it it will comply, with the applicable conditions, and
  - (j) contain an undertaking of the kind prescribed in the second indent of Article 6.2 of Directive 98/51/EC.

(3) Where a declaration complying with paragraph (2) is submitted under paragraph (1), the Minister shall approve the establishment as an establishment as to which any product manufactured thereon, in the course of carrying out the new establishment activity, may be imported into the United Kingdom.

(4) Where, pursuant to paragraph (3), the Minister approves an establishment, he shall amend the register maintained by him under regulation 27(1)(b), to show all the establishment activities in relation to which the establishment is approved under regulation 27(1)(a), or under paragraph (3).

(5) The Minister shall, for the purposes of paragraphs (3) and (4), treat a declaration submitted in anticipation of paragraph (1) as submitted thereunder and complying with paragraph (2) if the declaration either—

- (a) complies with all the requirements set out in paragraph (2), or
- (b) if made after 30th December 1998 but before 1st May 1999, complies with all those requirements other than the requirement set out in paragraph (2)(g)(ii).



### **Cancellation of approvals**

**29.**—(1) The Minister shall cancel an approval relating to the exercise of an establishment activity on an approved third country establishment if, as a result of official checks, or an on-the spot inspection carried out pursuant to Article 5.1 of Directive 98/51/EC, and after following the procedure in regulation 30, he is not satisfied that the person exercising on the establishment the activity concerned (“the manufacturer”), is fulfilling, in relation to that activity, the essential conditions, or that the representative of that establishment established within the United Kingdom is fulfilling the essential representative conditions.

(2) Where, pursuant to paragraph (1), the Minister cancels an approval, he shall amend the register maintained by him under regulation 27(1)(b) by deleting from it the entry in respect of the establishment activity in relation to which approval has been cancelled.

### **Procedure relating to the cancellation of approvals**

**30.**—(1) Where, in the circumstances described in regulation 29(1), the Minister proposes to cancel an approval relating to the exercise of an establishment activity on an approved third country establishment, he shall not cancel it unless—

- (a) he serves a written notice complying with the requirements of paragraph (2) on the representative established within the United Kingdom of the establishment (“the recipient”), and
  - (b) after the time for compliance with the notice has expired, he is not satisfied that the manufacturer or, as the case may be, the recipient, has complied with the requirements specified in the notice.
- (2) A notice served by the Minister under paragraph (1) shall—
- (a) state that he proposes to cancel the approval relating to the establishment activity concerned, because he is not satisfied that—
    - (i) the manufacturer is complying, in relation to that activity, with the essential conditions, or, as the case may be,
    - (ii) the recipient is complying with the essential representative conditions;
  - (b) specify—
    - (i) the essential conditions or, as the case may be, the essential representative conditions, he is not satisfied that the manufacturer or, as the case may be, the recipient, is complying with; and
    - (ii) the requirements that the manufacturer or, as the case may be, the recipient, must comply with in order to satisfy the Minister as to compliance with those essential conditions or, as the case may be, those essential representative conditions; and
  - (c) state that, unless he is satisfied that the manufacturer or, as the case may be, the recipient, has complied with those requirements, within such reasonable time as is specified in the notice, the approval relating to the establishment activity concerned will be cancelled.

### **Obligation of the enforcement authorities to supply certain information to the Minister of Agriculture, Fisheries and Food**

**31.** Where any enforcement authority comes into possession of information which it considers will assist the Minister to exercise his functions under regulations 29 and 30, it shall as soon as practicable provide that information to him in writing.

## **Interpretation of Part V**

### **32. In this Part—**

“the applicable Chapter” means—

- (a) in the case of a declaration made pursuant to regulation 26(1)(a), Chapter I.1(b) of the Annex to Directive 95/69/EC;
- (b) in the case of a declaration made pursuant to regulation 26(1)(b), Chapter I.2(b) of the Annex to Directive 95/69/EC; and
- (c) in the case of a declaration made pursuant to regulation 26(1)(c), Chapter I.3(b) of the Annex to Directive 95/69/EC;

“the applicable conditions” means conditions at least as stringent as the conditions laid down or referred to in the applicable Chapter;

“approved third country establishment” means an establishment approved by the Minister pursuant to regulation 27(1)(a) or, as the case may be, 28(3);

“eligible person” means a person who is entitled to submit a declaration to the Minister in accordance with Article 6.2 or 6.3 of Directive 98/51/EC;

“essential conditions” means the essential conditions contained or referred to in the applicable Chapter; and

“essential representative condition”, in relation to a representative established within the United Kingdom of a third country establishment, has the same meaning as the expression “essential condition applicable to their activities” in Article 6.4(b) of Directive 98/51/EC has in relation to him;

“establishment activity” means an activity specified in sub-paragraph (a), (b) or (c) of regulation 26(1).

## **PART VI**

### **CONTROL OF ZOOTECHNICAL ADDITIVES**

#### **Manufacture of zootechnical additives**

**33.** No person shall manufacture a zootechnical additive with a view to putting it into circulation except on a UK approved or permitted Chapter I.1 establishment.

#### **Duties on persons manufacturing zootechnical additives**

**34.** A person manufacturing a zootechnical additive on a UK approved Chapter I.1 establishment, with a view to putting it into circulation, shall fulfil the essential conditions contained in Chapter I.1(b) of the Annex to Directive 95/69/EC.

#### **Packaging of zootechnical additives**

**35.** No person shall market a zootechnical additive unless the additive is packaged in accordance with the requirements of Article 10 of Directive 70/524/EEC.

#### **Labelling of zootechnical additives**

**36.—(1)** No person shall put a zootechnical additive into circulation unless the labelling of the additive complies with the requirements of Article 14.1.A and B(a) of Directive 70/524/EEC

as amended by Directive 96/51/EC or, with effect from 1st October 1999, complies with those provisions as amended as aforesaid, and as amended further by Council Directive 1999/20/EC(21).

- (2) No person shall put a zootechnical additive into circulation if information other than that—
- (a) required by virtue of Articles 14.1.A and B(a) of Directive 70/524/EEC, as amended by Directive 96/51/EC or, with effect from 1st October 1999, as so amended and as amended further by Council Directive 1999/20/EC, or
  - (b) authorised by virtue of Article 14.2 of Directive 70/524/EEC, as amended by Directive 96/51/EC,

appears on the package, container or label of the additive, unless that information is clearly separated from the required and authorised information in accordance with Article 14.3 of Directive 70/524/EEC as amended by Directive 96/51/EC.

### **Wrapping, packaging and storage of zootechnical additives by intermediaries**

**37.** No intermediary shall wrap, package or store a zootechnical additive unless he is a UK approved or permitted Chapter I.1 intermediary.

### **Duties on intermediaries wrapping, packaging or storing zootechnical additives**

**38.** A UK approved Chapter I.1 intermediary wrapping, packaging or storing a zootechnical additive shall fulfil the applicable essential conditions referred to in point 7 of Chapter I.1(b) of the Annex to Directive 95/69/EC.

### **Putting zootechnical additives into circulation**

**39.**—(1) Subject to paragraph (2) and regulation 41(3), no person shall put a zootechnical additive into circulation other than an authorised zootechnical additive manufactured on—

- (a) a UK approved or permitted Chapter I.1 establishment;
- (b) an EC approved or permitted Chapter I.1 establishment;
- (c) a UK approved or permitted third country Chapter I.1 establishment; or
- (d) an EC approved or permitted third country Chapter I.1 establishment.

(2) Subject to regulation 41(3), no intermediary shall put an authorised zootechnical additive into circulation unless he is a UK or EC approved or permitted Chapter I.1 intermediary.

### **Duties on intermediaries putting zootechnical additives into circulation**

**40.** A UK approved Chapter I.1 intermediary putting a zootechnical additive into circulation shall fulfil the applicable essential conditions referred to in point 7 of Chapter I.1(b) of the Annex to Directive 95/69/EC.

### **Supply of zootechnical additives**

**41.**—(1) Subject to paragraph (3), no person shall supply an unauthorised zootechnical additive.

(2) Subject to paragraph (3), no person shall supply an authorised zootechnical additive other than to—

- (a) a UK or EC approved or permitted Chapter I.1 intermediary;
- (b) a person manufacturing, or intending to manufacture, a zootechnical premixture on a UK or EC approved or permitted Chapter I.2 establishment;

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(21) OJ No. L80, 25.3.99, p. 20.

