STATUTORY INSTRUMENTS

1998 No. 1047

AGRICULTURE

The Feedingstuffs (Zootechnical Products) Regulations 1998

Made - - - -	*9th April 1998*
Laid before Parliament	*15th April 1998*
Coming into force	
All regulations and Schedules except regulations 7, 8, 38, 39, 40, 63, 64 and 65	*6th May 1998*
Regulations 7, 8, 38, 39, 40, 63, 64 and 65	*1st October 1999*

The Minister of Agriculture, Fisheries and Food and the Secretary of State, being Ministers designated(**1**) for the purposes of section 2(2) of the European Communities Act 1972(**2**) 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 and commencement

1. These Regulations may be cited as the Feedingstuffs (Zootechnical Products) Regulations 1998 and shall come into force on the following dates—

(a) all regulations and Schedules, except for regulations 7, 8, 38, 39, 40, 63, 64 and 65, on 6th May 1998, and

(b) regulations 7, 8, 38, 39, 40, 63, 64 and 65 on 1st October 1999.

General interpretation

2.—(1) In these Regulations—

(**1**) S.I.1972/1811.
(**2**) 1972 c. 68.

"additive" has the meaning given by Article 2(a) of the Additives Directive;

"the Additives Directive" means Council Directive 70/524/EEC concerning additives in feeding-stuffs(**3**) as amended up to, but not including, the amendments affected by Directive 96/51/EC(**4**);

"Article 6.4 purpose" means a purpose specified in Article 6.4 of the Additives Directive;

"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;

"a BI zootechnical additive" means a zootechnical additive which is covered by Chapter I of Annex B to the Additives Directive 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 the Additives Directive 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 the Additives Directive 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;

"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 the Additives Directive;

"compound feedingstuff" has the meaning given by Article 2(g) of the Additives Directive;

"Directive 87/153/EEC" means Council Directive 87/153/EEC fixing guidelines for the assessment of additives in animal nutrition(**5**) as amended by Commission Directives 94/40/EC(**6**) and 95/11/EC(**7**);

"Directive 96/51/EC" means Council Directive 96/51/EC amending Directive 70/524/EEC concerning additives in feedingstuffs(**8**);

"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 the Additives Directive as amended by Directive 96/51/EC; and

(c) in the case of a zootechnical additive to which Article 7a of the Additives Directive, 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 the Additives Directive as so amended;

"E.E.A. Agreement" means the Agreement on the European Economic Area(**9**) signed at Oporto on 2nd May 1993 as adjusted by the Protocol(**10**) signed at Brussels on 17th March 1993;

(**3**) OJNo. L270, 14.12.70, p.1 OJ/SE Vol. 18, p.4.
(**4**) the next most recent amending instrument was Council Directive 96/25/EC (OJ No. L125, 23.5.96, p.35).
(**5**) OJ No. L64, 7.3.87, p.19.
(**6**) OJ No. L208, 11.8.94, p.15.
(**7**) OJ No. L106, 11.5.95, p.23.
(**8**) OJ No. L235, 17.9.96, p.39.
(**9**) OJ No. L1, 3.1.94, p.3.

"E.E.A. State" means a State which is a contracting party to the E.E.A. 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;

"the Establishments Directive" 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**)

"feedingstuff" has the meaning given by Article 2(b) of the Additives Directive;

"medicinal test on animals" has the meaning given by section 32(6) of the Medicines Act 1968(**12**) and "animal test certificate" shall be construed in accordance with that section;

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

"the Minister" means the Minister of Agriculture, Fisheries and Food;

"official checks" means official checks of the type specified in Article 21.1 of the Additives Directive and Article 13 of the Establishments Directive;

"personal licence" means a licence granted under section 4 of the Animals (Scientific Procedures) Act 1986(**13**);

"person responsible for putting into circulation" has the meaning given by Article 2(1) of the Additives Directive as amended by Directive 96/51/EC;

"premixture" has the meaning given by Article 2(h) of the Additives Directive;

"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 the Establishments Directive;

"regulated procedure" has the meaning given by section 2 of the Animals (Scientific Procedures) Act 1986;

"the Scientific Committee for Animal Nutrition" means the committee established by Commission Decision 76/791/EEC establishing a Scientific Committee for Animal Nutrition(**14**);

"supplementary feedingstuff" has the meaning given by Article 2(e) of the Additives Directive;

"third country" means a country other than a member State;

"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 the Additives Directive, 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

(**10**) OJ No. L1, 3.1.94, p.572.
(**11**) OJ No. L332, 30.12.95, p.15.
(**12**) 1968 c. 67.
(**13**) 1986 c. 14.
(**14**) OJ No. L279, 9.10.76, p.35.

