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STATUTORY INSTRUMENTS

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**1998 No. 1049**

**AGRICULTURE**

**The Feeding Stuffs (Establishments  
and Intermediaries) Regulations 1998**

<i>Made</i>	- - - -	<i>9th April 1998</i>
<i>Laid before Parliament</i>		<i>15th April 1998</i>
<i>Coming into force</i>	- -	<i>6th May 1998</i>

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

**PART I**  
**GENERAL**

**Title and commencement**

1. These Regulations may be cited as the Feeding Stuffs (Establishments and Intermediaries) Regulations 1998 and shall come into force on 6th May 1998.

**General interpretation**

2.—(1) In these Regulations—

“the Act” means the Agriculture Act 1970<sup>(3)</sup>;

“additive” has the meaning given by Article 2(a) of Directive 70/524;

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

“animal” includes any bird, insect or fish;

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(1) S.I.1972/1811.  
(2) 1972 c. 68.  
(3) 1970 c. 40.

“the Annex” means the Annex to Directive 95/69;

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

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

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

“the competent body” means—

(a) in Great Britain—

(i) in the case of establishments, the body referred to in section 67(1), (1A) or (2) of the Act in the area of which the establishment concerned is, and

(ii) in the case of intermediaries, the body referred to as aforesaid in the area of which an intermediary is exercising, or, as the case may be, proposes to exercise, any activity the exercising of which by intermediaries is controlled by these Regulations; and

(b) in Northern Ireland, the Department of Agriculture for Northern Ireland;

“complementary feeding stuff” means a mixture of feeding stuffs which has a high content of certain substances and which, by reason of its composition, is sufficient for a daily ration only if it is used in combination with other feeding stuffs;

“complete feeding stuff” means a compound feeding stuff which, by reason of its composition, is sufficient to ensure a daily ration;

“compound feeding stuff” means a mixture of products of vegetable or animal origin in their natural state, fresh or preserved, or products derived from the industrial processing thereof, or organic or inorganic substances, whether or not containing additives, for oral feeding, as a complete or a complementary feeding stuff, to any pet animals or any farmed creatures;

“controlled product” means any additive, premixture, Directive 82/471 product or compound feeding stuff, which is subject to any of the controls contained in these Regulations;

“daily ration” means the average total quantity of feeding stuff, expressed on a 12 per cent moisture basis, required daily by an animal of a given kind, age group and level of production, in order to satisfy all its nutritional needs;

“Directive 70/524” means Council Directive [70/524/EEC](#) concerning additives in feeding stuffs<sup>(4)</sup>;

“Directive 82/471” means Council Directive [82/471/EEC](#) concerning certain products used in animal nutrition<sup>(5)</sup>;

“Directive 82/471 product” means a product regulated by Directive 82/471;

“Directive 95/69” 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>(6)</sup>;

“feeding stuff” means—

(a) a product of vegetable or animal origin in its natural state (whether fresh or preserved);

(b) a product derived from the industrial processing of such a product; or

<sup>(4)</sup> OJ No. L270, 14.12.70, p.11 (OJ/SE Vol. 18, p.4), last amended by Council Directive [96/51/EC](#) (OJ No. L235, 17.9.96, p.39).

<sup>(5)</sup> OJ No. L213, 21.7.82, p.8, last amended by Council Directive [96/25/EC](#) (OJ No. L125, 23.5.96, p.35).

<sup>(6)</sup> OJ No. L332, 30.12.95, p.15.

(c) an organic or inorganic substance, used singly or in a mixture, whether or not containing additives, for oral feeding to any pet animals or any farmed creatures; “fish” includes shellfish;

“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 kinds specified in Article 13 of Directive 95/69 and Article 21.1 of Directive 70/524;

“pet animal” means any animal belonging to a species normally kept and nourished, but not consumed, by man;

“premises” includes any land, vehicle, vessel, aircraft or hovercraft;

“premixture” means a mixture of additives, or a mixture of one or more additives with substances used as carriers, intended for the manufacture of feeding stuffs;

“putting into circulation” has the meaning given by Article 1.3(a) of Directive 95/69;

“retained part of the sample” means that part of a sample retained by an authorised person pursuant to regulation 84(d);

“third country” means a country other than a member state;

“zootechnical additive” means an antibiotic, a coccidiostat or other medicinal substance, or a growth promoter;

“zootechnical premixture” means a premixture that contains a zootechnical additive.

(2) Unless the context otherwise requires, in these Regulations—

(a) any reference to a numbered regulation or Schedule is a reference to the regulation or Schedule so numbered in these Regulations,

(b) any reference in a regulation to a numbered paragraph is a reference to the paragraph so numbered in the regulation in which the reference occurs,

(c) the expressions listed in Part I of Schedule 1 have the same meaning as in Directive 70/524, and

(d) the expressions listed in Part II of Schedule 1 have the same meaning as in Directive 95/69.

(3) In these Regulations, any reference to a European Community Directive is a reference to that Directive as amended as at the date these Regulations are made.

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

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

“EC approved Article 2.2(a)(A) establishment” means an establishment listed on a register of approved establishments, maintained by a competent authority in a Member State, in implementation of Article 5 of Directive 95/69, as an establishment on which an additive, of any kind referred to in Chapter I.1(a) of the Annex, may be manufactured with a view to putting it into circulation;

“EC approved Article 2.2(a)(P) establishment” means an establishment listed on a register of approved establishments, maintained by a competent authority in a Member State, in implementation of Article 5 of Directive 95/69, as an establishment on which a Directive 82/471 product, of any kind referred to in Chapter I.1(a) of the Annex, may be manufactured with a view to putting it into circulation;

“EC approved Article 2.2(b) establishment” means an establishment listed on a register of approved establishments, maintained by a competent authority in a Member State, in implementation of Article 5 of Directive 95/69, as an establishment on which a premixture, which contains additives of any kind referred to in Chapter I.2(a) of the Annex, may be manufactured with a view to putting it into circulation;

“EC permitted Article 2.2(a)(A) establishment” means—

- (a) before 1st September 1998, an establishment located in a Member State (other than an EC approved Article 2.2(a)(A) establishment or an establishment which a competent authority in the Member State has declined to approve as such an establishment) if an additive, of any kind referred to in Chapter I.1(a) of the Annex, 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) an additive, of any kind referred to in sub-paragraph (a) above, 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 a competent authority in the Member State, in accordance with any requirements in the Member State for the making of such applications, to approve the establishment, pursuant to Directive 95/69, as an establishment on which an additive of any such kind may be manufactured with a view to putting it into circulation;

“EC permitted Article 2.2(a)(P) establishment” means—

- (a) before 1st September 1998, an establishment located in a Member State (other than an EC approved Article 2.2(a)(P) establishment or an establishment which a competent authority in the Member State has declined to approve as such an establishment) if a Directive 82/471 product, of any kind referred to in Chapter I.1(a) of the Annex, 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 Directive 82/471 product, of any kind referred to in sub-paragraph (a) above, 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 a competent authority in the Member State, in accordance with any requirements in the Member State for the making of such applications, to approve the establishment, pursuant to Directive 95/69, as an establishment on which a Directive 82/471 product of any such kind may be manufactured with a view to putting it into circulation;

“EC permitted Article 2.2(b) establishment” means—

- (a) before 1st September 1998, an establishment located in a Member State (other than an EC approved Article 2.2(b) establishment or an establishment which a competent authority in the Member State has declined to approve as such an establishment) if a premixture, which contained additives of any kind referred to in Chapter I.2(a) of the Annex, 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 premixture, of the kind referred to in sub-paragraph (a) above, 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 a competent authority in the Member State, in accordance with any requirements in the Member State for the making of such applications, to approve the establishment, pursuant to Directive 95/69, as an establishment on which a premixture of that kind may be manufactured with a view to putting it into circulation;

“EC permitted Article 7.2(a) establishment” means—

- (a) before 1st September 1998, an establishment located in a Member State (other than an EC registered Article 7.2(a) establishment) if an additive, of any kind the manufacture of which is regulated by Article 7.2(a) of Directive 95/69, 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) an additive, of any kind referred to in sub-paragraph (a) above, was being manufactured on the establishment, with a view to putting it into circulation, on 1st April 1998, and
  - (ii) before 1st September 1998, a declaration (consideration of which is pending) in respect of the establishment, has been submitted to a competent authority in the Member State, in accordance with any requirements in the Member State for the submission of such declarations, with a view to registration of the establishment, pursuant to Directive 95/69, as an establishment on which an additive of any such kind may be manufactured with a view to putting it into circulation;

“EC permitted Article 7.2(b) establishment” means—

- (a) before 1st September 1998, an establishment located in a Member State (other than an EC registered Article 7.2(b) establishment) if a premixture, which contained additives of any kind referred to in Chapter II(a) of the Annex, but did not contain an additive of any kind referred to in Chapter I.2(a) of the Annex, 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 premixture, of the kind referred to in sub-paragraph (a) above, was being manufactured on the establishment, with a view to putting it into circulation, on 1st April 1998, and
  - (ii) before 1st September 1998, a declaration (consideration of which is pending) in respect of the establishment, has been submitted to a competent authority in the Member State, in accordance with any requirements in the Member State for the submission of such declarations, with a view to registration of the establishment, pursuant to Directive 95/69, as an establishment on which a premixture of that kind may be manufactured with a view to putting it into circulation;