- (c) where the zootechnical additive is delivered at the last stage of circulation, a person manufacturing, or intending to manufacture, a compound feedingstuff on a UK or EC approved or permitted Chapter I.3(M) establishment, if the conditions specified in the first and third indented paragraphs of Article 13.4(b) of Directive 70/524/EEC, as amended by Directive 96/51/EC, are complied with; or
- (d) a person who intends to export it to a third country.

(3) Nothing in regulation 39(1) or paragraphs (1) or (2) shall prohibit a person from supplying an unauthorised or authorised zootechnical additive to a person (in this paragraph called “the recipient”) who intends—

- (a) to use the additive, or
- (b) to incorporate the additive in a feedingstuff and then use that feedingstuff,

for an Article 6.4 purpose if the use of the additive or the resulting feedingstuff, as the case may be, will constitute—

- (i) a medicinal test on animals for which the recipient has been issued with an animal test certificate, or
- (ii) a regulated procedure for which the recipient holds a personal licence and which is specified in a project licence which authorises the procedure.

#### **Use of zootechnical additives for the purpose of animal feeding**

**42.**—(1) Subject to paragraph (2), no person shall use a zootechnical additive for the purpose of animal feeding except an authorised zootechnical additive which—

- (a) has been incorporated in a feedingstuff, and
- (b) was incorporated in the feedingstuff in accordance with regulation 43.

(2) Nothing in paragraph (1) shall prohibit a person from feeding an animal—

- (a) an unauthorised zootechnical additive, or
- (b) a feedingstuff containing an unauthorised zootechnical additive,

for an Article 6.4 purpose if the use of the additive or the feedingstuff, as the case may be, will constitute—

- (i) a medicinal test on animals for which he has been issued with an animal test certificate, or
- (ii) a regulated procedure for which he holds a personal licence, and which is specified in a project licence which authorises the procedure.

#### **Incorporation of zootechnical additives**

**43.**—(1) Subject to paragraph (3), no person shall incorporate an unauthorised zootechnical additive into a feedingstuff.

(2) Subject to paragraph (3), no person shall incorporate an authorised zootechnical additive into a feedingstuff other than a compound feedingstuff.

(3) Nothing in paragraphs (1) or (2) shall prohibit a person (“the relevant person”) from incorporating—

- (a) an unauthorised zootechnical additive in a feedingstuff, or
- (b) an authorised zootechnical additive in a feedingstuff other than a compound feedingstuff,

where it is intended that the resulting feedingstuff will be fed to an animal for an Article 6.4 purpose and the use of the feedingstuff will constitute a use specified in paragraph (4).

(4) For the purpose of the previous paragraph the following uses are specified—

- (a) a medicinal test on animals for which the relevant person has been issued with an animal test certificate, or
  - (b) a regulated procedure for which the relevant person holds a personal licence and which is specified in a project licence that authorises the procedure.
- (5) No person shall incorporate an authorised zootechnical additive into a compound feedingstuff unless—
- (a) the additive has been prepared beforehand in the form of a premixture—
    - (i) on a UK or EC approved or permitted Chapter I.2 establishment, or
    - (ii) a UK or EC approved or permitted third country Chapter I.2 establishment,and in accordance with the requirements specified, or in the case of a third country establishment, requirements equivalent to those specified, in the first paragraph of Article 13.3 of Directive 70/524/EEC, as amended by Directive 96/51/EC, and he incorporates the premixture in the feedingstuff in accordance with regulation 59; or
  - (b) the incorporation is carried out on a UK approved or permitted Chapter I.3(M) establishment and the conditions specified in the first and third indented paragraphs of Article 13.4(b) of Directive 70/524/EEC, as amended by Directive 96/51/EC, are complied with;
- and, in either case, the additive is incorporated in accordance with the applicable provisions of the relevant Chapter entry covering the additive in Annex B to Directive 70/524/EEC as amended by Directive 96/51/EC.

#### **Mixing of zootechnical additives**

**44.**—(1) Subject to paragraph (3), no person shall mix a zootechnical additive with an additive which is not a zootechnical additive in a premixture or feedingstuff unless the mixing of the additives is permitted in accordance with the provisions contained in Article 6.2 of Directive 70/524/EEC.

(2) Subject to paragraph (3), no person shall mix a zootechnical additive with another zootechnical additive in a premixture or feedingstuff unless the mixing of the additives—

- (a) is permitted in accordance with the provisions contained in Article 6.2 of Directive 70/524/EEC, and
- (b) does not contravene the provisions contained in Article 6.3 of Directive 70/524/EEC.

(3) Nothing in paragraphs (1) or (2) shall prohibit a person from mixing a zootechnical additive with another zootechnical additive, or any other additive, where it is intended that—

- (a) the resulting mixture of additives, or
- (b) a premixture or feedingstuff containing the mixture of additives,

will be fed to an animal for an Article 6.4 purpose, and the use of the mixture of additives, or the premixture or the feedingstuff containing the mixture, as the case may be, will constitute—

- (i) a medicinal test on animals for which he has been issued with an animal test certificate, or
- (ii) a regulated procedure for which he holds a personal licence and which is specified in a project licence that authorises the procedure.

#### **Importation of zootechnical additives**

**45.** No person shall import into the United Kingdom, from a third country, a zootechnical additive manufactured in a third country, unless it was manufactured on a UK approved or permitted third country Chapter I.1 establishment, or an EC approved or permitted third country Chapter I.1 establishment.

### **Provision of samples**

46. The person responsible for putting a Community authorised zootechnical additive into circulation shall make a standard sample and a reference sample available to the enforcement authority in accordance with the requirements of Article 9p.1 and 2 of Directive 70/524/EEC as amended by Directive 96/51/EC.

### **Monitoring of undesirable interactions**

47.—(1) Where there is found to be an unforeseen undesirable interaction between a Community authorised zootechnical additive and another additive or veterinary medicine the relevant person shall comply with the requirements of Article 21a of Directive 70/524/EEC, as amended by Directive 96/51/EC, relating to the gathering of all the relevant information, and the forwarding on of such information to the enforcement authority.

(2) For the purposes of paragraph (1) the relevant person is—

- (a) the person responsible for putting the zootechnical additive into circulation where the zootechnical additive does not originate in a third country, and
- (b) the representative within the European Community of the person responsible for putting the zootechnical additive into circulation where the zootechnical additive originates in a third country.

### **Provision of information**

48. A person responsible for putting a zootechnical additive into circulation shall comply with the requirements relating to the provision of information contained in Article 9s of Directive 70/524/EEC as amended by Directive 96/51/EC.

## **PART VII**

### **CONTROL OF ZOOTECHNICAL PREMIXTURES**

#### **Manufacture of zootechnical premixtures**

49. No person shall manufacture a zootechnical premixture with a view to putting it into circulation except on a UK approved or permitted Chapter I.2 establishment.

#### **Duties on persons manufacturing zootechnical premixtures**

50. A person manufacturing a zootechnical premixture on a UK approved Chapter I.2 establishment, with a view to putting it into circulation, shall fulfil the essential conditions contained in Chapter I.2(b) of the Annex to Directive 95/69/EC.

#### **Packaging of zootechnical premixtures**

51. No person shall market a zootechnical premixture unless the premixture is packaged in accordance with the requirements of Article 10 of Directive 70/524/EEC.

#### **Labelling of zootechnical premixtures**

52.—(1) No person shall market a zootechnical premixture unless the labelling of the premixture complies with the provisions of Article 15.1.A and 15.1.B(a) (as read with Article 15.3) of Directive 70/524/EEC as amended by Directive 96/51/EC or, with effect from 1st October 1999, complies with

those provisions as amended as aforesaid, and as further amended by Council Directive [1999/20/EC](#)(22).

(2) No person shall market a zootechnical premixture if the premixture is labelled with information other than that—

- (a) required by virtue of Articles 15.1.A and 15.1.B(a) (as read with Article 15.3) of Directive 70/524/EEC, as amended by Directive 96/51/EC or, with effect from 1st October 1999, as so amended and as amended further by Council Directive [1999/20/EC](#), or
- (b) authorised by virtue of Article 15.2 of Directive 70/524/EEC, as amended by Directive 96/51/EC,

unless that information is clearly separated from the required and authorised information in accordance with Article 15.4 of Directive 70/524/EEC as amended by Directive 96/51/EC.

