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STATUTORY INSTRUMENTS

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**1998 No. 1047**

**The Feedingstuffs (Zootechnical Products) Regulations 1998**

**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—

“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<sup>(1)</sup> as amended up to, but not including, the amendments affected by Directive [96/51/EC](#)<sup>(2)</sup>;

“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;

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

(2) the next most recent amending instrument was Council Directive [96/25/EC](#) (OJ No. L125, 23.5.96, p.35).

“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<sup>(3)</sup> as amended by Commission Directives 94/40/EC<sup>(4)</sup> and 95/11/EC<sup>(5)</sup>;

“Directive 96/51/EC” means Council Directive 96/51/EC amending Directive 70/524/EEC concerning additives in feedingstuffs<sup>(6)</sup>;

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

- (a) a monograph;
- (b) an identification note containing the information specified in Article 9o.1 of 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<sup>(7)</sup> signed at Oporto on 2nd May 1993 as adjusted by the Protocol<sup>(8)</sup> signed at Brussels on 17th March 1993;

“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<sup>(9)</sup>

“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<sup>(10)</sup> 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;

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

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

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

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

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

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

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

(10) 1968 c. 67.

“personal licence” means a licence granted under section 4 of the Animals (Scientific Procedures) Act 1986<sup>(11)</sup>;

“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<sup>(12)</sup>;

“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

“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 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—

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<sup>(11)</sup> 1986 c. 14.

<sup>(12)</sup> OJ No. L279, 9.10.76, p.35.

“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 I.3(M) establishment” means an establishment approved pursuant to regulation 11 or 12 as an establishment on which a zootechnical compound feedstuff 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.