“EC permitted Article 7.2(c)(PA) establishment” means—

- (a) before 1st September 1998, an establishment located in a Member State (other than an EC registered Article 7.2(c)(PA) establishment) if a compound feeding stuff, containing a premixture which contained additives of any kind referred to in Chapter II(b) of the Annex, but did not contain 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) a compound feeding stuff, of the kind referred to in sub-paragraph (a) above, was being manufactured on the establishment, with a view to putting it into circulation, on 1st April 1998, and
- (ii) before 1st September 1998, a declaration (consideration of which is pending) in respect of the establishment, has been submitted to a competent authority in the Member State, in accordance with any requirements in the Member State for the submission of such declarations, with a view to registration of the establishment, pursuant to Directive 95/69, as an establishment on which a compound feeding stuff of that kind may be manufactured with a view to putting it into circulation;

“EC permitted Article 7.2(d)(PA) establishment” means—

- (a) before 1st September 1998, an establishment located in a Member State (other than an EC registered Article 7.2(d)(PA) establishment) if a compound feeding stuff, containing a premixture which contained additives of any kind referred to in Chapter II(b) of the Annex, but did not contain a zootechnical additive, 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 compound feeding stuff, of the kind referred to in sub-paragraph (a) above, 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, a declaration (consideration of which is pending) in respect of the establishment, has been submitted to a competent authority in the Member State, in accordance with any requirements in the Member State for the submission of such declarations, with a view to registration of the establishment, pursuant to Directive 95/69, as an establishment on which a compound feeding stuff of that kind may be produced for the exclusive requirements of the producer’s holding;

“EC registered Article 7.2(a) establishment” means an establishment included in a list of registered establishments, maintained by a competent authority in a Member State, in implementation of Article 10 of Directive 95/69, as an establishment on which an additive, of any kind the manufacture of which is regulated by Article 7.2(a) of Directive 95/69, may be manufactured with a view to putting it into circulation;

“EC registered Article 7.2(b) establishment” means an establishment included in a list of registered establishments, maintained by a competent authority in a Member State, in implementation of Article 10 of Directive 95/69, as an establishment on which a premixture, which contains additives of any kind referred to in Chapter II(a) of the Annex, but does not contain an additive of any kind referred to in Chapter I.2(a) of the Annex, may be manufactured with a view to putting it into circulation;

“EC registered Article 7.2(c)(PA) establishment” means an establishment included in a list of registered establishments, maintained by a competent authority in a Member State, in implementation of Article 10 of Directive 95/69, as an establishment on which a compound feeding stuff, containing a premixture which contains additives of any kind referred to in Chapter II(b) of the Annex, but does not contain a zootechnical additive, may be manufactured with a view to putting it into circulation;

“EC registered Article 7.2(d)(PA) establishment” means an establishment included in a list of registered establishments, maintained by a competent authority in a Member State, in implementation of Article 10 of Directive 95/69, as an establishment on which a compound feeding stuff, containing a premixture which contains additives of any kind referred to in

Chapter II(b) of the Annex, but does not contain a zootechnical additive, may be produced for the exclusive requirements of the producer's holding;

“UK approved Article 2.2(a)(A) establishment” means an establishment approved, pursuant to regulation 6 or 7, as an establishment on which an additive, of any kind referred to in the fourth to the ninth indents of Chapter I.1(a) of the Annex, may be manufactured with a view to putting it into circulation;

“UK approved Article 2.2(a)(P) establishment” means an establishment approved, pursuant to regulation 6 or 7, as an establishment on which a Directive 82/471 product, of any kind referred to in Chapter I.1(a) of the Annex, may be manufactured with a view to putting it into circulation;

“UK approved Article 2.2(b) establishment” means an establishment approved, pursuant to regulation 6 or 7, as an establishment on which a premixture, which contains additives of any kind referred to in the fourth or fifth indent of Chapter I.2(a) of the Annex, but does not contain a zootechnical additive, may be manufactured with a view to putting it into circulation;

“UK approved Article 2.2(d) establishment” means an establishment approved, pursuant to regulation 6 or 7, as an establishment on which a compound feeding stuff, of any kind the manufacture of which is regulated by Article 2.2(d) of Directive 95/69, may be manufactured with a view to putting it into circulation;

“UK approved Article 2.2(f) establishment” means an establishment approved, pursuant to regulation 6 or 7, as an establishment on which a compound feeding stuff, of any kind the production of which is regulated by Article 2.2(f) of Directive 95/69, may be produced for the exclusive requirements of the producer's holding;

“UK permitted Article 2.2(a)(A) establishment” means—

- (a) before 1st September 1998, an establishment located in the United Kingdom (other than a UK approved Article 2.2(a)(A) establishment or an establishment which the competent body has declined to approve as such an establishment) if an additive, of any kind referred to in Chapter I.1(a) of the Annex, 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) an additive, of any kind referred to in sub-paragraph (a) above, 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 under regulation 5(1)(a), or a corresponding application under regulation 7(1) (which in either case is pending), made in accordance with regulation 5(2) or, as the case may be, 7(2), has been submitted to the competent body in respect of the establishment;

“UK permitted Article 2.2(a)(P) establishment” means—

- (a) before 1st September 1998, an establishment located in the United Kingdom (other than a UK approved Article 2.2(a)(P) establishment or an establishment which the competent body has declined to approve as such an establishment) if a Directive 82/471 product, of any kind referred to in Chapter I.1(a) of the Annex, 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 Directive 82/471 product, of any kind referred to in sub-paragraph (a) above, 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 under regulation 5(1)(b), or a corresponding application under regulation 7(1) (which in either case is pending),

made in accordance with regulation 5(2), or, as the case may be, 7(2), has been submitted to the competent body in respect of the establishment;

“UK permitted Article 2.2(b) establishment” means—

- (a) before 1st September 1998, an establishment located in the United Kingdom (other than a UK approved Article 2.2(b) establishment or an establishment which the competent body has declined to approve as such an establishment) if a premixture, which contained additives of any kind referred to in Chapter I.2(a) of the Annex, 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 premixture, of the kind referred to in sub-paragraph (a) above, 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 under regulation 5(1)(c), or a corresponding application under regulation 7(1) (which in either case is pending), made in accordance with regulation 5(2), or, as the case may be, 7(2), has been submitted to the competent body in respect of the establishment;

“UK permitted Article 2.2(d) establishment” means—

- (a) before 1st September 1998, an establishment located in the United Kingdom (other than a UK approved Article 2.2(d) establishment or an establishment which the competent body has declined to approve as such an establishment) if a compound feeding stuff, of any kind the manufacture of which is regulated by Article 2.2(d) of Directive 95/69, was being manufactured on the establishment, with a view to putting it into circulation 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 compound feeding stuff, of any kind referred to in sub-paragraph (a) above, 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 under regulation 5(1)(d), or a corresponding application under regulation 7(1) (which in either case is pending), made in accordance with regulation 5(2), or, as the case may be, 7(2), has been submitted to the competent body in respect of the establishment;

“UK permitted Article 2.2(f) establishment” means—

- (a) before 1st September 1998, an establishment located in the United Kingdom (other than a UK approved Article 2.2(f) establishment or an establishment which the competent authority has declined to approve as such an establishment) if a compound feeding stuff, of any kind the production of which is regulated by Article 2.2(f) of Directive 95/69, 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 compound feeding stuff, of any kind referred to in sub-paragraph (a) above, 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 under regulation 5(1)(e), or a corresponding application under regulation 7(1) (which in either case is pending), made in accordance with regulation 5(2) or, as the case may be, 7(2), has been submitted to the competent body in respect of the establishment;

“UK permitted Article 7.2(a) establishment” means—



- (a) before 1st September 1998, an establishment located in the United Kingdom (other than a UK registered Article 7.2(a) establishment) if an additive, of any kind the manufacture of which is regulated by Article 7.2(a) of Directive 95/69, 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) an additive, of any kind referred to in sub-paragraph (a) above, was being manufactured on the establishment, with a view to putting it into circulation, on 1st April 1998, and
  - (ii) before 1st September 1998, a declaration under regulation 19(1)(a), or a corresponding declaration under regulation 21(1) (consideration of which in either case is pending), made in accordance with regulation 19(2), or, as the case may be, 21(2), has been submitted to the competent body in respect of the establishment;

“UK permitted Article 7.2(b) establishment” means—

- (a) before 1st September 1998, an establishment located in the United Kingdom (other than a UK registered Article 7.2(b) establishment) if a premixture, which contained additives of any kind referred to in Chapter II(a) of the Annex, but did not contain an additive of any kind referred to in Chapter I.2(a) of the Annex, 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 premixture, of the kind referred to in sub-paragraph (a) above, was being manufactured on the establishment, with a view to putting it into circulation, on 1st April 1998, and
  - (ii) before 1st September 1998, a declaration under regulation 19(1)(b), or a corresponding declaration under regulation 21(1) (consideration of which in either case is pending), made in accordance with regulation 19(2), or, as the case may be, 21(2), has been submitted to the competent body in respect of the establishment;

“UK permitted Article 7.2(c)(A) establishment” means—

- (a) before 1st September 1998, an establishment located in the United Kingdom (other than a UK registered Article 7.2(c)(A) establishment) if a compound feeding stuff, which contained an additive of any kind (other than copper, selenium, vitamin A and vitamin D) referred to in Chapter II(a) of the Annex, but did not contain an additive of any kind referred to in Chapter I.2(a) of the Annex, 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 compound feeding stuff, of the kind referred to in sub-paragraph (a) above, was being manufactured on the establishment, with a view to putting it into circulation, on 1st April 1998, and
  - (ii) before 1st September 1998, a declaration under regulation 19(1)(e), or a corresponding declaration under regulation 21(1) (consideration of which in either case is pending), made in accordance with regulation 19(2), or, as the case may be, 21(2), has been submitted to the competent body in respect of the establishment;