### **Wrapping, packaging and storage of zootechnical premixtures by intermediaries**

**53.** No intermediary shall wrap, package or store a zootechnical premixture unless he is a UK approved or permitted Chapter I.2 intermediary.

### **Duties on intermediaries wrapping, packaging or storing zootechnical premixtures**

**54.** A UK approved Chapter I.2 intermediary wrapping, packaging or storing a zootechnical premixture shall fulfil the applicable essential conditions referred to in point 7 of Chapter I.2(b) of the Annex to Directive 95/69/EC.

### **Putting zootechnical premixtures into circulation**

**55.**—(1) No person shall put a zootechnical premixture into circulation unless it has been manufactured—

- (a) on a UK or EC approved or permitted Chapter I.2 establishment, or
- (b) a UK or EC approved or permitted third country Chapter I.2 establishment.

(2) No intermediary shall put a zootechnical premixture into circulation unless he is a UK or EC approved or permitted Chapter I.2 intermediary.

### **Duties on intermediaries putting zootechnical premixtures into circulation**

**56.** A UK approved Chapter I.2 intermediary putting a zootechnical premixture into circulation shall fulfil the applicable essential conditions referred to in point 7 of Chapter I.2(b) of the Annex to Directive 95/69/EC.

### **Supply of zootechnical premixtures**

**57.**—(1) Subject to paragraph (2), no person shall supply a zootechnical premixture otherwise than to—

- (a) a UK or EC approved or permitted Chapter I.2 intermediary;
- (b) a person manufacturing, or intending to manufacture, a compound feedingstuff on a UK or EC approved or permitted Chapter I.3(M) establishment;
- (c) a person producing, or intending to produce, a compound feedingstuff on a U.K. or EC approved or permitted Chapter I.3(P) establishment; or
- (d) a person who intends to export it to a third country.

(2) Nothing in paragraph (1) shall prohibit a person from supplying a zootechnical premixture to a person (in this paragraph called “the recipient”) who intends—

- (a) to use the premixture, or
- (b) to incorporate the premixture in a feedingstuff and then use that feedingstuff,

for an Article 6.4 purpose if the use of the premixture or the feedingstuff, as the case may be, will constitute—

- (i) a medicinal test on animals for which the recipient has been issued with an animal test certificate, or
- (ii) a regulated procedure for which the recipient holds a personal licence and which is specified in a project licence which authorises the procedure.

### **Use of zootechnical premixtures for the purpose of animal feeding**

**58.**—(1) Subject to paragraph (2), no person shall use a zootechnical premixture for the purpose of animal feeding unless the premixture is incorporated in a compound feedingstuff and was incorporated in the feedingstuff in accordance with regulation 59.

- (2) Nothing in paragraph (1) shall prohibit a person from feeding an animal—
  - (a) a zootechnical premixture that has not been incorporated in a compound feedingstuff, or
  - (b) a feedingstuff containing a zootechnical premixture that was not incorporated in the feedingstuff in accordance with regulation 59,

for an Article 6.4 purpose if the use of the premixture or the feedingstuff, as the case may be, constitutes—

- (i) a medicinal test on animals for which he has been issued with an animal test certificate, or
- (ii) a regulated procedure for which he holds a personal licence, and which is specified in a project licence which authorises the procedure.

### **Incorporation of zootechnical premixtures**

**59.**—(1) Subject to paragraph (2), no person shall incorporate a zootechnical premixture into a compound feedingstuff unless—

- (a) the incorporation of the premixture is in accordance with any applicable provisions of Annex B to Directive 70/524/EEC, as amended by Directive 96/51/EC, covering the incorporation, and
- (b) the establishment on which the premixture is incorporated in the compound feedingstuff is—
  - (i) a UK approved or permitted Chapter I.3(M) establishment or a UK approved or permitted Chapter I.3(P) establishment and the premixture is incorporated in the compound feedingstuff in a proportion of at least 0.2 per cent by weight, or
  - (ii) a specially approved manufacturing establishment and the premixture is incorporated in the compound feedingstuff in a proportion of at least 0.05 per cent by weight.

(2) Nothing in paragraph (1) shall prohibit a person from incorporating a zootechnical premixture in a feedingstuff otherwise than in accordance with the provisions of paragraph (1) where it is intended that the resulting feedingstuff will be fed to an animal for an Article 6.4 purpose and the use of the feedingstuff will constitute—

- (a) a medicinal test on animals for which he has been issued with an animal test certificate, or



- (b) a regulated procedure for which he holds a personal licence and which is specified in a project licence that authorises the procedure.

#### **Importation of zootechnical premixtures**

**60.** No person shall import into the United Kingdom, from a third country, a zootechnical premixture manufactured in a third country, unless it was manufactured on a UK approved or permitted third country Chapter I.2 establishment, or an EC approved or permitted third country Chapter I.2 establishment.

## **PART VIII**

### **CONTROL OF ZOOTECHNICAL FEEDINGSTUFFS**

#### **Manufacture of zootechnical compound feedingstuffs**

**61.** No person shall manufacture a zootechnical compound feedingstuff with a view to putting it into circulation except on a UK approved or permitted Chapter I.3(M) establishment.

#### **Duties on persons manufacturing zootechnical compound feedingstuffs**

**62.** A person manufacturing a zootechnical compound feedingstuff on a UK approved Chapter I.3(M) establishment, with a view to putting it into circulation, shall fulfil the essential conditions contained in Chapter I.3(b) of the Annex to Directive 95/69/EC.

#### **Production of zootechnical compound feedingstuffs**

**63.** No person shall produce a zootechnical compound feedingstuff for the exclusive requirements of his holding except on a UK approved or permitted Chapter I.3(P) establishment.

#### **Duties on persons producing zootechnical compound feedingstuffs**

**64.** A person producing a zootechnical compound feedingstuff for the exclusive requirements of his holding on a UK approved Chapter I.3(P) establishment shall fulfil the essential conditions contained in Chapter I.3(b) of the Annex to Directive 95/69/EC with the exception of point 7.

#### **Levels of zootechnical additives in complete feedingstuffs**

**65.—(1)** No person shall put a complete feedingstuff containing a zootechnical additive into circulation unless the level of the additive in the feedingstuff is not less than any relevant minimum level and not more than any relevant maximum level for the additive covered by Annex B to Directive 70/524/EEC as amended by Directive 96/51/EC.

(2) Where applicable, the zootechnical additive level in a complete feedingstuff shall be determined taking into account the provisions contained in Article 6.1 of Directive 70/524/EEC.

#### **Level of zootechnical additives in supplementary feedingstuffs**

**66.—(1)** Subject to paragraph (2), no person shall market a supplementary feedingstuff containing a zootechnical additive unless the level of the additive in the feedingstuff is in accordance with the provisions of Article 12.1 of Directive 70/524/EEC.

(2) Nothing in paragraph (1) shall prohibit a person from marketing a supplementary feedingstuff containing a zootechnical additive at a level that is higher than that provided for in Article 12.1 of

Directive 70/524/EEC if (in circumstances in which marketing is permissible under Article 12.2 thereof)—

- (a) the zootechnical additive contained in the feedingstuff belongs to the antibiotics or growth promoters group of additives and the level of the additive in the feedingstuff is in accordance with the provisions of Article 12.2(a) of Directive 70/524/EEC;
- (b) the zootechnical additive contained in the feedingstuff belongs to the antibiotics or growth promoters group of additives and the level of the additive in the feedingstuff is in accordance with the provisions of the first indent of Article 12.2(b) of Directive 70/524/EEC; or
- (c) the zootechnical additive contained in the feedingstuff belongs to the coccidiostats and other medicinal substances group of additives and the level of the additive in the feedingstuff is in accordance with the provisions of the second indent of Article 12.2(b) of Directive 70/524/EEC;

and, in each case, the compositional characteristics of the feedingstuff comply with the provisions of Article 12.3 of Directive 70/524/EEC.

#### **Labelling of zootechnical feedingstuffs**

**67.** No person shall put into circulation a zootechnical feedingstuff unless the labelling of the feedingstuff complies with the provisions of paragraphs 1(a), 2, 4, 5, 6 and 8 of Article 16 of Directive 70/524/EEC as amended by Directive 96/51/EC or, with effect from 1st October 1999, complies with those provisions as amended as aforesaid, and as further amended by Council Directive [1999/20/EC](#).