"zootechnical product" means a zootechnical additive, a zootechnical premixture or a zootechnical feedingstuff.

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

(3) The expressions listed in Part II of Schedule 1 have the same meaning as in the Additives Directive as amended by Directive 96/51/EC.

(4) Insofar as the context admits the expressions listed in Part III of Schedule 1 have the same meaning as in the Establishments Directive.

(5) In these Regulations—

(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, and

(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.

Definition of "establishment" and other related definitions

3. In these Regulations "establishment" has the meaning given by Article 1.3(b) of the Establishments Directive and—

"an E.C. 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 the Establishments Directive as being an establishment on which a zootechnical additive may be manufactured with a view to putting it into circulation;

"an E.C. 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 the Establishments Directive as being an establishment on which a zootechnical premixture may be manufactured with a view to putting it into circulation;

"an E.C. 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 the Establishments Directive as being an establishment on which a zootechnical compound feedingstuff may be manufactured with a view to putting it into circulation;

"an E.C. 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 the Establishments Directive as being an establishment on which a zootechnical compound feedingstuff may be produced for the exclusive requirements of the producer's holding;

"an E.C. permitted Chapter I.1 establishment" means—

(a) before 1st September 1998, an establishment located in a member State (other than an E.C. approved chapter I.1 establishment or an establishment which a competent authority in the member State has declined to approve as such an establishment) if a zootechnical additive was being manufactured on the establishment, with a view to putting it into circulation, on 1st April 1998, and

(b) on and after 1st September 1998, an establishment located in a member State if—

(i) such an additive was being manufactured on the establishment, with a view to putting it into circulation, on 1st April 1998, and

(ii) before 1st September 1998 an application (which is pending) in respect of the establishment has been 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 the Establishments Directive, as an establishment on which a zootechnical additive may be manufactured with a view to putting it into circulation;

"an E.C. permitted Chapter I.2 establishment" means—

(a) before 1st September 1998, an establishment located in a member State (other than an E.C. approved Chapter I.2 establishment or an establishment which the competent authority in the member State has declined to approve as such an establishment) if a zootechnical premixture was being manufactured on the establishment on 1st April 1998 with a view to putting it into circulation, and

(b) on and after 1st September 1998, an establishment located in a member State if—

(i) such a premixture was being manufactured on the establishment on 1st April 1998, and

(ii) before 1st September 1998 an application (which is pending) in respect of the establishment has been 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 the Establishments Directive, as an establishment on which a zootechnical premixture may be manufactured with a view to putting it into circulation;

"an E.C. permitted Chapter I.3(M) establishment" means—

(a) before 1st September 1998, an establishment located in a member State (other than an E.C. approved Chapter I.3(M) establishment or an establishment which a competent authority in the member State has declined to approve as such an establishment) if a zootechnical compound feedingstuff was being manufactured on the establishment with a view to putting it into circulation on 1st April 1998, and

(b) on and after 1st September 1998, an establishment located in a member State if—

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

(ii) before 1st September 1998 an application (which is pending) in respect of the establishment has been 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 the Establishments Directive, as an establishment on which a zootechnical compound feedingstuff may be manufactured with a view to putting it into circulation;

"an E.C. permitted Chapter I.3(P) establishment" means—

(a) before 1st September 1998, an establishment located in a member State (other than an E.C. approved Chapter I.3(P) establishment or an establishment which a competent authority in the member State has declined to approve as such an establishment) if 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) on and after 1st September 1998, an establishment located in a member State if—

(i) a zootechnical compound feedingstuff was being produced on the establishment for the exclusive requirements of the producer's holding on 1st April 1998, and

(ii) before 1st September 1998 an application (which is pending) in respect of the establishment has been 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 the Establishments Directive, as an establishment on which a zootechnical compound feedingstuff may be produced for the exclusive requirements of the producer's holding;

"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 per cent by weight of a premixture;

"a U.K. approved Chapter I.1 establishment" means an establishment approved pursuant to regulation 11 or 12 as an establishment on which a zootechnical additive may be manufactured with a view to putting it into circulation;