“UK permitted Article 7.2(c)(PA) establishment” means—

- (a) before 1st September 1998, an establishment located in the United Kingdom (other than a UK registered Article 7.2(c)(PA) establishment) if a compound feeding stuff, containing a premixture which contained additives of any kind referred to in Chapter II(b) of the Annex, but did not contain 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) a compound feeding stuff, of the kind referred to in sub-paragraph (a) above, was being manufactured on the establishment, with a view to putting it into circulation, on 1st April 1998, and
  - (ii) before 1st September 1998, a declaration under regulation 19(1)(c), or a corresponding declaration under regulation 21(1) (consideration of which in either case is pending), made in accordance with regulation 19(2), or, as the case may be, 21(2), has been submitted to the competent body in respect of the establishment;

“UK permitted Article 7.2(d)(A) establishment” means—

- (a) before 1st September 1998, an establishment located in the United Kingdom (other than a UK registered Article 7.2(d)(A) establishment) if a compound feeding stuff, which contained an additive of any kind (other than copper, selenium, vitamin A and vitamin D) referred to in Chapter II(a) of the Annex, but did not contain an additive of any kind referred to in Chapter I.2(a) of the Annex, 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 compound feeding stuff, of the kind referred to in sub-paragraph (a) above, 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, a declaration under regulation 19(1)(f), or a corresponding declaration under regulation 21(1) (consideration of which in either case is pending), made in accordance with regulation 19(2), or, as the case may be, 21(2), has been submitted to the competent body in respect of the establishment;

“UK permitted Article 7.2(d)(PA) establishment” means—

- (a) before 1st September 1998, an establishment located in the United Kingdom (other than a UK registered Article 7.2(d)(PA) establishment) if a compound feeding stuff, containing a premixture which contained additives of any kind referred to in Chapter II(b) of the Annex, but did not contain a zootechnical additive, 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 compound feeding stuff, of the kind referred to in sub-paragraph (a) above, 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, a declaration under regulation 19(1)(d), or a corresponding declaration under regulation 21(1) (consideration of which in either case is pending), made in accordance with regulation 19(2), or, as the case may be, 21(2), has been submitted to the competent body in respect of the establishment;

“UK registered Article 7.2(a) establishment” means an establishment registered, pursuant to regulation 20 or 21, as an establishment on which an additive, of any kind the manufacture of which is regulated by Article 7.2(a) of Directive 95/69, may be manufactured with a view to putting it into circulation;

“UK registered Article 7.2(b) establishment” means an establishment registered, pursuant to regulation 20 or 21, as an establishment on which a premixture, which contains additives of any kind referred to in Chapter II(a) of the Annex, but does not contain an additive of any kind referred to in Chapter I.2(a) of the Annex, may be manufactured with a view to putting it into circulation;

“UK registered Article 7.2(c)(A) establishment” means an establishment registered, pursuant to regulation 20 or 21, as an establishment on which a compound feeding stuff, which contains an additive of any kind (other than copper, selenium, vitamin A and vitamin D) referred to in Chapter II(a) of the Annex, but does not contain an additive of any kind referred to in Chapter I.2(a) of the Annex, may be manufactured with a view to putting it into circulation;

“UK registered Article 7.2(c)(PA) establishment” means an establishment registered, pursuant to regulation 20 or 21, as an establishment on which a compound feeding stuff, containing a premixture which contains additives of any kind referred to in Chapter II(b) of the Annex, but does not contain a zootechnical additive, may be manufactured with a view to putting it into circulation;

“UK registered Article 7.2(d)(A) establishment” means an establishment registered, pursuant to regulation 20 or 21, as an establishment on which a compound feeding stuff, which contains an additive of any kind (other than copper, selenium, vitamin A and vitamin D) referred to in Chapter II(a) of the Annex, but does not contain an additive of any kind referred to in Chapter I.2(a) of the Annex, may be produced for the exclusive requirements of the producer’s holding;

“UK registered Article 7.2(d)(PA) establishment” means an establishment registered, pursuant to regulation 20 or 21, as an establishment on which a compound feeding stuff, containing a premixture which contains additives of any kind referred to in Chapter II(b) of the Annex, but does not contain a zootechnical additive, may be produced for the exclusive requirements of the producer’s holding.

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

4. In these Regulations, “intermediary” has the meaning given by Article 1.3 of Directive 95/69 and—

“EC approved Article 3.1(A) intermediary” means an intermediary listed on a register of approved intermediaries, maintained by a competent authority in a Member State, in implementation of Article 5 of Directive 95/69, as an intermediary who may wrap, package, store and put into circulation an additive of any kind referred to in Chapter I.1(a) of the Annex;

“EC approved Article 3.1(P) intermediary” means an intermediary listed on a register of approved intermediaries, maintained by a competent authority in a Member State, in implementation of Article 5 of Directive 95/69, as an intermediary who may wrap, package, store and put into circulation a Directive 82/471 product of any kind referred to in Chapter I.1(a) of the Annex;

“EC approved Article 3.1(PA) intermediary” means an intermediary listed on a register of approved intermediaries, maintained by a competent authority in a Member State, in implementation of Article 5 of Directive 95/69, as an intermediary who may wrap, package, store and put into circulation a premixture which contains additives of any kind referred to in Chapter I.2(a) of the Annex;

“EC permitted Article 3.1(A) intermediary” means—

- (a) before 1st September 1998, an intermediary whose facilities are located in a Member State (other than an EC approved Article 3.1(A) intermediary or an intermediary whom a competent authority in a Member State has declined to approve as such an intermediary) and who, on 1st April 1998, was wrapping, packaging, storing or putting into circulation an additive of any kind referred to in Chapter I.1(a) of the Annex, and
- (b) on and after 1st September 1998, an intermediary whose facilities are located in a Member State, who—
  - (i) on 1st April 1998 was wrapping, packaging, storing or putting into circulation an additive of any kind referred to in sub-paragraph (a) above, and

- (ii) before 1st September 1998 has submitted to a competent authority in the Member State an application (which is pending), made in accordance with any requirements in the Member State for the making of such applications, to be approved pursuant to Directive 95/69 as an intermediary who may wrap, package, store and put into circulation an additive of any such kind;

“EC permitted Article 3.1(P) intermediary” means—

- (a) before 1st September 1998, an intermediary whose facilities are located in a Member State (other than an EC approved Article 3.1(P) intermediary or an intermediary whom a competent authority in the Member State has declined to approve as such an intermediary) and who, on 1st April 1998, was wrapping, packaging, storing or putting into circulation a Directive 82/471 product of any kind referred to in Chapter I.1(a) of the Annex, and
- (b) on and after 1st September 1998, an intermediary whose facilities are located in a Member State, who—
  - (i) on 1st April 1998 was wrapping, packaging, storing or putting into circulation a Directive 82/471 product of any kind referred to in sub-paragraph (a) above, and
  - (ii) before 1st September 1998 has submitted to a competent body in the Member State an application (which is pending), made in accordance with any requirements in the Member State for the making of such applications, to be approved pursuant to Directive 95/69 as an intermediary who may wrap, package, store and put into circulation a product of any such kind;

“EC permitted Article 3.1(PA) intermediary” means—

- (a) before 1st September 1998, an intermediary whose facilities are located in a Member State (other than an EC approved Article 3.1(PA) intermediary or an intermediary whom a competent authority in a Member State has declined to approve as such an intermediary) and who, on 1st April 1998, was wrapping, packaging, storing or putting into circulation a premixture which contained additives of any kind referred to in Chapter I.2(a) of the Annex, and
- (b) on and after 1st September 1998, an intermediary whose facilities are located in a Member State, who—
  - (i) on 1st April 1998 was wrapping, packaging, storing or putting into circulation a premixture of the kind referred to in sub-paragraph (a) above, and
  - (ii) before 1st September 1998 has submitted to a competent authority in the Member State an application (which is pending), made in accordance with any requirements in the Member State for the making of such applications, to be approved pursuant to Directive 95/69 as an intermediary who may wrap, package, store and put into circulation a premixture of that kind;

“EC permitted Article 8.1(A) intermediary” means—

- (a) before 1st September 1998, an intermediary whose facilities are located in a Member State (other than an EC registered Article 8.1(A) intermediary) and who, on 1st April 1998, was wrapping, packaging, storing or putting into circulation an additive of any kind the wrapping, packaging, storing and putting into circulation of which is regulated by Article 8.1 of Directive 95/69, and
- (b) on and after 1st September 1998, an intermediary whose facilities are located in a Member State, who—
  - (i) on 1st April 1998 was wrapping, packaging, storing or putting into circulation an additive of any kind referred to in sub-paragraph (a) above, and

- (ii) before 1st September 1998 has submitted to a competent authority in the Member State a declaration (consideration of which is pending), made in accordance with any requirements in the Member State for the submission of such declarations, with a view to his being registered pursuant to Directive 95/69 as an intermediary who may wrap, package, store and put into circulation an additive of any such kind;

“ermitted Article 8.1(PA) intermediary” means—

- (a) before 1st September 1998, an intermediary whose facilities are located in a Member State (other than an EC registered Article 8.1(PA) intermediary) and who, on 1st April 1998, was wrapping, packaging, storing or putting into circulation a premixture which contained additives of any kind referred to in Chapter II(a) of the Annex, but did not contain an additive of any kind referred to in Chapter I.2(a) of the Annex, and
- (b) on and after 1st September 1998, an intermediary whose facilities are located in a Member State, who—
  - (i) on 1st April 1998 was wrapping, packaging, storing or putting into circulation a premixture of the kind referred to in sub-paragraph (a) above, and
  - (ii) before 1st September 1998 has submitted to a competent authority in the Member State a declaration (consideration of which is pending), made in accordance with any requirements in the Member State for the submission of such declarations, with a view to his being registered pursuant to Directive 95/69 as an intermediary who may wrap, package, store and put into circulation a premixture of that kind;