#### **Labelling of supplementary zootechnical feedingstuffs**

**68.**—(1) Subject to paragraph (2), no person shall place a supplementary feedingstuff on the market which contains a zootechnical additive at a level in excess of the maximum additive level fixed for a complete feedingstuff containing the additive unless the directions for use relating to the supplementary feedingstuff are in accordance with the provisions of the first and second paragraphs of Article 17.1, and Article 17.2, of Directive 70/524/EEC.

(2) The provisions of paragraph (1) shall not apply in the circumstances specified in the third paragraph of Article 17.1 of Directive 70/524/EEC.

#### **Export of zootechnical feedingstuffs to EEA States**

**69.** No person shall export a zootechnical feedingstuff for marketing in an EEA State unless the details given on the package or container of, or label attached to, the feedingstuff and covered by Article 18 of Directive 70/524/EEC comply with that Article.

#### **Importation of zootechnical feedingstuffs**

**70.**—(1) No person shall import from an EEA State a zootechnical feedingstuff for marketing in the United Kingdom unless the details given on the package or container of, or label attached to, the feedingstuff and covered by Article 18 of Directive 70/524/EEC comply with that Article.

(2) No person shall import into the United Kingdom, from a third country, a zootechnical compound feedingstuff manufactured in a third country, unless it was manufactured on a UK approved or permitted third country Chapter I.3(M) establishment, or an EC approved or permitted third country Chapter I.3(M) establishment.

### **Putting zootechnical compound feedingstuffs into circulation**

71. No person shall put a zootechnical compound feedingstuff into circulation unless it has been manufactured on—

- (a) a UK or EC approved or permitted Chapter I.3(M) establishment, or
- (b) a UK or EC approved or permitted third country Chapter I.3(M) establishment.

## **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(23), 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(24),

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

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(24) 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.”**(25)**.



(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(26) (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(27)(manner of taking, preparing, marking, sealing and fastening of samples) there shall be substituted the following regulation:

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(27) S.I. 1999/1663.

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

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**“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.”.

29th June 1999

*Jeff Rooker*  
Minister of State, Ministry of Agriculture,  
Fisheries and Food

29th June 1999

*Calum MacDonald*  
Parliamentary Under Secretary of State, Scottish  
Office

## SCHEDULE 1

Regulation 2(1)

### EC REGULATIONS DELETING ADDITIVES FROM ANNEX B OF DIRECTIVE 70/524/EEC

1. Commission Regulation (EC) No. 2788/98 (OJ No. L347, 23.12.98, p. 31) amending Council Directive 70/524/EEC concerning additives in feedingstuffs as regards the withdrawal of authorisation for certain growth promoters.
2. Council Regulation (EC) No. 2821/98 (OJ No. L351, 29.12.98, p. 4) amending, as regards withdrawal of the authorisation of certain antibiotics, Directive 70/524/EEC concerning additives in feedingstuffs.
3. Commission Regulation (EC) No. 45/1999 (OJ No. L6, 12.1.1999, p. 3) amending Council Directive 70/524/EEC concerning additives in feedingstuffs as regards withdrawal of the authorisation of certain additives belonging to the group of coccidiostats and other medicinal substances.

## SCHEDULE 2

Regulation 2(2), (3) and (4)

### SUPPLEMENTARY PROVISIONS RELATING TO INTERPRETATION

#### PART I

Expressions having the same meaning as in Directive 70/524/EEC

animal feeding  
antibiotics  
coccidiostats and other medicinal substances  
compositional characteristics  
country of destination  
growth promoters  
market  
use

#### PART II

Expressions having the same meaning as in Directive  
70/524/EEC as amended by Directive 96/51/EC

Community authorisation  
delivered  
identification note  
incorporate  
last stage of circulation  
monograph  
originate  
period of authorisation

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reference sample  
 representative within the Community  
 standard sample  
 supply  
 toxicological tests on vertebrates  
 unforeseen undesirable interaction  
 veterinary medicine

### PART III

Expressions having the same meaning as in Directive 95/69/EC

cease  
 demonstrate  
 essential condition  
 exclusive requirements  
 facilities  
 holding  
 located  
 manufacture  
 on the spot verification  
 package  
 produce  
 reasonable time  
 register  
 store  
 update  
 wrap

#### SCHEDULE 3

Regulations 6(8)(b), 9(1), 15(1) and 23(1)

#### FEES

### PART I

Fees payable in relation to the submission of dossiers

Application	Fee (£) per dossier
Application under regulation 5(3)	25,000
Application under regulation 6(1)	25,000
Application under regulation 7(1)(a)	25,000

Application	Fee (£) per dossier
Application under regulation 7(1)(b)	10,000
Application under regulation 8(1)	2,500

## PART II

### Fees payable in relation to the approval of establishments

Application	Fee (£)
Application under regulation 10(1)(a) or 12 for approval of an establishment to manufacture a zootechnical additive	405
Application under regulation 10(1)(b) or 12 for approval of an establishment to manufacture a zootechnical premixture	405
Application under regulation 10(1)(c) or 12 for approval of an establishment to manufacture a zootechnical compound feedingstuff	113
Application under regulation 10(1)(d) or 12 for approval of an establishment to produce a zootechnical compound feedingstuff for the exclusive requirements of the applicant's holding	113
Application under regulation 10(1)(e) or 12 for approval of an establishment to manufacture a zootechnical compound feedingstuff using a minimum proportion of 0.05% by weight of a premixture	405

## PART III

### Fees payable in relation to the approval of intermediaries

Application	Fee (£)
Application for approval under regulation 18 or 20 to exercise an intermediary activity	151

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I, the undersigned, analyst at the (2) laboratory/agricultural analyst for the (3) /agricultural analyst in Northern Ireland/Government Chemist/Chief Agricultural Analyst, in pursuance of the provisions of the Feedingstuffs (Zootechnical Products) Regulations 1999, hereby certify that I received on the day of 19 , from (4) one part of a sample of (5) for analysis; which was duly sealed and fastened up and marked (6) and was accompanied by a (7) and also by a signed statement that the sample was taken in the manner referred to in regulation 76(8) of those Regulations; that (8) and that the said part has been analysed by me, or under my direction, and I declare the results of analysis to be as follows:-(9)

(A) specific method(s) is/are prescribed in the Feedingstuffs (Zootechnical Products) Regulations 1999 for the analysis of (10) and that/those method(s) was/were used in the analysis and/or

No specific method(s) is/are prescribed in the Feedingstuffs (Zootechnical Products) Regulations 1999 for the analysis of (10) and the method(s) used complied with regulation 84(4) of those Regulations (11)

Name of analyst/agricultural analyst/Government Chemist/Chief Agricultural Analyst (print)

Signature of analyst/agricultural analyst/Government Chemist/Chief Agricultural Analyst/  
person authorised by person named above to sign this certificate

Address

Date

## NOTES

- (1) Statements made in certificates are to be confined to matters which are necessary to verify compliance with the Feedingstuffs (Zootechnical Products) Regulations 1999.
- (2) Insert name of laboratory.
- (3) Insert the name of the local authority.
- (4) Insert the name of the authorised person who submitted the sample of analysis; and also the mode of transit, for example "by hand", "by registered post", "by rail", as the case may be.
- (5) Insert the name or description applied to the material.
- (6) Insert the distinguishing mark on the sample and the date of sampling shown thereon.
- (7) Insert description of any document accompanying the sample.
- (8) Insert details of particulars contained in any accompanying document, or particulars marked on, or indicated by a mark applied to, the material, or as the case may be.
- (9) Insert relevant results, including—
  - (a) identification of the type of product concerned (e.g. compound feeding stuff, complete feeding stuff, additive etc.);
  - (b) the name or names of any additive or premixture comprising or contained in the product;
  - (c) the amount of any additive comprising or contained in the product, having regard to any maximum or minimum level specified in respect of the additive for the purposes of Directive 70/524/EEC as amended by Directive 96/51/EC, and referred to a complete feeding stuff with a moisture content of 12%.
- (10) List substance(s).
- (11) Delete as applicable and indicate the method of analysis used. If analysis cannot be carried out because no suitable method exists then the certificate should be noted accordingly.



