#### STATUTORY INSTRUMENTS

# 1999 No. 1871

# The Feedingstuffs (Zootechnical Products) Regulations 1999

# 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(1) ("the 1998 Regulations") are hereby revoked.

## General interpretation and application

- 2.—(1) In these Regulations—
  - "the 1968 Act" means the Medicines Act 1968(2).
  - "the 1970 Act" means the Agriculture Act 1970(3).
  - "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;

<sup>(1)</sup> S.I. 1998/1047.

<sup>(2) 1968</sup> c. 67.

<sup>(3) 1970</sup> c. 40.

- "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(4) as amended up to, but not including, the amendments effected by Directive 96/51/EC(5);
- "Directive 87/153/EEC" means Council Directive 87/153/EEC fixing guidelines for the assessment of additives in animal nutrition(6) as amended by Commission Directives 94/40/ EC(7) and 95/11/EC(8);
- "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(9) (with effect from 1st October 1999 as amended by Council Directive 1999/20/EC(10));
- "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(11) (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(12);
- "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(13);
- "dossier" means a dossier compiled in accordance with the relevant provisions of Directive 87/153/EEC and which includes-

<sup>(4)</sup> OJNo. L270, 14.12.70, p. 1 (OJ/SE Vol. 18, p. 4)

<sup>(5)</sup> The next most recent amending instrument was Council Directive 96/25/EC (OJ No. L125, 23.5.96, p. 35).
(6) OJ No. L64, 7.3.87, p. 19.

<sup>(7)</sup> OJ No. L208, 11.8.94, p. 15.

<sup>(8)</sup> OJ No. L106, 11.5.95, p. 23. (9) OJ No. L265, 8.11.95, p. 17.

<sup>(10)</sup> OJ No. L80, 25.3.1999, p. 20. (11) OJ No. L332, 30.12.95, p. 15.

<sup>(12)</sup> OJ No. L235, 17.9.96, p. 39.

<sup>(13)</sup> OJ No. L208, 24.7.98, p. 43.

- (a) a monograph;
- (b) an identification note containing the information specified in Article 90.1 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(14) signed at Oporto on 2nd May 1993 as adjusted by the Protocol(15) 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;

"Member State" means a member State other than the United Kingdom;

"the MF Regulations" means the Medicated Feedingstuffs Regulations 1998(16);

"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(17);

"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);

<sup>(14)</sup> OJ No. L1, 3.1.94, p. 3.

<sup>(15)</sup> OJ No. L1, 3.1.94, p. 572.

<sup>(16)</sup> S.I. 1998/1046.

<sup>(17) 1986</sup> c. 14.

"the Scientific Committee for Animal Nutrition" means the committee established by Commission Decision 76/791/EEC establishing a Scientific Committee for Animal Nutrition(18);

"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.
- (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;

<sup>&</sup>quot;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—

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- (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).