“EC registered Article 8.1(A) intermediary” means an intermediary included in a list of registered intermediaries, maintained by a competent authority in a Member State, in implementation of Article 10 of Directive 95/69, as an intermediary who may wrap, package, store and put into circulation an additive of any kind the wrapping, packaging, storing and putting into circulation of which is regulated by Article 8.1 of Directive 95/69;

“EC registered Article 8.1(PA) intermediary” means an intermediary included in a list of registered intermediaries, maintained by a competent authority in a Member State, in implementation of Article 10 of Directive 95/69, as an intermediary who may wrap, package, store and put into circulation a premixture which contains additives of any kind referred to in Chapter II(a) of the Annex, but does not contain an additive of any kind referred to in Chapter I.2(a) of the Annex;

“UK approved Article 3.1(A) intermediary” means an intermediary approved, pursuant to regulation 13 or 14, as an intermediary who may wrap, package, store and put into circulation an additive of any kind referred to in the fourth to the ninth indents of Chapter I.1(a) of the Annex;

“UK approved Article 3.1(P) intermediary” means an intermediary approved, pursuant to regulation 13 or 14, as an intermediary who may wrap, package, store and put into circulation a Directive 82/471 product of any kind referred to in Chapter I.1(a) of the Annex;

“UK approved Article 3.1(PA) intermediary” means an intermediary approved, pursuant to regulation 13 or 14, as an intermediary who may wrap, package, store and put into circulation a premixture which contains additives of any kind referred to in the fourth or fifth indent of Chapter I.2(a) of the Annex, but does not contain a zootechnical additive;

“UK permitted Article 3.1(A) intermediary” means—

- (a) before 1st September 1998, an intermediary whose facilities are located in the United Kingdom (other than a UK approved Article 3.1(A) intermediary or an intermediary whom the competent body has declined to approve as such an intermediary) and who, on 1st April 1998, was wrapping, packaging, storing or putting into circulation an additive of any kind referred to in Chapter I.1(a) of the Annex, and

- (b) on and after 1st September 1998, an intermediary whose facilities are located in the United Kingdom, who—
  - (i) on 1st April 1998, was wrapping, packaging, storing or putting into circulation an additive of any kind referred to in sub-paragraph (a) above, and
  - (ii) before 1st September 1998, has submitted to the competent body an application under regulation 12(1)(a), or a corresponding application under regulation 14(1) (which in either case is pending), made in accordance with regulation 12(2), or, as the case may be, 14(2);

“UK permitted Article 3.1(P) intermediary” means—

- (a) before 1st September 1998, an intermediary whose facilities are located in the United Kingdom (other than a UK approved Article 3.1(P) intermediary or an intermediary whom the competent body has declined to approve as such an intermediary) and who, on 1st April 1998, was wrapping, packaging, storing or putting into circulation a Directive 82/471 product of any kind referred to in Chapter I.1(a) of the Annex, and
- (b) on and after 1st September 1998, an intermediary whose facilities are located in the United Kingdom, who—
  - (i) on 1st April 1998, was wrapping, packaging, storing or putting into circulation a Directive 82/471 product of any kind referred to in sub-paragraph (a) above, and
  - (ii) before 1st September 1998, has submitted to the competent body an application under regulation 12(1)(b), or a corresponding application under regulation 14(1) (which in either case is pending), made in accordance with regulation 12(2), or, as the case may be, 14(2);

“UK permitted Article 3.1(PA) intermediary” means—

- (a) before 1st September 1998, an intermediary whose facilities are located in the United Kingdom (other than a UK approved Article 3.1(PA) intermediary or an intermediary whom the competent body has declined to approve as such an intermediary) and who, on 1st April 1998, was wrapping, packaging, storing or putting into circulation a premixture which contained additives of any kind referred to in Chapter I.2(a) of the Annex, and
- (b) on and after 1st September 1998, an intermediary whose facilities are located in the United Kingdom, who—
  - (i) on 1st April 1998, was wrapping, packaging, storing or putting into circulation a premixture of the kind referred to in sub-paragraph (a) above, and
  - (ii) before 1st September 1998, has submitted to the competent body an application under regulation 12(1)(c), or a corresponding application under regulation 14(1) (which in either case is pending), made in accordance with regulation 12(2), or, as the case may be, 14(2);

“UK permitted Article 8.1(A) intermediary” means—

- (a) before 1st September 1998, an intermediary whose facilities are located in the United Kingdom (other than a UK registered Article 8.1(A) intermediary) and who, on 1st April 1998, was wrapping, packaging, storing or putting into circulation an additive of any kind the wrapping, packaging, storing and putting into circulation of which is regulated by Article 8.1 of Directive 95/69, and
- (b) on and after 1st September 1998, an intermediary whose facilities are located in the United Kingdom, who—
  - (i) on 1st April 1998, was wrapping, packaging, storing or putting into circulation an additive of any kind referred to in sub-paragraph (a) above, and

- (ii) before 1st September 1998, has submitted to the competent body a declaration under regulation 26(1)(a), or a corresponding declaration under regulation 28(1) (consideration of which in either case is pending), made in accordance with regulation 26(2), or, as the case may be, 28(2);

“UK permitted Article 8.1(PA) intermediary” means—

- (a) before 1st September 1998, an intermediary whose facilities are located in the United Kingdom (other than a UK registered Article 8.1(PA) intermediary) and who, on 1st April 1998, was wrapping, packaging, storing or putting into circulation a premixture which contained additives of any kind referred to in Chapter II(a) of the Annex, but did not contain an additive of any kind referred to in Chapter I.2(a) of the Annex, and
- (b) on and after 1st September 1998, an intermediary whose facilities are located in the United Kingdom, who—
  - (i) on 1st April 1998, was wrapping, packaging, storing or putting into circulation a premixture of the kind referred to in sub-paragraph (a) above, and
  - (ii) before 1st September 1998, has submitted to the competent body a declaration under regulation 26(1)(b), or a corresponding declaration under regulation 28(1) (consideration of which in either case is pending), made in accordance with regulation 26(2), or, as the case may be, 28(2);

“UK registered Article 8.1(A) intermediary” means an intermediary registered, pursuant to regulation 27 or 28, as an intermediary who may wrap, package, store and put into circulation an additive of any kind the wrapping, packaging, storing and putting into circulation of which is regulated by Article 8.1 of Directive 95/69;

“UK registered Article 8.1(PA) intermediary” means an intermediary registered, pursuant to regulation 27 or 28, as an intermediary who may wrap, package, store and put into circulation a premixture which contains additives of any kind referred to in Chapter II(a) of the Annex, but does not contain an additive of any kind referred to in Chapter I.2(a) of the Annex.

## PART II

### APPROVAL OF ESTABLISHMENTS

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

5.—(1) An eligible person may apply to the competent body to approve an establishment as an establishment on which one or more of the following activities may be exercised—

- (a) the manufacture of an additive of any kind referred to in the fourth to the ninth indents of Chapter I.1(a) of the Annex, with a view to putting it into circulation;
- (b) the manufacture of a Directive 82/471 product of any kind referred to in Chapter I.1(a) of the Annex, with a view to putting it into circulation;
- (c) the manufacture of a premixture, containing additives of any kind referred to in the fourth or fifth indent of Chapter I.2(a) of the Annex, but not containing a zootechnical additive, with a view to putting it into circulation;
- (d) the manufacture of a compound feeding stuff, of any kind the manufacture of which is regulated by Article 2.2(d) of Directive 95/69, with a view to putting it into circulation; or
- (e) the production of a compound feeding stuff, of any kind the production of which is regulated by Article 2.2(f) of Directive 95/69, for the exclusive requirements of the applicant’s holding.

- (2) An application made under paragraph (1) shall—
- (a) be in writing,
  - (b) be in the English language,
  - (c) be signed by or on behalf of the applicant,
  - (d) contain the name and address of the applicant,
  - (e) identify the establishment in respect of which the application is made,
  - (f) identify the establishment activity which the applicant is exercising or, as the case may be, intends to exercise, on that establishment, and
  - (g) (if made by 31st August 1998) state whether the establishment activity was being exercised on the establishment on 1st April 1998.

### **Approval of establishments**

6.—(1) Where an application complying with regulation 5(2) is made under paragraph (1) of that regulation, the competent body shall—

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

(2) Where the competent body is satisfied that the establishment meets the applicable conditions, the competent body shall—

- (a) approve the establishment as an establishment on which the establishment activity concerned may be exercised, and
- (b) in accordance with Article 5.1 of Directive 95/69, enter the establishment on a register, which the competent body shall maintain, under an individual approval number which identifies the establishment, as an establishment approved under this paragraph for the exercise of that activity.

### **Amendment of approvals**

7.—(1) An eligible person may apply to the competent body to approve an approved establishment as an establishment on which an establishment activity (“the new establishment activity”) may be exercised—

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

(2) An application made under paragraph (1) shall—

- (a) be in writing,
- (b) be in the English language,
- (c) be signed by or on behalf of the applicant,
- (d) contain the name and address of the applicant,
- (e) identify the establishment in respect of which the application is made,
- (f) identify the new establishment activity which the applicant is exercising or, as the case may be, intends to exercise on that establishment,
- (g) (if made by 31st August 1998) state whether the new establishment activity was being exercised on the establishment on 1st April 1998, and



- (h) state under which sub-paragraph of paragraph (1) the application is made.
- (3) Where an application complying with paragraph (2) is made under paragraph (1)—
  - (a) regulation 6(1) shall apply, as if the application was made under regulation 5(1), and
  - (b) if the competent body is satisfied that the establishment meets the applicable conditions, it shall approve the establishment as an establishment on which the new establishment activity may be exercised.
- (4) Where, pursuant to paragraph (3), the competent body approves an establishment, the competent body shall amend the register maintained by it under regulation 6(2)(b), to show all the establishment activities the exercise of which on that establishment is approved under regulation 6(2) (a) or under paragraph (3).