## SCHEDULE 5

Regulation 84(1), (2) and (3)

## METHODS OF ANALYSIS

## PART I

## COMMUNITY METHODS OF ANALYSIS

Column (1) Substance	Column (2) Community provision
Amprolium	Part 1 of Annex II to Directive <a href="#">74/203/EEC</a> ( <b>28</b> ) as corrected by a corrigendum published on 1st May 1974( <b>29</b> )
Avoparcin	Part 1 of the Annex to Directive <a href="#">81/715/EEC</a> ( <b>30</b> )
Carbadox	Part C of the Annex to Directive <a href="#">1999/27/EC</a> ( <b>31</b> )
Copper	Part 3 of the Annex to Directive <a href="#">78/633/EEC</a> ( <b>32</b> )
Diclazuril	Part B of the Annex to Directive <a href="#">1999/27/EC</a> ( <b>d</b> )
Dinitolmide (DOT)	Part 3 of Annex II to Directive <a href="#">74/203/EEC</a> ( <b>a</b> )
Ethopabate	Part 2 of Annex II to Directive <a href="#">74/203/EEC</a> ( <b>a</b> )
Flavophospholipol	Part 2 of the Annex to Directive <a href="#">78/633/EEC</a> ( <b>e</b> )
Halofuginone	The Annex to Directive <a href="#">93/70/EEC</a> ( <b>33</b> )
Menadione (vitamin K3)	Part 5 of Annex II to Directive <a href="#">74/203/EEC</a> ( <b>a</b> )
Methyl benzoate	Part 2 of the Annex to Directive <a href="#">93/117/EC</a> ( <b>34</b> )
Monensin sodium	Part 2 of the Annex to Directive <a href="#">81/715/EEC</a> ( <b>c</b> )
Nicarbazine	Part 4 of Annex II to Directive <a href="#">74/203/EEC</a> ( <b>a</b> )
Olaquinox	Part C of the Annex to Directive <a href="#">98/64/EC</a> ( <b>35</b> )
Robenidine	Part 1 of the Annex to Directive <a href="#">93/117/EC</a> ( <b>g</b> )
Spiramycin	The Annex to Directive <a href="#">84/425/EEC</a> ( <b>36</b> )
Tylosin	Part 4 of Annex II to Directive <a href="#">72/199/EEC</a> ( <b>37</b> )

(28) OJ No. L108, 22.4.74, p. 7.

(29) OJ No. L121, 3.5.74, p. 56.

(30) OJ No. L257, 10.9.81, p. 38.

(31) OJ No. L118, 6.5.99, p. 36.

(32) OJ No. L206, 29.7.78, p. 43.

(33) OJ No. L234, 17.9.93, p. 17.

(34) OJ No. L329, 30.12.93, p. 54.

(35) OJ No. L257, 19.9.98, p. 14.

(36) OJ No. L238, 6.9.84, p. 34.

(37) OJ No. L123, 29.5.72, p. 6 (OJ/SE 1966—72, p. 74).

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Column (1) Substance	Column (2) Community provision
Virginiamycin	Part 5 of Annex II of Directive <a href="#">72/199/EEC(j)</a> as replaced by Article 2 of, and Annex II to, Directive <a href="#">84/4/EEC(38)</a>
Vitamin A	Part 1 of Annex II to Directive <a href="#">73/46/EC(39)</a>
Zinc bacitracin	Part 1 of the Annex to Directive <a href="#">78/633/EEC(e)</a> as replaced by Article 3 of, and Annex III to, Directive <a href="#">84/4/EEC(k)</a>

## PART II

### DETERMINATION OF METICLORPINDOL (3,5-dichloro-2,6- dimethylpyridine-4-ol)

#### 1. SCOPE AND FIELD OF APPLICATION

The method is for the determination of the quantity of meticlorpindol in complete feeding stuffs, protein concentrates and feed supplements. The lower limit of the determination is 60mg/kg.

#### 2. PRINCIPLE

Meticlorpindol is extracted from the feed with methanolic ammonia solution, and a portion of the extract is passed through a column of aluminium oxide onto a column of ion-exchange resin. The meticlorpindol is retained on the resin and interfering substances are removed by washing with 80% methanol. The meticlorpindol is eluted from the resin with 40% acetic acid and the absorbance is measured at 267nm.

#### 3. REAGENTS

Note: The suitability of a batch of aluminium oxide and of the other reagents should be tested before use by analysing a blank feed to which a known amount of meticlorpindol has been added.

- 3.1. Aluminium oxide for column chromatography, 100 to 250 mesh, alkaline, Brockman activity 1.
- 3.2. Ammonia (density 0.88g per ml).
- 3.3. Anion exchange resin, AG1-X8 or Dowex 1-X8, 100 to 200 mesh—To convert Dowex resin in the chloride form to the acetate form add 1 litre of 6M hydrochloric acid to 350g of resin in a 3 litre beaker, and heat the mixture on a steam bath for 2 to 3 hours. Pour the slurry into a glass Buchner funnel, and wash the resin with water until the washings are free from chloride (about 6 litres of water are required). Transfer the resin to a 50mm diameter glass column having a coarse sintered-glass disc at the bottom end, and wash with sodium acetate solution (5g sodium acetate, anhydrous, dissolved in water and diluted to 100ml) until the column effluent gives only a cloudy solution on addition of silver nitrate solution. Return the resin to the glass Buchner funnel, and wash with water. Transfer the resin to a 3 litre beaker, add 1 litre of 40% v/v acetic acid solution (3.4) and heat on a steam bath for 3 hours or longer. Filter, and wash the resin again with water until the washings are free from chloride. Store the resin in water.

(38) OJ No. L15, 18.1.84, p. 28.

(39) OJ No. L83, 30.3.73, p. 21.

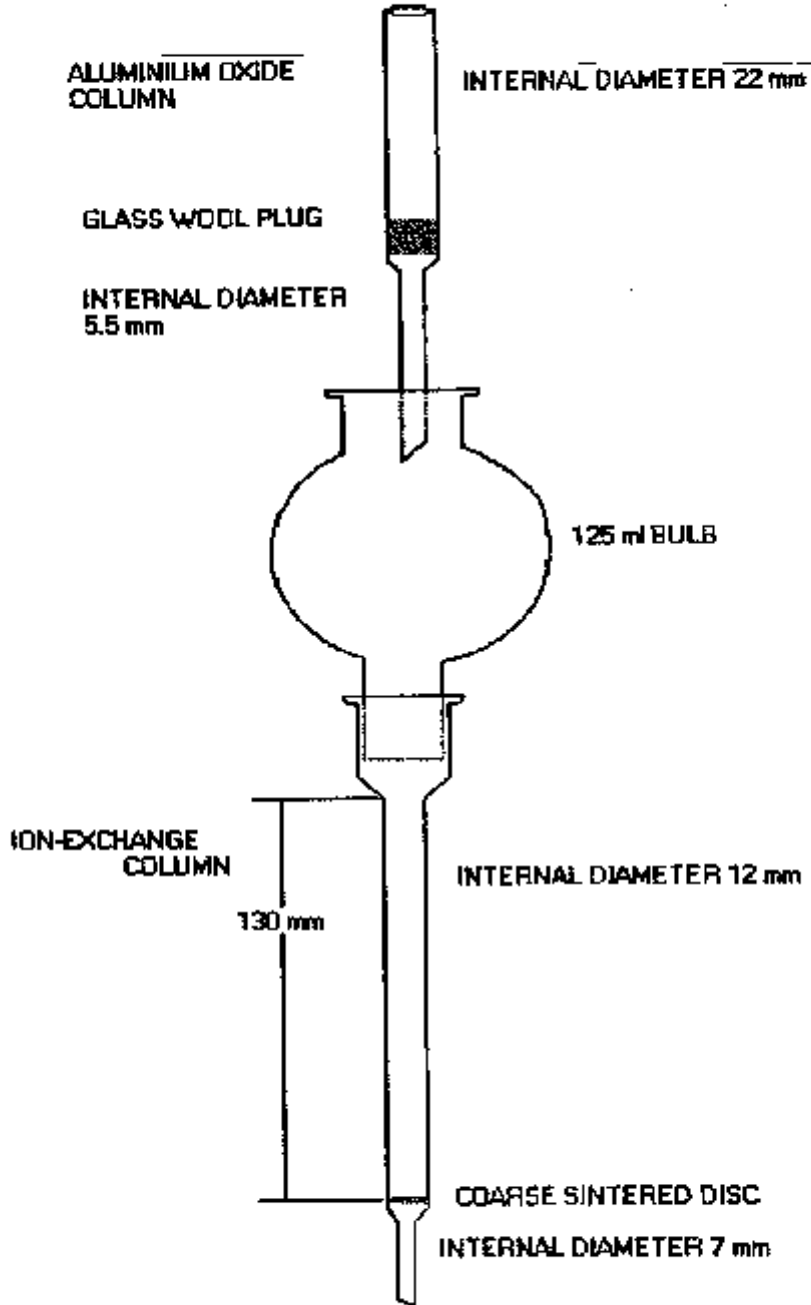
- 3.4. Acetic acid solution 40% v/v.
- 3.5. Methanol.
- 3.6. Methanol solution 80% v/v.
- 3.7. Ammoniacal methanol solution: dilute 1 volume of ammonia (3.2) with 19 volumes of methanol (3.5).
- 3.8. Meticlorpindol standard solution: weigh, to the nearest 0.1mg, 125mg of meticlorpindol into a beaker, add 25ml of sodium hydroxide solution (2g sodium hydroxide dissolved in water and diluted to 100ml) to dissolve the meticlorpindol, transfer the solution to a 500ml graduated flask, and dilute to the mark with water. This solution contains 250µg per ml meticlorpindol.