"a U.K. approved Chapter I.2 establishment" means an establishment approved pursuant to regulation 11 or 12 as an establishment on which a zootechnical premixture may be manufactured with a view to putting it into circulation;

"a U.K. approved Chapter 1.3(M) establishment" means an establishment approved pursuant to regulation 11 or 12 as an establishment on which a zootechnical compound feedigstuff may be manufactured with a view to putting it into circulation, and includes a specially approved manufacturing establishment;

"a U.K. approved Chapter I.3(P) establishment" means an establishment approved pursuant to regulation 11 or 12 as an establishment on which a zootechnical compound feedingstuff may be produced for the exclusive requirements of the producer's holding;

"a U.K. permitted Chapter I.1 establishment" means—

(a) before 1st September 1998 an establishment located in the United Kingdom (other than a U.K. approved Chapter I.1 establishment or an establishment which the enforcement authority has declined to approve as such an establishment) if a zootechnical additive was being manufactured on the establishment, with a view to putting it into circulation, on 1st April 1998, and

(b) on and after 1st September 1998 an establishment located in the United Kingdom if—

(i) such an additive was being manufactured on the establishment on 1st April 1998, and

(ii) before 1st September 1998 an application (which is pending and complies with regulation 10(2), has been submitted in respect of the establishment under regulation 10(1)(a) (or under regulation 12(1) in relation to zootechnical additive manufacture);

"a U.K. permitted Chapter I.2 establishment" means—

(a) before 1st September 1998 an establishment located in the United Kingdom (other than a U.K. approved Chapter I.2 establishment or establishment which the enforcement authority has declined to approve as such an establishment) if a zootechnical premixture was being manufactured on the establishment, with a view to putting it into circulation, on 1st April 1998, and

(b) on and after 1st September 1998 an establishment located in the United Kingdom if—

(i) such a premixture was being manufactured on the establishment on 1st April 1998, and

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

"a U.K. permitted Chapter I.3(M) establishment" means—

(a) before 1st September 1998 an establishment located in the United Kingdom (other than a U.K. approved Chapter I.3(M) establishment or an establishment which the enforcement authority has declined to approve as such an establishment) if a zootechnical compound feedingstuff was being manufactured on the establishment, with a view to putting it into circulation, on 1st April 1998, and

(b) on and after 1st September 1998 an establishment located in the United Kingdom if—

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

(ii) before 1st September 1998 an application (which is pending and complies with regulation 10(2)) has been submitted in respect of the establishment under regulation 10(1)(c) (or under regulation 12(1) in relation to zootechnical compound feedingstuff manufacture); and

"a U.K. permitted Chapter I.3(P) establishment" means—

(a) before 1st September 1998 an establishment located in the United Kingdom (other than a U.K. approved Chapter I.3(P) establishment or an establishment which the enforcement authority has declined to approve as such an establishment) if 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) on and after 1st September 1998 an establishment located in the United Kingdom if—

(i) a zootechnical compound feedingstuff was being produced on the establishment for the exclusive requirements of the producer's holding on 1st April 1998, and

(ii) before 1st September 1998 an application (which is pending and complies with regulation 10(2)) has been 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).

Definition of "intermediary" and other related definitions

4. In these Regulations "intermediary" has the meaning given by Article 1.3(c) of the Establishments Directive and—

"an E.C. 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 the Establishments Directive as being an intermediary who may wrap, package, store and put into circulation a zootechnical additive;

"an E.C. 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 the Establishments Directive as being an intermediary who may wrap, package, store and put into circulation a zootechnical premixture;

"an E.C. permitted Chapter I.1 intermediary" means—

(a) before 1st September 1998, an intermediary whose facilities are located in a member State (other than an E.C. approved Chapter I.1 intermediary or an intermediary whom a competent authority in the member State has declined to approve as such an intermediary) and who was wrapping, packaging, storing or putting into circulation a zootechnical additive on 1st April 1998, and

(b) on and after 1st September 1998, an intermediary whose facilities are located in a member State and who—

(i) was wrapping, packaging, storing or putting into circulation such an additive on 1st April 1998, and

(ii) 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 the Establishments Directive as an intermediary who may wrap, package, store and put into circulation a zootechnical additive;