### **Withdrawal of approvals**

- 8.—**(1) The competent body shall withdraw an approval for the exercise of an establishment activity on an approved establishment if the competent body is satisfied that the exercise of that activity on the establishment has ceased.
- (2) The competent body shall withdraw an approval for the exercise of an establishment activity on an approved establishment if, following the procedure in regulation 9, the competent body is not satisfied that the person exercising on the establishment the activity concerned is complying, in relation to that activity, with regulation 34, 49, 64, 71 or 73, as the case may be.
- (3) Where, pursuant to paragraph (1) or (2), the competent body withdraws an approval, it shall amend the register maintained by it under regulation 6(2)(b), by deleting from it the entry recording approval in respect of the establishment activity for which approval has been withdrawn.

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

- 9.—**(1) Where, in the circumstances described in regulation 8(2), the competent body proposes to withdraw an approval relating to the exercise of an establishment activity on an approved establishment, the competent body shall not withdraw the approval unless—
- (a) it serves a written notice complying with the requirements of paragraph (2) on the person exercising the activity concerned on the establishment (“the recipient”), and
  - (b) after the time for compliance with the notice has expired, it is not satisfied that the recipient has complied with the requirements specified in the notice.
- (2) A notice served by the competent body under paragraph (1) shall—
- (a) state that it proposes to withdraw the approval relating to the establishment activity concerned, because it is not satisfied that the recipient is complying, in relation to that activity, with regulation 34, 49, 64, 71 or 73, as the case may be,
  - (b) specify—
    - (i) the essential conditions it is not satisfied that the recipient is complying with; and
    - (ii) the requirements that the recipient of the notice must comply with in order to satisfy it as to compliance with those essential conditions; and
  - (c) state that, unless it is satisfied that the recipient has complied with those requirements, within such reasonable time as is specified in the notice, the approval for the exercise of the establishment activity concerned will be withdrawn.

**National lists of approved establishments**

10. Every competent body shall provide to 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 of Directive 95/69 in relation to lists of approved establishments.

**Interpretation of Part II****11. In this Part—**

“the applicable conditions” means the conditions laid down or referred to in—

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

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

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

“essential conditions” means the essential conditions laid down or referred to in—

- (a) Chapter I.1(b) of the Annex, in the case of the exercise of the establishment activities specified in regulation 5(1)(a) and (b);
- (b) Chapter I.2(b) of the Annex, in the case of the exercise of the establishment activity specified in regulation 5(1)(c);
- (c) Chapter I.4 of the Annex, in the case of the exercise of the establishment activity specified in regulation 5(1)(d); and
- (d) with the exception of the requirements set out in point 7, Chapter I.4 of the Annex, in the case of the exercise of the establishment activity specified in regulation 5(1)(e); and

“establishment activity” means an activity specified in paragraph (a), (b), (c), (d) or (e) of regulation 5(1).

## PART III

### APPROVAL OF INTERMEDIARIES

#### **Applications for the approval of intermediaries**

**12.**—(1) An eligible person may apply to the competent body to be approved as an intermediary who may exercise one or more of the following activities—

- (a) wrapping, packaging, storing and putting into circulation an additive of any kind referred to in the fourth to the ninth indents of Chapter I.1(a) of the Annex,
- (b) wrapping, packaging, storing and putting into circulation a Directive 82/471 product of any kind referred to in Chapter I.1(a) of the Annex, or
- (c) wrapping, packaging, storing and putting into circulation a premixture, containing additives of any kind referred to in the fourth or fifth indent of Chapter I.2(a) of the Annex, but not containing a zootechnical additive.

(2) An application made under paragraph (1) shall—

- (a) be in writing,
- (b) be in the English language,
- (c) be signed by or on behalf of the applicant,
- (d) contain the name and address of the applicant,
- (e) identify the intermediary activity which the applicant is exercising or, as the case may be, intends to exercise,
- (f) identify the facilities in respect of which the application is made, and
- (g) (if made by 31st August 1998) state whether the applicant was exercising the intermediary activity at those facilities on 1st April 1998.

(3) A person making an application under paragraph (1) may lodge with the competent body a declaration of the type specified in the second paragraph of Article 5.1 of Directive 95/69.

#### **Approval of intermediaries**

**13.**—(1) Where an application complying with regulation 12(2) is made under paragraph (1) of that regulation, the competent body shall—

- (a) subject to paragraph (2), check by means of an on the spot verification whether the applicant meets the applicable conditions, and
- (b) process the application in accordance with the requirements of the second paragraph of Article 4.1, or the second paragraph of Article 4.2, of Directive 95/69, as the case may be.

(2) Paragraph (1)(a) shall not apply in the case of a person who makes an application under regulation 12(1) if—

- (a) he is a person of the kind referred to in the second paragraph of Article 5.1 of Directive 95/69, and
- (b) at the time he makes his application, he lodges with the competent body a declaration of the kind specified in that paragraph.

(3) Where the competent body is satisfied that the applicant—

- (a) meets the applicable conditions, or
- (b) is a person of the kind referred to in paragraph (2)(a) who satisfies paragraph (2)(b),

it shall—

- (A) approve the applicant as an intermediary who may exercise the intermediary activity concerned, and
- (B) in accordance with Article 5.1 of Directive 95/69, enter the applicant on a register, which the competent body shall maintain, under an individual approval number which identifies the applicant, as an intermediary approved under this paragraph for the exercise of that activity.

### **Amendment of approvals**

**14.**—(1) An eligible person may apply to the competent body to be approved as a person who may exercise an intermediary activity (“the new intermediary activity”)—

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

(2) An application made under paragraph (1) shall—

- (a) be in writing,
- (b) be in the English language,
- (c) be signed by or on behalf of the applicant,
- (d) contain the name and address of the applicant,
- (e) identify the new intermediary activity which the applicant is exercising or, as the case may be, intends to exercise,
- (f) identify the facilities in respect of which the application is made,
- (g) (if made by 31st August 1998) state whether the applicant was exercising the new intermediary activity at those facilities on 1st April 1998, and
- (h) state under which sub-paragraph of paragraph (1) the application is made.

(3) Where an application complying with paragraph (2) is made under paragraph (1)—

- (a) regulations 12(3) and 13(1) and (2) shall apply, as if the application were made under regulation 12(1), and
- (b) if the competent body is satisfied that the applicant—
  - (i) meets the applicable conditions, or
  - (ii) is a person who—

(A) is of the kind referred to in the second paragraph of Article 5.1 of Directive 95/69, and

(B) at the time he made his application, lodged with the competent body a declaration of the kind specified in that paragraph,

it shall approve the applicant as an intermediary who may exercise the new intermediary activity.

(4) Where, pursuant to paragraph (3), the competent body approves an intermediary, it shall amend the register maintained by it under regulation 13(3)(B), to show all the intermediary activities for the exercise of which that intermediary is approved under regulation 13(3)(A) or under paragraph (3).

### **Withdrawal of approvals**

**15.**—(1) The competent body shall withdraw an approval for the exercise of an intermediary activity by an approved intermediary if the competent body is satisfied that the intermediary has ceased exercising that activity.

(2) The competent body shall withdraw an approval for the exercise of an intermediary activity by an approved intermediary if, following the procedure in regulation 16, the competent body is not satisfied that, in relation to that activity, the intermediary is complying with regulation 38, 42, 53, 57, 66 or 68, as the case may be.

(3) Where, pursuant to paragraphs (1) or (2), the competent body withdraws an approval, it shall amend the register maintained by it under regulation 13(3)(B), by deleting from it the entry recording approval in respect of the intermediary activity for which approval has been withdrawn.

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

**16.**—(1) Where, in the circumstances described in regulation 15(2), the competent body proposes to withdraw an approval relating to the exercise of an intermediary activity by an approved intermediary, the competent body shall not withdraw the approval unless—

- (a) it serves a written notice complying with the requirements of paragraph (2) on the intermediary, and
  - (b) after the time for compliance with that notice has expired, it is not satisfied that the intermediary has complied with the requirements specified in the notice.
- (2) A notice served by the competent body under paragraph (1) shall—
- (a) state that it proposes to withdraw the approval relating to the intermediary activity concerned, because it is not satisfied that the intermediary is complying, in relation to that activity, with regulation 38, 42, 53, 57, 66 or 68, as the case may be;
  - (b) specify—
    - (i) the essential conditions it is satisfied that the intermediary is not complying with; and
    - (ii) the requirements that the intermediary must comply with in order to satisfy it as to compliance with those essential conditions; and
  - (c) state that, unless it is satisfied that the intermediary has complied with those requirements, within such reasonable time as is specified in the notice, the approval for the exercise of the intermediary activity concerned will be withdrawn.

### **National lists of approved intermediaries**

**17.** Every competent body shall provide to 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 of Directive 95/69 in relation to lists of approved intermediaries.

### **Interpretation of Part III**

**18.** In this Part—

“the applicable conditions” means the conditions laid down or referred to in—

- (a) point 7 of Chapter I.1(b) of the Annex, in the case of an application to approve a person as an intermediary who may exercise the intermediary activity specified in regulation 12(1) (a) or who may exercise that specified in regulation 12(1)(b); and
- (b) point 7 of Chapter I.2(b) of the Annex, in the case of an application to approve a person as an intermediary who may exercise the intermediary activity specified in regulation 12(1) (c).