#### **4. APPARATUS**

- (4.1) Aluminium oxide column: constructed as indicated in the diagram included in this method of analysis.
- (4.2) Ion exchange column: constructed as indicated in the diagram included in this method of analysis.
- (4.3) Spectrophotometer, recording, with 10mm silica cells.

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DIAGRAM REFERRED TO IN PARAGRAPH 4



## 5. PROCEDURE

### (5.1) Extraction of meticlorpindol

Weigh, to the nearest 0.001g, approximately 50g of the finely divided and mixed sample, or a suitable amount expected to contain about 12mg of metictlorpindol, transfer to a 500ml graduated flask, and add 400ml of ammoniacal methanol solution (3.7). Place a magnetic stirring bar in the flask and stir the mixture on a magnetic stirrer for 20 minutes. Remove the stirring bar from the flask, dilute to the mark with ammoniacal methanol solution (3.7), mix the contents well, and set aside for 20 to 30 minutes.

## (5.2) Purification

- (5.2.1) Aluminium oxide column: For each column required weigh approximately 25g of aluminium oxide (3.1) into an aluminium foil dish and place in an oven at  $105\pm 5^{\circ}\text{C}$  for 1 hour. Remove the dish from the oven and cool to room temperature in a desiccator. Make a slurry of the aluminium oxide with 25ml of ammoniacal methanol solution (3.7) and filter on a Buchner funnel. Wash the aluminium oxide with methanol (3.5) until the washings are neutral. Form a slurry of the aluminium oxide with 50ml of methanol (3.5) and pour the slurry into the column (4.1). Allow the methanol to drip through the column. Place a plug of glass wool lightly on top of the aluminium oxide and then wash with 25ml of methanol (3.5). Do not allow the liquid in the column to fall below the top of the aluminium oxide. Discard the eluate.
- (5.2.2) Anion exchange column: Form a slurry in acetic acid (3.4) of sufficient resin (3.3) to fill the columns required. Filter on a Buchner funnel, wash the resin with twice its own volume of acetic acid (3.4) and then with aqueous methanol (3.6) until the washings are neutral. Form a slurry of a resin with aqueous methanol (3.6) and add sufficient to a column (4.2) to give a resin bed 20 to 30 mm deep after settling. Place a small plug of glass wool on top of the resin and wash the column with two 13ml portions of aqueous methanol (3.6). Do not allow the liquid level in the column to fall below the top of the resin. Discard the eluate.
- (5.2.3) Chromatographic procedure: By pipette transfer 10.0ml of the extract of the feed sample (5.1) directly onto an aluminium oxide column and at the same time transfer the same volume of ammoniacal methanol solution (3.7) directly onto a second aluminium oxide column (reagent blank). Allow the solutions to drain to the top of the aluminium oxide and then wash each column with three 12ml portions of aqueous methanol (3.6), allowing the liquid to drain to the top of the aluminium oxide each time. Let all the eluate from each column drain directly into separate ion-exchange columns, and then remove the aluminium oxide columns. Allow the liquid to drain to the top of the ion-exchange resin and then wash each column with four 13ml portions of aqueous methanol (3.6). Discard the eluates.

Elute each column with two 10ml and then one 4ml portions of acetic acid (3.4). Collect the eluates from each column in separate 25ml graduated flasks and dilute the contents of each to the mark with acetic acid (3.4).

## (5.3) Determination

Record the absorption spectrum of the sample extract between 350 and 245nm in 10mm silica cells with the reagent blank solution (5.2.3) as reference. Measure the absorbance of the sample extract at 267nm above a baseline obtained by drawing a line through the absorbance at 327 and 297nm and extending it through 267nm.

(Note: Background absorption due to the feed approaches a linear function that can be described by the points on the curve at 296 and 327nm. Occasionally this is not the case, as can be detected by absorption peaks in the region between 350 and 297nm).

Determine the concentration of metictlorpindol in the sample by reference to the calibration curve (5.4).

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#### (5.4) Calibration curve

By pipette transfer 1, 5, 7.5, 10, 12.5 and 15ml portions of meticlorpindol standard solution (3.8) to separate 250ml graduated flasks. Dilute the contents of each flask to the mark with acetic acid (3.4). Record the absorption spectra of these solutions in 10mm silica cells between 350 and 245nm with acetic acid (3.4) as reference. Construct a calibration curve using the absorbances at 267nm as ordinates and the corresponding concentrations of meticlorpindol in µg per ml as abscissae.

### 6. CALCULATION OF RESULTS

The meticlorpindol contents in mg/kg of sample is given by the formula:

$$\frac{23.23 \times C \times 50}{M}$$

in which:

C=concentration of meticlorpindol, in µg per ml, read from the calibration curve equivalent to the absorbance of the test solution;

23.23=a factor that makes allowance for the volume of the feed sample in the flask;

and

M=mass of test portion in g.

Absorbance at 327 and 297nm should not differ by more than 0.05 units and both points should be below 0.2. Results should be satisfactory as long as these criteria are kept in mind along with any obvious distortion in the appearance of the curve. No maximum other than that of meticlorpindol should be present.

## PART III

### DETERMINATION OF NIFURSOL [3,5-dinitro-2-(5-nitrofurfuryli dene)salicylohydrazide]

#### 1. SCOPE AND FIELD OF APPLICATION

The method is for the determination of the quantity of nifursol in complete feeding stuffs, protein concentrates and feed supplements. Other substances that will provide a nitro group under the conditions of the method, e.g. nitrofurazone and furazolidone, will interfere. The lower limit of the determination is 20mg/kg.

#### 2. PRINCIPLE

The sample is extracted with dimethylformamide and the extract is purified on a column of aluminium oxide. A portion of the purified extract containing the nifursol is treated with phenylhydrazine hydrochloride and the resulting phenylhydrazone extracted into toluene. The addition of methylbenzethonium hydroxide to the toluene solution produces a blue colour, the absorbance of which is measured as 515nm.

#### 3. REAGENTS

(3.1) Toluene.

(3.2) Aluminium oxide for column chromatography, 80 to 200 mesh, alkaline, Brockman activity 1. To 100 parts of the aluminium oxide add 6 parts of powdered magnesium hydroxide. Shake in a screw-cap bottle to mix, add 8 parts of water, and mix until free from lumps.

(3.3) Sand; acid washed.

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- (3.4) Dimethylformamide solution, 95% v/v.
- (3.5) Dimethylformamide solution, 50% v/v.
- (3.6) Phenylhydrazine, hydrochloride solution: shake 0.25±0.005g of phenylhydrazine hydrochloride in 25ml of water, add 25ml of concentrated hydrochloric acid, and shake to dissolve the solid, filtering if necessary. Prepare this reagent immediately before use.
- (3.7) Methylbenzethonium hydroxide solution: about 10% in methanol.
- (3.8) Nifursol standard solution: weigh, to the nearest 0.1mg, 25mg of pure nifursol into a 100ml graduated flask, add 5ml of 95% v/v dimethylformamide solution (3.4), and mix until all the solid has dissolved. Dilute to the mark with methanol. Prepare this solution freshly each day.