"an E.C. permitted Chapter I.2 intermediary" means—

(a) before 1st September 1998, an intermediary whose facilities are located in a member State (other than an E.C. approved Chapter I.2 intermediary or an intermediary whom a competent authority in the member State has declined to approve as such an intermediary) and who was wrapping, packaging, storing or putting into circulation a zootechnical premixture on 1st April 1998, and

(b) on and after 1st September 1998, an intermediary whose facilities are located in a member State and who—

(i) was wrapping, packaging, storing or putting into circulation such a premixture on 1st April 1998, and

(ii) 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 the Establishments Directive as an intermediary who may wrap, package, store and put into circulation a zootechnical premixture;

"a U.K. approved Chapter I.1 intermediary" means an intermediary approved pursuant to regulation 19 or 20 as an intermediary who may wrap, package, store and put into circulation a zootechnical additive;

"a U.K. approved Chapter I.2 intermediary" means an intermediary approved pursuant to regulation 19 or 20 as an intermediary who may wrap, package, store and put into circulation a zootechnical premixture;

"a U.K. permitted Chapter I.1 intermediary" means—

(a) before 1st September 1998, an intermediary (other than a UK approved Chapter I.1 intermediary or an intermediary whom the enforcement authority has declined to approve as such an intermediary) whose facilities are located in the United Kingdom and who was wrapping, packaging, storing or putting into circulation a zootechnical additive on 1st April 1998, and

(b) on and after 1st September 1998, an intermediary whose facilities are located in the United Kingdom and who—

(i) was wrapping, packaging, storing or putting into circulation such an additive on 1st April 1998, and

(ii) 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

"a U.K. permitted Chapter I.2 intermediary" means—

(a) before 1st September 1998, an intermediary (other than an approved Chapter I.2 intermediary or an intermediary whom the enforcement authority has declined to approve as such an intermediary) whose facilities are located in the United Kingdom and who was wrapping, packaging, storing or putting into circulation a zootechnical premixture on 1st April 1998, and

(b) on and after 1st September 1998, an intermediary whose facilities are located in the United Kingdom and who—

(i) was wrapping, packaging, storing or putting into circulation such a premixture on 1st April 1998, and

(ii) has submitted an application (which is pending) under regulation 18(1)(b) (or under regulation 20(1) in relation to zootechnical premixture intermediary activity).

Application of these Regulations

5. These Regulations shall apply in the field of animal feeding to zootechnical products to which the Additives Directive applies.

PART II

APPLICATIONS FOR THE COMMUNITYAUTHORISATION OF ZOOTECHNICAL ADDITIVES

Transitional applications

6.—(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 the Additives Directive, as amended by Directive 96/51/EC, in the case of an application relating to a BI zootechnical additive;

(b) Article 9h.2 of the Additives Directive, 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 the Additives Directive, 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 the Additives Directive, 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 the Additives Directive 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 the Additives Directive, as amended by Directive 96/51/EC, in the case of a BI zootechnical additive;

(b) Article 9h.2 of the Additives Directive, as amended by Directive 96/51/EC, in the case of a BII zootechnical additive; and

(c) Article 9i.2 of the Additives Directive, as amended by Directive 96/51/EC, in the case of a BIII zootechnical additive.

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 the Additives Directive, 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 the Additives Directive 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 as specified 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 the Additives Directive 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, means the fee specified opposite the application in question in Part I of Schedule 2, and it shall be payable by the person who submits a dossier to the Minister in connection with that application pursuant to regulation 6(3), 7(1) or 8(1).

(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 6(3), 7(1) or 8(1), unless the application is accompanied by the relevant fee.

PART III

APPROVAL OF ESTABLISHMENTS

Application 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, signed by or on behalf of the applicant, and shall contain the name and address of the applicant, shall specify each activity in relation to which the application is made and (if made by 31st August 1998) whether the activity in question was being exercised on the establishment on 1st April 1998, and shall be accompanied by particulars which seek to demonstrate that the establishment meets the applicable minimum conditions laid down in the Annex to the Establishments Directive.

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 the Establishments Directive, 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 the Establishments Directive 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 the Establishments Directive, 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 the Establishments Directive 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 the Establishments Directive.