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

“eligible person” means a person who is entitled to apply to the competent body, in accordance with the provisions of the first paragraph of Article 4.1 of Directive 95/69, or the first paragraph

of Article 4.2 thereof, to be approved as an intermediary who may exercise an intermediary activity;

“essential conditions” means the essential conditions laid down or referred to in—

- (a) point 7 of Chapter I.1(b) of the Annex, in the case of the exercise of the intermediary activities specified in regulation 12(1)(a) and (b), and
- (b) point 7 of Chapter I.2(b) of the Annex, in the case of the exercise of the intermediary activity specified in regulation 12(1)(c);

“intermediary activity” means an activity specified in paragraph (a), (b) or (c) of regulation 12(1).

## PART IV

### REGISTRATION OF ESTABLISHMENTS

#### **Declarations leading to the registration of establishments**

**19.**—(1) An eligible person may submit to the competent body a declaration relating to an establishment on which he intends to exercise one or more of the following activities—

- (a) the manufacture of an additive of any kind the manufacture of which is regulated by Article 7.2(a) of Directive 95/69, with a view to putting it into circulation;
  - (b) the manufacture of a premixture, containing additives of any kind referred to in Chapter II(a) of the Annex, but not containing an additive of any kind referred to in Chapter I.2(a) of the Annex, with a view to putting it into circulation;
  - (c) the manufacture of a compound feeding stuff containing a premixture containing additives of any kind referred to in Chapter II(b) of the Annex, but not containing a zootechnical additive, with a view to putting it into circulation;
  - (d) the production of any such compound feeding stuff, for the exclusive requirements of the applicant’s holding;
  - (e) the manufacture of a compound feeding stuff, containing an additive of any kind (other than copper, selenium, vitamin A and vitamin D) referred to in Chapter II(a) of the Annex, but not containing an additive of any kind referred to in Chapter I.2(a) of the Annex, with a view to putting it into circulation; or
  - (f) the production of any such compound feeding stuff, for the exclusive requirements of the applicant’s holding.
- (2) A declaration submitted under paragraph (1) shall—
- (a) be in writing,
  - (b) be in the English language,
  - (c) be signed by or on behalf of the person submitting the declaration,
  - (d) contain the name and address of that person,
  - (e) identify the establishment to which the declaration relates,
  - (f) identify the establishment activity which the person submitting the declaration is exercising or, as the case may be, intends to exercise, on that establishment,
  - (g) (if made by 31st August 1998) state whether the establishment activity was being exercised on the establishment on 1st April 1998, and
  - (h) contain a statement that the establishment complies, and an undertaking that when the establishment activity is exercised on it, it will comply, with the applicable conditions.

(3) For the purposes of the statement referred to in paragraph (2)(h), and pursuant to Article 7.3 of Directive 95/69, an establishment shall be deemed to comply with the applicable conditions if it is an establishment which, pursuant to these Regulations, the Feedingstuffs (Zootechnical Products) 1998(7) or both, is approved for the exercise on that establishment of a corresponding activity referred to in Article 2.2(a), (b), (c) or (e) of that Directive.

### **Registration of establishments**

**20.** Where a declaration complying with regulation 19(2) is submitted under paragraph (1) of that regulation, the competent body shall—

- (a) register the establishment as an establishment on which the establishment activity concerned may be exercised, and
- (b) in accordance with Article 10.1 of Directive 95/69, enter the establishment on a list, which the competent body shall maintain, under an individual registration number which identifies the establishment, as an establishment registered under this paragraph for the exercise of that activity.

### **Amendment of registrations**

**21.—(1)** An eligible person may submit to the competent body a declaration relating to a registered establishment on which he intends to exercise an establishment activity (“the new establishment activity”)—

- (a) in addition to an establishment activity for the exercise of which the establishment is already registered, or
  - (b) instead of that activity.
- (2) A declaration submitted under paragraph (1) shall—
- (a) be in writing,
  - (b) be in the English language,
  - (c) be signed by or on behalf of the person submitting the declaration,
  - (d) contain the name and address of that person,
  - (e) identify the establishment to which the declaration relates,
  - (f) identify the new establishment activity which the person submitting the declaration is exercising or, as the case may be, intends to exercise, on that establishment,
  - (g) (if made by 31st August 1998) state whether the new establishment activity was being exercised on the establishment on 1st April 1998,
  - (h) state under which sub-paragraph of paragraph (1) the declaration is submitted, and
  - (i) contain a statement that the establishment complies, and an undertaking that when the establishment activity is exercised on it, it will comply, with the applicable conditions.

(3) For the purposes of the statement referred to in paragraph (2)(i), and pursuant to Article 7.3 of Directive 95/69, an establishment shall be deemed to comply with the applicable conditions if it is an establishment which, pursuant to these Regulations, the Feedingstuffs (Zootechnical Products) Regulations 1998 or both, is approved for the exercise on that establishment of a corresponding activity referred to in Article 2.2(a), (b), (c) or (e) of that Directive.

(4) Where a declaration complying with paragraph (2) is submitted under paragraph (1), the competent body shall register the establishment as an establishment on which the new establishment activity may be exercised.

(5) Where, pursuant to paragraph (4), the competent body registers an establishment, the competent body shall amend the list maintained by it under regulation 20(b), to show all the establishment activities for the exercise of which on that establishment the establishment is registered under regulation 20(a) or under paragraph (4).

### **Cancellation of registrations**

**22.**—(1) The competent body shall cancel a registration for the exercise of an establishment activity on a registered establishment if the competent body is satisfied that the exercise of that activity on the establishment has ceased.

(2) The competent body shall cancel a registration for the exercise of an establishment activity on a registered establishment if, following the procedure in regulation 23, the competent body is not satisfied that the person exercising on the establishment the activity concerned is complying, in relation to that activity, with regulation 36, 51, 75, 77, 79 or 81, as the case may be.

(3) Where, pursuant to paragraphs (1) or (2), the competent body cancels a registration, it shall amend the list maintained by it under regulation 20(b), by deleting from it the entry effecting registration in respect of the establishment activity for which registration has been cancelled.

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

**23.**—(1) Where, in the circumstances described in regulation 22(2), the competent body proposes to cancel a registration relating to the exercise of an establishment activity on a registered establishment, the competent body shall not cancel the registration unless—

- (a) it serves a written notice complying with the requirements of paragraph (2) on the person exercising the activity concerned on the establishment (“the recipient”), and
  - (b) after the time for compliance with the notice has expired, it is not satisfied that the recipient has complied with the requirements specified in the notice.
- (2) A notice served by the competent body under paragraph (1) shall—
- (a) state that it proposes to cancel the registration relating to the establishment activity concerned, because it is not satisfied that the recipient is complying, in relation to that activity, with regulation 36, 51, 75, 77, 79 or 81, as the case may be;
  - (b) specify—
    - (i) the essential conditions it is not satisfied that the recipient is complying with; and
    - (ii) the requirements that the recipient of the notice must comply with in order to satisfy it as to compliance with those essential conditions; and
  - (c) state that, unless it is satisfied that the recipient has complied with those requirements, within such reasonable time as is specified in the notice, the registration for the exercise of the establishment activity concerned will be cancelled.

### **National lists of registered establishments**

**24.** Every competent body shall provide to 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 11 of Directive 95/69, as read with Article 13.3 and 4 of Directive 70/524, in relation to lists of registered establishments.

### **Interpretation of Part IV**

**25.** In this Part—



“the applicable conditions” means the conditions laid down or referred to in Chapter II(c) of the Annex;

“eligible person” means a person who is entitled to apply to the competent body, in accordance with Article 9.1 or 9.2 of Directive 95/69, for an establishment to be registered as an establishment on which an establishment activity may be exercised;

“essential conditions” means the essential conditions laid down or referred to in Chapter II(c) of the Annex;

“establishment activity” means an activity specified in paragraph (a), (b), (c), (d), (e) or (f) of regulation 19(1);

“registered establishment” means an establishment registered by the competent body as an establishment on which an establishment activity may be exercised.

## PART V

### REGISTRATION OF INTERMEDIARIES

#### **Declarations leading to the registration of intermediaries**

**26.**—(1) An eligible person may submit to the competent body a declaration, with a view to being registered by it as an intermediary who may carry out either or both of the following activities—

- (a) wrapping, packaging, storing and putting into circulation an additive of any kind the wrapping, packaging, storing and putting into circulation of which is regulated by Article 8.1 of Directive 95/69; or
- (b) wrapping, packaging, storing and putting into circulation a premixture containing additives of any kind referred to in Chapter II(a) of the Annex, but not containing an additive of any kind referred to in Chapter I.2(a) of the Annex.

(2) A declaration submitted under paragraph (1) shall—

- (a) be in writing,
- (b) be in the English language,
- (c) be signed by or on behalf of the person submitting the declaration,
- (d) contain the name and address of that person,
- (e) identify the intermediary activity which that person is exercising or, as the case may be, intends to exercise,
- (f) identify the facilities in respect of which the declaration is submitted,
- (g) (if made by 31st August 1998) state whether the person submitting the declaration was exercising the intermediary activity at those facilities on 1st April 1998, and
- (h) contain a statement that that person complies, and an undertaking that when he exercises the intermediary activity he will comply, with the applicable conditions.

(3) For the purposes of the statement referred to in paragraph (2)(h), and pursuant to Article 8.2 of Directive 95/69, an intermediary shall be deemed to comply with the applicable conditions if he is an intermediary the exercise by whom of a corresponding activity referred to in Article 3.1 of that Directive, is approved pursuant to these Regulations, the Feedingstuffs (Zootechnical Products) Regulations 1998 or both.

**Registration of intermediaries**

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

- (a) register the person submitting the declaration as an intermediary who may exercise the intermediary activity concerned, and
- (b) in accordance with Article 10.1 of Directive 95/69, enter the intermediary on a list, which the competent body shall maintain, under an individual registration number which identifies the intermediary, as an intermediary registered under this paragraph for the exercise of that activity.