#### 4. APPARATUS

- (4.1) Chromatographic column—A glass column, internal diameter: 20 to 25mm; length: 100 to 150mm plugged at the lower end with glass wool.
- (4.2) Spectrophotometer, with 10mm cells.

#### 5. PROCEDURE

##### (5.1) Extraction

Weigh to the nearest 0.001g, approximately 5g of the finely divided and mixed sample, or a suitable amount expected to contain about 350µg of nifursol and transfer to a 125ml conical flask. Add 50.0ml of 95% v/v dimethylformamide solution (3.4), insert a stopper loosely, and place the flask in a water-bath at 60°C±5°C for 30 minutes. Swirl the contents of the flask occasionally during this period. Shake the flask on a mechanical shaker for 30 minutes and then filter the contents through a rapid filter-paper, preferably under reduced pressure on a Buchner funnel. Transfer 40.0ml of water, and stir. Set the beaker aside, protected from light, for 30 minutes.

##### (5.2) Purification

Pack the chromatographic column (4.1) to a depth of 70mm with the prepared aluminium oxide (3.2) and on top of the aluminium oxide add a layer of sand (3.3) 15mm deep. Wash the column with 50ml of 50% v/v dimethylformamide solution (3.5) and then pass the dimethylformamide extract of the test sample through the column; reject the first 45ml of eluate and collect the next 17ml.

##### (5.3) Determination

Pipette 5.0ml of the eluate to a 20ml centrifuge tube, add 5ml of phenylhydrazine hydrochloride solution (3.6), mix, and place the tube in a water-bath at 40°C±2°C for 20 minutes. Remove the tube from the water-bath and cool it in running water for 5 minutes. Add 5.0ml of toluene (3.1) to the contents of the tube, insert a glass or plastic stopper (a rubber stopper must not be used), and shake vigorously 40 times. Centrifuge for 5 minutes to clear the toluene layer, and transfer 3.0ml of the toluene layer to a 10mm spectrophotometer cell. Add 0.2ml of methylbenzethonium hydroxide solution (3.7), mix immediately, and measure the absorbance of the solution within one minute at 515nm with toluene as reference. Determine the quantity of nifursol by reference to the calibration curve (5.4).

##### (5.4) Calibration curve

Pipette 5.0ml of nifursol standard solution (3.8) to a 200ml graduated flask, add 100ml of 95% v/v dimethylformamide solution (3.4), dilute to the mark with water and mix. Into separate 20ml centrifuge tubes transfer by pipette 1, 2, 3, 4 and 5ml portions of this solution and dilute the contents of each tube to 5ml with 50% v/v dimethylformamide solution (3.5).

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Treat the contents of each tube as described under “Determination” (5.3) beginning at “... add 5ml of phenylhydrazine hydrochloride solution (3.6) ...”. Plot the calibration curve using the absorbance as the ordinates and the corresponding quantities of nifursol in µg as abscissae.

## 6. CALCULATING THE RESULTS

The nifursol content in mg/kg of sample is given by the formula:

$$\frac{20 \times A}{M}$$

in which:

A=µg of nifursol read from the calibration curve; and

M=mass of the test portion in g.

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

1. These Regulations, which extend to the United Kingdom, implement—
  - (a) insofar as they relate to zootechnical products, the following European Community Directives—
    - Council Directive 70/524/EEC concerning additives in feeding stuffs (OJ No. L270, 14.12.70, p. 1, OJ/SE Vol. 18, p. 4), including the amendments thereto in Council Directive 96/51/EC (OJ No. L235, 17.9.96, p. 39);
    - Third Commission Directive 72/199/EC (OJ No. L123, 29.5.72, p. 6) (OJ/SE 1966—72 p. 74) establishing Community methods of analysis for the official control of feeding stuffs;
    - Fifth Commission Directive 74/203/EEC (OJ No. L108, 22.4.74, p. 7) establishing Community methods of analysis for the official control of feeding stuffs;
    - First Commission Directive 76/371/EEC (OJ No. L102, 15.4.76, p. 1) establishing Community methods of sampling for the official control of feeding stuffs;
    - Eighth Commission Directive 78/633/EEC (OJ No. L206, 29.7.78, p. 43) establishing Community methods of analysis for the official control of feeding stuffs;
    - Commission Directive 81/680/EEC (OJ No. L246, 29.8.81, p. 32) amending Directives 71/250/EEC, 71/393/EEC, 72/199/EEC, 73/46/EEC, 74/203/EEC, 75/84/EEC, 76/372/EEC and 78/633/EEC establishing Community methods of analysis for the official control of feeding stuffs;
    - Commission Directive 84/4/EEC (OJ No. L15, 18.1.84, p. 28) amending Directives 71/393/EEC, 72/199/EEC and 78/633/EEC establishing Community methods of analysis for the official control of feeding stuffs;
    - The requirements of Council Directive 95/53/EC fixing the principles governing the organisation of official inspections in the field of animal nutrition (OJ No. L265, 8.11.95, p. 17);



Council Directive 95/69/EC laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector and amending Directives [70/524/EEC](#), [74/63/EEC](#), [79/373/EEC](#) and [82/471/EEC](#) (OJ No. L332, 30.12.95, p. 15);

Council Directive 96/51/EC amending Directive 70/524/EEC concerning additives in feedingstuffs (OJ No. L235, 17.9.96, p. 39);

Articles 6, 8 and 9 of Commission Directive 98/51/EC laying down certain measures for implementing Council Directive 95/69/EC laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector (OJ No. L208, 24.7.98, p. 43);

Commission Directive [98/54/EC](#) (OJ No. L208, 24.7.98, p. 49) amending Directives [71/250/EEC](#), [72/199/EEC](#), [73/46/EEC](#) and repealing Directive [75/84/EEC](#);

Commission Directive [98/64/EC](#) (OJ No. L257, 19.9.98, p. 14) establishing Community methods of analysis for the determination of amino acids, crude oils and fats, and olaquinox in feedingstuffs and amending Directive [71/393/EEC](#);

Council Directive [1999/20/EC](#) (OJ No. L80, 25.3.1999, p. 20) amending Directives [70/524/EEC](#) concerning additives in feedingstuffs, [82/471/EEC](#) concerning certain products used in animal nutrition, [95/53/EC](#) fixing the principles governing the organisation of official inspections in the field of animal nutrition and [95/69/EC](#) laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector; and

Commission Directive [1999/27/EC](#) (OJ No. L118, 6.5.99, p. 36) establishing Community methods of analysis for the determination of amprolium, diclazuril and carbadox in feedingstuffs and amending Directives [71/250/EEC](#), [73/46/EEC](#) and repealing Directive [74/203/EEC](#); and

(b) in full, the following Community Directives—

Ninth Commission Directive [81/715/EEC](#) (OJ No. L257, 10.9.81, p. 38) establishing Community methods of analysis for the official control of feedingstuffs;

Tenth Commission Directive [84/425/EEC](#) (OJ No. L238, 6.9.84, p. 34) establishing Community methods of analysis for the official control of feedingstuffs;

Eleventh Commission Directive [93/70/EEC](#) (OJ No. L234, 17.9.93, p. 17) establishing Community methods of analysis for the official control of feedingstuffs; and

Twelfth Commission Directive [93/117/EEC](#) (OJ No. L329, 30.12.93, p. 54) establishing Community methods of analysis for the official control of feedingstuffs.

2. The Regulations also provide for the enforcement of the following European Community Regulations—

Commission Regulation (EC) No. [2788/98](#) (OJ No. L347, 23.12.98, p. 31) amending Council Directive 70/524/EEC concerning additives in feedingstuffs as regards the withdrawal of authorisation for certain growth promoters;

Council Regulation (EC) No. [2821/98](#) (OJ No. L351, 29.12.98, p. 4) amending, as regards withdrawal of the authorisation of certain antibiotics, Directive 70/524/EEC concerning additives in feedingstuffs; and

Commission Regulation (EC) No. [45/1999](#) (OJ No. L6, 12.1.1999, p. 3) amending Council Directive 70/524/EEC concerning additives in feedingstuffs as regards withdrawal of the authorisation for certain additives belonging to the group of coccidiostats and other medicinal substances.