(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 regulation 27, 42, 53 or 55 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 27, 42, 53 or 55, 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 27, 42, 53 or 55 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 2, 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 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 Medicated Feedingstuffs Regulations 1998(**15**) 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 Medicated Feedingstuffs Regulations 1998 and, where the relevant fee differs in amount from the fee payable under the Medicated Feedingstuffs Regulations 1998, 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 Medicated Feedingstuffs Regulations 1998 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 Medicated Feedingstuffs Regulations 1998 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 Medicated Feedingstuffs Regulations 1998, or

(b) the relevant authority has conducted such inspection and has granted approval pursuant to regulation 4 of the Medicated Feedingstuffs Regulations 1998 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

(**15**) S.I. 1998/1046.

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 Medicated Feedingstuffs Regulations 1998 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 Medicated Feedingstuffs Regulations 1998 and, where the relevant fee differs in amount from the fee payable under the Medicated Feedingstuffs Regulations 1998, 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 Medicated Feedingstuffs Regulations 1998 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 Medicated Feedingstuffs Regulations 1998 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 Medicated Feedingstuffs Regulations 1998, or

(b) the relevant authority has conducted such inspection and has granted approval pursuant to regulation 4 of the Medicated Feedingstuffs Regulations 1998 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 the Establishments Directive relating to the publication of the national list of approved establishments, as read with Articles 13.3 and 13.4 of the Additives Directive 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 the Establishments Directive" means the minimum conditions laid down in—

(a) Chapter I.1(b) of the Annex to the Establishments Directive 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 the Establishments Directive 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 the Establishments Directive 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 the Establishments Directive 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 the Establishments Directive, 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;

"Article 12 establishment" means an establishment to which Article 12 of the Establishments Directive applies;

"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 the Establishments Directive 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 the Establishments Directive 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 the Establishments Directive 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 the Establishments Directive in the case of the exercise of the establishment activity specified in regulation 10(1)(c); and

(d) with the exception of the requirements set out in point 7, Chapter I.3(b) of the Annex to the Establishments Directive in the case of the exercise of the establishment activity specified in regulation 10(1)(d); and

"establishment activity" means an activity specified in 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, signed by or on behalf of the applicant, and shall contain the name and address of the applicant, shall specify each activity in relation to which the application is made and (if made by 31st August 1998) whether the activity in question was being exercised by him on 1st April 1998 and shall be accompanied

by particulars which demonstrate that the applicant meets the applicable minimum conditions laid down in the Annex to the Establishments Directive.

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 the Establishments Directive, 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 the Establishments Directive 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 the Establishments Directive 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 the Establishments Directive, 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 the Establishments Directive as being an approved intermediary who may exercise that activity.

Amendment 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 paragraph 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 the Establishments Directive.

(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 regulations 31, 33, 46 or 48 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 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 31, 33, 46 or 48, 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 31, 33, 46 or 48, 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 2, 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 the Establishments Directive 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 the Establishments Directive" means the minimum conditions laid down or referred to in—

(a) point 7 of Chapter I.1(b) of the Annex to the Establishments Directive 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 the Establishments Directive 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 the Establishments Directive 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 the Establishments Directive 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 the Establishments Directive in the case of the exercise of the intermediary activity specified in regulation 18(1)(b); and

"intermediary activity" means an activity specified in paragraph (a) or (b) of regulation 18(1).

PART V

CONTROL OF ZOOTECHNICAL ADDITIVES

Manufacture of zootechnical additives

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

Duties on persons manufacturing zootechnical additives

27. A person manufacturing a zootechnical additive on a U.K. 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 the Establishments Directive.

Packaging of zootechnical additives

28. No person shall market a zootechnical additive unless the additive is packaged in accordance with the requirements of Article 10 of the Additives Directive.

Labelling of zootechnical additives

29.—(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 the Additives Directive as amended by Directive 96/51/EC.

(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 the Additives Directive, as amended by Directive 96/51/EC, or

(b) authorised by virtue of Article 14.2 of the Additives Directive, 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 the Additives Directive as amended by Directive 96/51/EC.

Wrapping, packaging and storage of zootechnical additives by intermediaries

30. No intermediary shall wrap, package or store a zootechnical additive unless he is a U.K. approved or permitted Chapter I.1 intermediary.