**Amendment of registrations**

28.—(1) An eligible person may submit to the competent body a declaration, with a view to being registered by it as a registered intermediary who may exercise an intermediary activity (“the new intermediary activity”)—

- (a) in addition to an intermediary activity for the exercise of which he is already registered, or
  - (b) instead of that activity.
- (2) A declaration submitted under paragraph (1) shall—
- (a) be in writing,
  - (b) be in the English language,
  - (c) be signed by or on behalf of the person submitting the declaration,
  - (d) contain the name and address of that person,
  - (e) identify the new intermediary activity which that person is exercising or, as the case may be, intends to exercise,
  - (f) identify the facilities in respect of which the declaration is submitted,
  - (g) (if made by 31st August 1998) state whether the person submitting the declaration was exercising the new intermediary activity at those facilities on 1st April 1998,
  - (h) state under which sub-paragraph of paragraph (1) the declaration is submitted, and
  - (i) contain a statement that the person submitting the declaration complies, and an undertaking that when he exercises the new intermediary activity he will comply, with the applicable conditions.

(3) For the purposes of the statement referred to in paragraph (2)(i), and pursuant to Article 8.2 of Directive 95/69, an intermediary shall be deemed to comply with the applicable conditions if he is an intermediary the exercise by whom of a corresponding activity referred to in Article 3.1 of that Directive, is approved pursuant to these Regulations, the Feedingstuffs (Zootechnical Products) Regulations 1998 or both.

(4) Where a declaration complying with paragraph (2) is submitted under paragraph (1), the competent body shall register the intermediary as an intermediary who may exercise the new intermediary activity.

(5) Where, pursuant to paragraph (4), the competent body registers an intermediary, the competent body shall amend the list maintained by it under regulation 27(b), to show all the intermediary activities for the exercise of which the intermediary is registered under regulation 27(a) or under paragraph (4).

### **Cancellation of registrations**

**29.**—(1) The competent body shall cancel a registration for the exercise by a registered intermediary of an intermediary activity if the competent body is satisfied that the intermediary has ceased exercising that activity.

(2) The competent body shall cancel a registration for the exercise of an intermediary activity by a registered intermediary if, following the procedure in regulation 30, the competent body is not satisfied that, in relation to that activity, the intermediary is complying with regulation 40, 44, 55 or 59, as the case may be.

(3) Where, pursuant to paragraphs (1) or (2), the competent body cancels a registration, it shall amend the list maintained by it under regulation 27(b), by deleting from it the entry effecting registration in respect of the intermediary activity for which registration has been cancelled.

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

**30.**—(1) Where, in the circumstances described in regulation 29(2), the competent body proposes to cancel a registration relating to the exercise of an intermediary activity by a registered intermediary, the competent body shall not cancel the registration unless—

- (a) it serves a written notice complying with the requirements of paragraph (2) on the intermediary, and
  - (b) after the time for compliance with that notice has expired, it is not satisfied that the intermediary has complied with the requirements specified in the notice.
- (2) A notice served by the competent body under paragraph (1) shall—
- (a) state that it proposes to cancel the registration relating to the intermediary activity concerned, because it is not satisfied that the intermediary is complying, in relation to that activity, with regulation 40, 44, 55 or 59, as the case may be;
  - (b) specify—
    - (i) the essential conditions it is not satisfied that the intermediary is complying with; and
    - (ii) the requirements that the intermediary must comply with in order to satisfy it as to compliance with those essential conditions; and
  - (c) state that, unless it is satisfied that the intermediary has complied with those requirements, within such reasonable time as is specified in the notice, the registration for the exercise of the intermediary activity concerned will be cancelled.

### **National lists of registered intermediaries**

**31.** Every competent body shall provide to 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 11 of Directive 95/69 in relation to lists of registered intermediaries.

### **Interpretation of Part V**

**32.** In this Part—

“the applicable conditions” means the conditions laid down or referred to in point 7 of Chapter II(c) of the Annex;

“eligible person” means a person who is entitled to apply to the competent body, in accordance with Article 9.1 or 9.2 of Directive 95/69, to be registered as an intermediary who may exercise an intermediary activity;

“essential conditions” means the essential conditions laid down or referred to in point 7 of Chapter II(c) of the Annex;

“intermediary activity” means an activity specified in sub-paragraph (a) or (b) of regulation 26(1);

“registered intermediary” means a person registered by the competent body as an intermediary who may exercise an intermediary activity.

## PART VI

### CONTROL OF ADDITIVES

#### **Manufacture of certain additives referred to in Article 2.2(a) of Directive 95/69**

**33.** No person shall manufacture an additive of any kind referred to in the fourth to the ninth indents of Chapter I.1(a) of the Annex, with a view to putting it into circulation, except on a UK approved or permitted Article 2.2(a)(A) establishment.

#### **Further control of manufacture of additives to which regulation 33 applies**

**34.** No person shall manufacture an additive of any kind to which regulation 33 applies on a UK approved Article 2.2(a)(A) establishment, with a view to putting it into circulation, unless he fulfils the essential conditions contained or referred to in Chapter I.1(b) of the Annex.

#### **Manufacture of additives referred to in Article 7.2(a) of Directive 95/69**

**35.** No person shall manufacture an additive of any kind the manufacture of which is regulated by Article 7.2(a) of Directive 95/69, with a view to putting it into circulation, except on a UK registered or permitted Article 7.2(a) establishment.

#### **Further control of manufacture of additives to which regulation 35 applies**

**36.** No person shall manufacture an additive of any kind to which regulation 35 applies on a UK registered Article 7.2(a) establishment, with a view to putting it into circulation, unless he fulfils the essential conditions contained or referred to in Chapter II(c) of the Annex.

#### **Wrapping, packaging and storage by intermediaries of certain additives referred to in Article 3.1 of Directive 95/69**

**37.** No intermediary shall wrap, package or store an additive of any kind referred to in the fourth to the ninth indents of Chapter I.1(a) of the Annex, other than a UK approved or permitted Article 3.1(A) intermediary.

#### **Further control of wrapping, packaging or storing by intermediaries of additives to which regulation 37 applies**

**38.** No UK approved Article 3.1(A) intermediary shall wrap, package or store an additive of any kind to which regulation 37 applies, unless he fulfils the essential conditions contained or referred to in point 7 of Chapter I.1(b) of the Annex.

### **Wrapping, packaging and storage by intermediaries of additives referred to in Article 8.1 of Directive 95/69**

**39.** No intermediary shall wrap, package or store an additive of any kind the wrapping, packaging, storing and putting into circulation of which is regulated by Article 8.1 of Directive 95/69, other than a UK registered or permitted Article 8.1(A) intermediary.

### **Further control of wrapping, packaging or storing by intermediaries of additives to which regulation 39 applies**

**40.** No UK registered Article 8.1(A) intermediary shall wrap, package or store an additive of any kind to which regulation 39 applies, unless he fulfils the essential conditions contained or referred to in point 7 of Chapter II(c) of the Annex.

### **Putting into circulation by intermediaries of additives to which regulation 37 applies**

**41.** No intermediary shall put into circulation an additive of any kind to which regulation 37 applies, other than an EC or UK approved or permitted Article 3.1(A) intermediary.

### **Further control of putting into circulation by intermediaries of additives to which regulation 37 applies**

**42.** No EC or UK approved Article 3.1(A) intermediary shall put into circulation an additive of any kind to which regulation 37 applies, unless he fulfils the essential conditions contained or referred to in point 7 of Chapter I.1(b) of the Annex.

### **Putting into circulation by intermediaries of additives to which regulation 39 applies**

**43.** No intermediary shall put into circulation an additive of any kind to which regulation 39 applies, other than an EC or UK registered or permitted Article 8.1(A) intermediary.

### **Further control of putting into circulation by intermediaries of additives to which regulation 39 applies**

**44.** No EC or UK registered Article 8.1(A) intermediary shall put into circulation an additive of any kind to which regulation 39 applies, unless he fulfils the essential conditions contained or referred to in point 7 of Chapter II(c) of the Annex.

### **Putting into circulation of certain additives**

**45.—(1)** No person shall put into circulation an additive of any kind referred to in the fourth to ninth indents of Chapter I.1(a) of the Annex, except an additive of any such kind manufactured on a UK approved or permitted Article 2.2(a)(A) establishment, an EC approved or permitted Article 2.2(a)(A) establishment or an establishment located in a third country.

(2) No person shall put into circulation an additive of any kind the manufacture of which is regulated by Article 7.2(a) of Directive 95/69, except an additive of any such kind manufactured on a UK registered or permitted Article 7.2(a) establishment, an EC registered or permitted Article 7.2(a) establishment or an establishment located in a third country.

### **Supply of certain additives**

**46.—(1)** Subject to paragraph (2), no person shall supply, as an additive, any copper, selenium, vitamin A or vitamin D, unless—

(a) the additive concerned has been manufactured on—

- (i) a UK approved or permitted Article 2.2(a)(A) establishment,
  - (ii) an EC approved or permitted Article 2.2(a)(A) establishment, or
  - (iii) an establishment located in a third country, and
- (b) the additive concerned—
- (i) is supplied to—
    - (A) a UK approved or permitted Article 2.2(b) establishment,
    - (B) an establishment located in the United Kingdom which, pursuant to the Feedingstuffs (Zootechnical Products) Regulations 1998<sup>(8)</sup>, has been approved for the manufacture on that establishment of a zootechnical premixture, or on which it is permitted under those Regulations to manufacture such a premixture,
    - (C) an EC approved or permitted Article 2.2(b) establishment,
    - (D) a UK approved or permitted Article 3.1(A) intermediary,
    - (E) an EC approved or permitted Article 3.1(A) intermediary,
    - (F) a UK registered or permitted Article 7.2(c)(PA) establishment, engaged in the manufacture of compound feeding stuffs for pet animals,
    - (G) an EC registered or permitted Article 7.2(c)(PA) establishment, engaged as aforesaid,
    - (H) a UK registered or permitted Article 7.2(d)(PA) establishment, engaged as aforesaid, or
    - (I) an EC registered or permitted Article 7.2(d)(PA) establishment, engaged as aforesaid,
- or
- (ii) is supplied by way of export to a third country, and the requirement specified in Article 22 of Directive 70/524 is satisfied in relation to it.