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3. In implementation of Directive 70/524/EEC as amended (other than Article 13), the Regulations prescribe the requirements for Community authorisation of zootechnical additives (regulations 5 to 9), control the marketing, as regards certain compositional and related matters and labelling, of zootechnical additives, zootechnical premixtures and zootechnical compound feeding stuffs and make provision relating to tests and use of information (regulations 35, 36, 41(1) and (3), 42, 43(1) to (4), 44, 46 to 8, 51, 52, 57(2), 58(2), 59(2), 65 to 70(1) and 72 to 4). In both cases the Regulations re-enact (or re-enact with modifications) provisions previously contained in Regulations revoked by these Regulations—the Feedingstuffs (Zootechnical Products) Regulations 1998 (“the 1998 Regulations”—S.I. 1998/1047).

4. There exists a category of additive producers who are not “eligible persons” within the meaning of regulation 5 but who are putting an additive into circulation and require Community authorisation under Directive 70/524/EEC as amended to continue marketing the additive on or after 1st October 1999. To enable such producers to apply before 1st October 1999 for Community authorisation of the additive they are currently putting into circulation, regulation 6 has been introduced. A fee is payable by an applicant when the Minister forwards the dossier, in support of the application for Community authorisation, to the Commission and other member States (regulation 6(4) and Schedule 3).

5. In implementation of Article 13 of Directive 70/524/EEC as amended, the Regulations also re-enact provisions in the 1998 Regulations regulating, in relation to establishments and intermediaries requiring approval—

- (a) the putting into circulation of zootechnical additives, zootechnical premixtures and zootechnical compound feeding stuffs (regulations 39(1), 55(1) and 71);
- (b) the supply of zootechnical additives, or of zootechnical premixtures (regulations 41(2) and 57(1)); and
- (c) the incorporation of zootechnical additives, and of zootechnical premixtures, in compound feeding stuffs (regulations 43(5), 58(1) and 59(1)).

6. In implementation of Directive 95/69/EC, the Regulations re-enact requirements previously contained in the 1998 Regulations under which—

- (a) “establishments” (as defined in Article 1.3 of Directive 95/69/EC) in the United Kingdom must be approved by the relevant competent authority (the Royal Pharmaceutical Society of Great Britain in Great Britain and the Department of Agriculture for Northern Ireland in Northern Ireland) for the manufacture with a view to putting them into circulation of zootechnical additives, zootechnical premixtures and zootechnical compound feeding stuffs,
- (b) “intermediaries” based in the United Kingdom (also defined in Article 1.3 of Directive 95/69/EC) must be approved by the same competent authorities for the wrapping, packaging, storing and “putting into circulation” (see definition in Article 1.3 of Directive 95/69/EC) of zootechnical additives and zootechnical premixtures, and
- (c) intermediaries based in a member State other than the United Kingdom, and putting into circulation in the United Kingdom products of the kinds referred to in sub-paragraph (b), must be approved by the competent authorities in the member State concerned,

and each category must comply with approval conditions in relation to the activities in question (regulations 33, 34, 37, 38, 39(2), 40, 49, 50, 53, 54, 55(2), 56 and 61 to 64).

7. Both establishments and intermediaries must comply with detailed “quality control” requirements specified in the Annex to Directive 95/69/EC, and that is a precondition before approval (which can only be given following an inspection by the competent authority) can be given.

8. Application for approval (which may now be made in the Welsh language in certain circumstances) must be made to the competent authority, and the application must contain

specified information. The competent authority must keep registers of approved establishments and intermediaries and must update them as necessary. Applicants may apply for approval in respect of activities additional to, or replacing, any for which they are already approved, and the competent authority can cancel approval in cases where an activity is no longer being exercised, or where the quality control requirements are not being met (regulations 10 to 25).

**9.** Transitional arrangements apply in the case of establishments and intermediaries which were already exercising, on 1st April 1998, activities of a kind for which approval is necessary. In particular, they may continue to exercise the activities concerned until their application is processed, provided they applied before 1st September 1998—(see the definitions in regulations 3 and 4 commencing with “EC permitted Chapter” or “UK permitted Chapter”).

**10.** The Regulations provide for examination of dossiers (regulations 5 to 8) and set fees for the examination (regulation 9), for the approval of establishments (regulation 15) and for the approval of intermediaries (regulation 23), all as read with Schedule 3. The fees replicate those in the 1998 Regulations, with the exception that the fee for applications under regulation 6 (a new type of application) and the fee for acting under regulation 7 in relation to new Community authorisation of an additive (£10,000 under the 1998 Regulations) are both aligned with that for acting under regulation 5 (£25,000).

**11.** The Regulations exclude the application of the Medicines Act 1968 to zootechnical additives, except in relation to—

- (a) any advisory function of a committee relating to veterinary medicinal products, and
- (b) animal test certificates for unauthorised zootechnical additives (regulation 92).

**12.** The Regulations provide for their enforcement by the competent authority and contain detailed provisions for that purpose, including provision for the taking of samples of products controlled by the Regulations, analysis of such samples, offences and penalties (regulations 75 to 91 and Schedules 4 and 5).

**13.** The principal changes effected by the Regulations are as follows—

- (a) among the provisions referred to in paragraph 12 there are included a number which, for the purposes of control of zootechnical products, and in relation to substances covered by the instruments referred to in paragraph 1, give effect to certain of the requirements of Directive 95/53/EC, including those relating to sampling and analysis and the manner of carrying out, and the frequency of, enforcement checks to be carried out by competent authorities;
- (b) in accordance with Article 6 of Directive 98/51/EC, the Regulations introduce, in relation to establishments located in third countries and their UK based representatives, as regards the products referred to in sub-paragraph (a), requirements similar to those described in paragraphs 5(a) and 6 to 8, the main differences being that—
  - (i) approval is granted by the Minister of Agriculture, Fisheries and Food and is for the importation into the United Kingdom of the products concerned. (It is made an offence to import those products from a third country into the United Kingdom, unless such approval has been obtained or the transitional arrangements described in sub-paragraph (iv) apply, or importation is permitted by virtue of parallel arrangements operating in another member State—regulations 45, 60 and 70(2));
  - (ii) application for approval, including amendment applications, is made by the UK based representative to the Minister, who will maintain the register of approved third country establishments, and have the power to withdraw approvals where there is non-compliance by an establishment or its representative with quality control requirements (regulations 26 to 32);

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- (iii) no prior inspection by the competent authority (the Royal Pharmaceutical Society for Great Britain in Great Britain and the Department of Agriculture for Northern Ireland in Northern Ireland) is necessary before approval is granted;
- (iv) the applicable transitional provisions operate in the case of third country establishments manufacturing the product concerned on 1st December 1998, and which at all times since have had a representative established in the European Community. Importation from such establishments may lawfully continue after the Regulations come into force, (provided the necessary application is made by 30th September 1999), until the application is processed. (See the definitions in regulation 3 commencing with “EC permitted third country” and “UK permitted third country”);
- (c) certain provisions in the 1998 Regulations applied to establishments “located in a third country”. In the corresponding provisions in these Regulations there is substituted for that expression reference to the relevant type of approved or permitted third country establishment provided for in these Regulations (regulations 39(1), 43(5), 55(1) and 71);
- (d) in implementation of Articles 8 and 9 of Directive 98/51/EC, the Regulations prescribe the formats of the register and approval numbers provided for in Article 5 of Directive 95/69/EC (regulations 11(2), 19(3)(b) and 27(1)(b));
- (e) for enforcement purposes, the Regulations include reference to European Community Regulations withdrawing Community authorisations previously accorded to the (growth promoter) additives carbadox and olaquinox, to the (antibiotic) additives bacitracin zinc, spiramycin, virginiamycin and tylosin phosphate and, with effect from 30th September 1999, to the (coccidiostats and other medicinal substances) additives arprinocid, dinitolmide and ipronidazole (regulation 2(1) and Schedule 1);
- (f) the Regulations create a new offence of making a false statement in connection with the Regulations (regulation 85(c));
- (g) the Regulations omit from those definitions in regulations 3 and 4 which also appear in the 1998 Regulations all wording which is now spent; and
- (h) the Regulations amend regulation 3 of the Feeding Stuffs (Sampling and Analysis) Regulations 1999 (S.I. 1999/1663) in order to rectify drafting errors (regulation 93).

**14.** The provisions referred to in paragraph 1 implemented by these Regulations are implemented, so far as relevant to certain feeding stuffs and products not containing zootechnical additives, by the Feeding Stuffs (Establishments and Intermediaries) Regulations 1999.

**15.** A Regulatory Appraisal has been prepared and a copy has been placed in the library of each House of Parliament.