Duties on intermediaries wrapping, packaging or storing zootechnical additives

31. A U.K. 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 the Establishments Directive.

Putting zootechnical additives into circulation

32.—(1) Subject to paragraph (2) and regulation 34(3), no person shall put a zootechnical additive into circulation other than a BI, BII or BIII zootechnical additive manufactured on—

(a) a U.K. approved or permitted Chapter I.1 establishment;

(b) an E.C. approved or permitted Chapter I.1 establishment; or

(c) an establishment located in a third country—

(i) if it is listed in relation to zootechnical additives under arrangements to implement the second indent of the second paragraph of Article 15(a) of the Establishments Directive,

or

(ii) pending the making of those arrangements, if it is reasonable to conclude that it would have been so listed if those arrangements had been made.

(2) Subject to regulation 34(3), no intermediary shall put a BI, BII or BIII zootechnical additive into circulation unless he is a U.K. or E.C. approved or permitted Chapter I.1 intermediary.

Duties on intermediaries putting zootechnical additives into circulation

33. A U.K. 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 the Establishments Directive.

Supply of zootechnical additives

34.—(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 U.K. or E.C. approved or permitted Chapter I.1 intermediary;

(b) a person manufacturing, or intending to manufacture, a zootechnical premixture on a U.K. or E.C. approved or permitted Chapter I.2 establishment;

(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 the Additives Directive, 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 32(1) or paragraph (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

35.—(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 36.

(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

36.—(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 U.K. or E.C. approved or permitted Chapter I.2 establishment, or

(ii) on an establishment located in a third country:

(A) if it is listed in relation to zootechnical premixtures under arrangements to implement the second indent of the second paragraph of Article 15(a) of the Establishments Directive, or

(B) pending the making of those arrangements, if it is reasonable to conclude that it would have been so listed if those arrangements had been made,

and in accordance with the requirements specified, or in the case of an establishment located in a third country, requirements equivalent to those specified, in the first paragraph of Article 13.3 of the Additives Directive, as amended by Directive 96/51/EC, and he incorporates the premixture in the feedingstuff in accordance with regulation 51; or

(b) the incorporation is carried out on a U.K. 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 the Additives Directive, 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 the Additives Directive as amended by Directive 96/51/EC.

Mixing of zootechnical additives

37.—(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 the Additives Directive.

(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 the Additives Directive, and

(b) does not contravene the provisions contained in Article 6.3 of the Additives Directive.

(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.

Provision of samples

38. 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 the Additives Directive as amended by Directive 96/51/EC.

Monitoring of undesirable interactions

39.—(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 the Additives Directive, 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 Community of the person responsible for putting the zootechnical additive into circulation where the zootechnical additive originates in a third country.

Provision of information

40. 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 the Additives Directive as amended by Directive 96/51/EC.

PART VI

CONTROL OF ZOOTECHNICAL PREMIXTURES

Manufacture of zootechnical premixtures

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

Duties on persons manufacturing zootechnical premixtures

42. A person manufacturing a zootechnical premixture on a U.K. 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 the Establishments Directive.

Packaging of zootechnical premixtures

43. No person shall market a zootechnical premixture unless the premixture is packaged in accordance with the requirements of Article 10 of the Additives Directive.

Labelling of zootechnical premixtures

44.—(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 the Additives Directive as amended by Directive 96/51/EC.

(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 the Additives Directive, as amended by Directive 96/51/EC, or

(b) authorised by virtue of Article 15.2 of the Additives Directives, 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 the Additives Directive as amended by Directive 96/51/EC.

Wrapping, packaging and storage of zootechnical premixtures by intermediaries

45. No intermediary shall wrap, package or store a zootechnical premixture unless he is a U.K. approved or permitted Chapter I.2 intermediary.

Duties on intermediaries wrapping, packaging or storing zootechnical premixtures

46. A U.K. 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 the Establishments Directive.

Putting zootechnical premixtures into circulation

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

(a) on a U.K. or E.C. approved or permitted Chapter I.2 establishment, or

(b) on an establishment located in a third country:

(i) if it is listed in relation to zootechnical premixtures under arrangements to implement the second indent of the second paragraph of Article 15(a) of the Establishments Directive,

or

(ii) pending the making of those arrangements, if it is reasonable to conclude that it would have been so listed if those arrangements had been made.

(2) No intermediary shall put a zootechnical premixture into circulation unless he is a U.K. or E.C. approved or permitted Chapter I.2 intermediary.

Duties on intermediaries putting zootechnical premixtures into circulation

48. A U.K. 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 the Establishments Directive.

Supply of zootechnical premixtures

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

(a) a U.K. or E.C. approved or permitted Chapter I.2 intermediary;

(b) a person manufacturing, or intending to manufacture, a compound feedingstuff on a U.K. or E.C. approved or permitted Chapter I.3(M) establishment;

(c) a person producing, or intending to produce, a compound feedingstuff on a U.K. or E.C. 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

50.—(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 51.

(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 51

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

51.—(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 the Additives Directive, 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 U.K. approved or permitted Chapter I.3(M) establishment or a U.K. 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.

PART VII

CONTROL OF ZOOTECHNICAL FEEDINGSTUFFS

Manufacture of zootechnical compound feedingstuffs

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

Duties on persons manufacturing zootechnical compound feedingstuffs

53. A person manufacturing a zootechnical compound feedingstuff on a U.K. 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 the Establishments Directive.

Production of zootechnical compound feedingstuffs

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

Duties on persons producing zootechnical compound feedingstuffs

55. A person producing a zootechnical compound feedingstuff for the exclusive requirements of his holding on a U.K. approved Chapter I.3(P) establishment shall fulfil the essential conditions contained in Chapter I.3(b) of the Annex to the Establishments Directive with the exception of point 7.

Level of zootechnical additives in complete feedingstuffs

56.—(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 the Additives Directive 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 the Additives Directive.

Level of zootechnical additives in supplementary feedingstuffs

57.—(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 the Additives Directive.

(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 the Additives Directive 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 the Additives Directive;

(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 the Additives Directive; 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 the Additives Directive;

and, in each case, the compositional characteristics of the feedingstuff comply with the provisions of Article 12.3 of the Additives Directive.

Labelling of zootechnical feedingstuffs

58. 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 the Additives Directive as amended by Directive 96/51/EC.

Labelling of supplementary zootechnical feedingstuffs

59.—(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 the Additives Directive.

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

Export of zootechnical feedingstuffs to E.E.A. States

60. No person shall export a zootechnical feedingstuff for marketing in an E.E.A. State unless the details given on the package or container of, or label attached to, the feedingstuff and covered by Article 18 of the Additives Directive comply with that Article.

Import of zootechnical feedingstuffs

61. No person shall import from an E.E.A. 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 the Additives Directive comply with that Article.

Putting zootechnical compound feedingstuffs into circulation

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

(a) a U.K. or E.C. approved or permitted Chapter I.3(M) establishment, or

(b) on an establishment located in a third country:

(i) if it is listed in relation to zootechnical compound feedingstuffs under arrangements to implement the second indent of the second paragraph of Article 15(a) of the Establishments Directive, or

(ii) pending the making of those arrangements, if it is reasonable to conclude that it would have been so listed if those arrangements had been made.

PART VIII

MISCELLANEOUS AND SUPPLEMENTAL PROVISIONS

Restrictions on toxicological tests on vertebrates

63. 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 the Additives Directive, 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 the Additives Directive as amended by Directive 96/51/EC.

Confidential information relating to zootechnical additives

64.—(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 the Additives Directive, the Additives Directive as amended by Directive 96/51/EC or the Establishments Directive.

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

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

Use of Article 9c data

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

Official checks and enforcement

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

Powers of authorised persons

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

(a) carrying out any official checks, and

(b) ascertaining whether an offence under regulation 68 has been or is being committed.

(2) An authorised person shall have the right to enter—

(a) any premises on which he has reasonable cause to believe that a zootechnical product has been manufactured 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 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.

(3) An authorised person entering any premises by virtue of this regulation may take with him such other persons and such equipment as may appear to him to be necessary for the purposes mentioned in sub-paragraphs (a) and (b) of paragraph (1).

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

(a) any substance or article 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 of any zootechnical product and any process of manufacture of such a product, and the means employed, at any stage in the process of manufacture, for testing the product after it has been subject to those processes.

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

(a) a substance or article used, or intended to be used, in the manufacture of a zootechnical product;

(b) a product appearing to him to be a zootechnical product manufactured, wrapped, packaged, stored, circulated, marketed or supplied, or intended to be circulated, marketed or supplied; or

(c) a product appearing to him to be a zootechnical product, used, or intended to be used, for the purpose of animal feeding.

(6) An authorised person shall have the right—

(a) to require any person carrying on a business which consists of or includes the activities of manufacture, wrapping, packaging, storage, circulation, marketing, supply or use of zootechnical products, and any person employed in connection with such a business, to produce any record (in whatever form it is held) relating to those activities which is in his possession or under his control, and

(b) to inspect and take copies of a record, or of an entry in a record, produced in pursuance of the preceding sub-paragraph.

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

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

(b) may require—

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

(ii) any person having charge of, or otherwise concerned with the operation of, the computer, apparatus or material, to afford the authorised person such reasonable assistance as he may require for the purpose; and

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

(8) An authorised person shall have the right to seize and detain a 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.

(9) In this regulation, "premises" includes any land, vehicle, vessel, aircraft or hovercraft.

Offences

68. It shall be an offence for a person—

(a) without reasonable excuse, to contravene any provision of regulation 26, 28, 29, 30, 32, 34(1) or (2), 35(1), 36(1), (2) or (5), 37(1) or (2), 41, 43, 44, 45, 47, 49(1), 50(1), 51(1), 52, 54, 56, 57(1), 58, 59(1), 60 to 63 inclusive, 64(1) or 65;

(b) without reasonable excuse, to fail to comply with any provision of regulation 27, 31, 33, 38, 39(1), 40, 42, 46, 48, 53 or 55;

(c) intentionally to obstruct an authorised person in the exercise of a power conferred by regulation 67; or

(d) without reasonable excuse, to fail to comply with any requirement made of him, pursuant to regulation 67, by an authorised person.

Punishment of offences

69.—(1) Any person who commits any of the offences set out in regulation 68(a) shall be liable—

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

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

(2) Any person who commits any of the offences set out in regulation 68(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 68(c) or 68(d) shall be liable on summary conviction to a fine not exceeding level 3 on the standard scale.

Time limit for prosecutions

70.—(1) Proceedings for an offence under regulation 68(b) 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(**16**) (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

71.—(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

72. 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.

Service of notices

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

(a) by delivering it to him;

(**16**) 1995 c. 46.

(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

74.—(1) Except as specified in paragraph (2), the Medicines Act 1968(**17**), and instruments made wholly or partly under that Act, shall not apply to zootechnical products.

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

Revocation of product licences

75. Any product licence granted in respect of a zootechnical product under the Medicines Act 1968 which is extant immediately before this regulation comes into force shall automatically be revoked on the coming into force of this regulation.

Jeff Rooker
Minister of State, Ministry of Agriculture,
9th April 1998 Fisheries and Food

Sewel
Parliamentary Under-Secretary of State, Scottish
1st April 1998 Office

(**17**) 1968 c. 67.

SCHEDULE 1 Regulation 2(2), (3) and (4)

INTERPRETATION

PART I

Expressions having the same meaning as in the Additives Directive

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 the Additives Directive as amended by Directive 96/51/EC

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

cease
demonstrate

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

SCHEDULE 2 Regulations 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 6(3)	25,000
Application under regulation 7(1)	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 for the manufacture of a zootechnical additive	405
Application under regulation 10(1)(b) or 12 for approval of an establishment to manufacture a zootechnical premixture	405

Application	Fee (£)
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

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement, insofar as they relate to zootechnical additives and products with zootechnical additives in them, the provisions of Council Directive 70/524/EEC, as last amended by Council Directive 96/51/EC, on additives in feedingstuffs, and of Council Directive 95/69/EC which lay down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector. A zootechnical additive is an additive which is classified as an antibiotic, a coccidiostat or other medicinal substance, or a growth promoter and which is used for eventual incorporation in a feedingstuff.

The Regulations set out the requirements for applications for Community authorisation of zootechnical additives (regulations 6 to 9) and the approval of establishments (regulations 10 to 17) and intermediaries (regulations 18 to 25).

The Regulations control the manufacture and marketing of zootechnical additives, zootechnical premixtures (i.e. mixtures of additives in compound feedingstuffs) and zootechnical feedingstuffs (regulations 26 to 62).

These Regulations set fees for the examination of dossiers (regulation 9) and for the approval of establishments (regulation 15) and intermediaries (regulation 23).

Supplementary provisions (regulations 63 to 75) include provisions for offences (regulation 69) and penalties (regulation 70). The application of the Medicines Act 1968 to zootechnical products is excluded except in relation to animal test certificates for unauthorised zootechnical additives (regulation 74).

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