(2) Notwithstanding paragraph (1), copper, selenium, vitamin A or vitamin D may be delivered at the last stage of circulation, as an additive, to—

- (a) a UK registered or permitted Article 7.2(c)(PA) establishment, or
- (b) an EC registered or permitted Article 7.2(c)(PA) establishment,

if the requirements specified in the first and, in the case of registered establishments, third, indented paragraphs of Article 13.4(b) of Directive 70/524 are satisfied.

#### **Incorporation of certain additives into compound feeding stuffs**

**47.** No person shall incorporate into a compound feeding stuff any copper, selenium, vitamin A or vitamin D, unless—

- (a) the additive concerned has been prepared beforehand, in a premixture containing a substance used as a carrier, but not containing a zootechnical additive, on an EC or UK approved or permitted Article 2.2(b) establishment, or an establishment located in a third country, and he incorporates the premixture in accordance with regulation 62,
- (b) the additive concerned has been prepared beforehand, in a premixture containing a substance used as a carrier, and containing also a zootechnical additive, on—

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<sup>(8)</sup> S.I. 1998/1047.

- (i) an establishment located in the United Kingdom which, pursuant to the Feedingstuffs (Zootechnical Products) Regulations 1998, has been approved for the manufacture on that establishment of a zootechnical premixture, or on which it is permitted under those Regulations to manufacture such a premixture,
  - (ii) an EC approved or permitted Article 2.2(b) establishment, or
  - (iii) an establishment located in a third country
- and he incorporates the premixture in accordance with regulation 51 of those Regulations,
- (c) the incorporation is carried out on a UK registered or permitted Article 7.2(c)(PA) establishment, and the requirements specified in the first and, in the case of registered establishments, third, indented paragraphs of Article 13.4(b) of Directive 70/524 are satisfied, or
  - (d) the incorporation is carried out on—
    - (i) a UK registered or permitted Article 7.2(c)(PA) establishment, or
    - (ii) a UK registered or permitted Article 7.2(d)(PA) establishment,engaged in the manufacture of compound feeding stuffs for pet animals.

## PART VII

### CONTROL OF PREMIXTURES

#### **Manufacture of certain premixtures referred to in Article 2.2(b) of Directive 95/69**

**48.** No person shall manufacture a premixture, which contains additives of any kind referred to in the fourth or fifth indents of Chapter I.2(a) of the Annex, but does not contain a zootechnical additive, with a view to putting it into circulation, except on a UK approved or permitted Article 2.2(b) establishment.

#### **Further control of manufacture of premixtures to which regulation 48 applies**

**49.** No person shall manufacture a premixture of the kind to which regulation 48 applies on a UK approved Article 2.2(b) establishment, with a view to putting it into circulation, unless he fulfils the essential conditions contained or referred to in Chapter I.2(b) of the Annex.

#### **Manufacture of premixtures referred to in Article 7.2(b) of Directive 95/69**

**50.** No person shall manufacture a premixture, which contains additives of any kind referred to in Chapter II(a) of the Annex, but does not contain an additive of any kind referred to in Chapter I.2(a) of the Annex, with a view to putting it into circulation, except on a UK registered or permitted Article 7.2(b) establishment.

#### **Further control of manufacture of premixtures to which regulation 50 applies**

**51.** No person shall manufacture a premixture of the kind to which regulation 50 applies on a UK registered Article 7.2(b) establishment, with a view to putting it into circulation, unless he fulfils the essential conditions contained or referred to in Chapter II(c) of the Annex.

**Wrapping, packaging and storage by intermediaries of certain premixtures referred to in Article 3.1 of Directive 95/69**

52. No intermediary shall wrap, package or store a premixture which contains additives of any kind referred to in the fourth or fifth indents of Chapter I.2(a) of the Annex, but does not contain a zootechnical additive, other than a UK approved or permitted Article 3.1(PA) intermediary.

**Further control of wrapping, packaging or storing by intermediaries of premixtures to which regulation 52 applies**

53. No UK approved Article 3.1(PA) intermediary shall wrap, package or store a premixture of the kind to which regulation 52 applies, unless he fulfils the essential conditions contained or referred to in point 7 of Chapter I.2(b) of the Annex.

**Wrapping, packaging and storage by intermediaries of premixtures referred to in Article 8.1 of Directive 95/69**

54. No intermediary shall wrap, package or store a premixture which contains additives of any kind referred to in Chapter II(a) of the Annex, but does not contain an additive of any kind referred to in Chapter I.2(a) of the Annex, other than a UK registered or permitted Article 8.1(PA) intermediary.

**Further control of wrapping, packaging or storing by intermediaries of premixtures to which regulation 54 applies**

55. No UK registered Article 8.1(PA) intermediary shall wrap, package or store a premixture of the kind to which regulation 54 applies, unless he fulfils the essential conditions contained or referred to in point 7 of Chapter II(c) of the Annex.

**Putting into circulation by intermediaries of premixtures to which regulation 52 applies**

56. No intermediary shall put into circulation a premixture of the kind to which regulation 52 applies, other than an EC or UK approved or permitted Article 3.1(PA) intermediary.

**Further control of putting into circulation by intermediaries of premixtures to which regulation 52 applies**

57. No EC or UK approved Article 3.1(PA) intermediary shall put into circulation a premixture of the kind to which regulation 52 applies, unless he fulfils the essential conditions contained or referred to in point 7 of Chapter I.2(b) of the Annex.

**Putting into circulation by intermediaries of premixtures to which regulation 54 applies**

58. No intermediary shall put into circulation a premixture of the kind to which regulation 54 applies, other than an EC or UK registered or permitted Article 8.1(PA) intermediary.

**Further control of putting into circulation by intermediaries of premixtures to which regulation 54 applies**

59. No EC or UK registered Article 8.1(PA) intermediary shall put into circulation a premixture of the kind to which regulation 54 applies, unless he fulfils the essential conditions contained or referred to in point 7 of Chapter II(c) of the Annex.



### **Putting into circulation of certain premixtures**

**60.**—(1) No person shall put into circulation a premixture which contains additives of any kind referred to in the fourth or fifth indent of Chapter I.2(a) of the Annex, but does not contain a zootechnical additive, with a view to incorporation of the premixture in a compound feeding stuff, except a premixture manufactured on a UK approved or permitted Article 2.2(b) establishment, an EC approved or permitted Article 2.2(b) establishment or an establishment located in a third country.

(2) No person shall put into circulation a premixture which contains additives of any kind referred to in Chapter II(a) of the Annex, but does not contain an additive of any kind referred to in Chapter I.2(a) of the Annex, with a view to incorporation of the premixture in a compound feeding stuff, except a premixture manufactured on a UK registered or permitted Article 7.2(b) establishment, an EC registered or permitted Article 7.2(b) establishment or an establishment located in a third country.

### **Supply of certain premixtures**

**61.**—(1) No person shall supply a premixture containing any copper, selenium, vitamin A or vitamin D, but not containing a zootechnical additive, unless the premixture concerned has been manufactured on—

- (a) a UK approved or permitted Article 2.2(b) establishment,
- (b) an EC approved or permitted Article 2.2(b) establishment, or
- (c) an establishment located in a third country.

(2) No person shall supply a premixture containing any copper, selenium, vitamin A or vitamin D, but not containing a zootechnical additive, unless it is supplied—

- (a) to a UK approved or permitted Article 3.1(PA) intermediary,
- (b) to an EC approved or permitted Article 3.1(PA) intermediary,
- (c) to a UK registered or permitted Article 7.2(c)(PA) establishment,
- (d) to an EC registered or permitted Article 7.2(c)(PA) establishment,
- (e) to a UK registered or permitted Article 7.2(d)(PA) establishment,
- (f) to an EC registered or permitted Article 7.2(d)(PA) establishment, or
- (g) by way of export to a third country, and the requirement specified in Article 22 of Directive 70/524 is satisfied in relation to it.

### **Incorporation of certain premixtures into compound feeding stuffs**

**62.**—(1) Subject to paragraph (2), no person shall incorporate into a compound feeding stuff a premixture containing a substance used as a carrier, and containing any copper, selenium, vitamin A or vitamin D, but not containing a zootechnical additive, unless he incorporates it in a proportion of at least 0.2% by weight of the feeding stuff.

(2) Notwithstanding paragraph (1), but without prejudice to regulations 74 and 75, if the requirement as to premixtures specified in the second paragraph of Article 13.3 of Directive 70/524 is met in relation to the premixture concerned, a person may incorporate it into a compound feeding stuff, in any proportion of not less than 0.05% by weight of the feeding stuff, on—

- (a) a UK approved or permitted Article 2.2(b) establishment,
- (b) an establishment (not being a UK approved or permitted Article 2.2(b) establishment) as to which the competent body is satisfied that the conditions for approval as a UK approved Article 2.2(b) establishment are met, or

- (c) an establishment (not being a UK approved or permitted Article 2.2(b) establishment, or an establishment which the competent body has declined to approve as a UK approved Article 2.2(b) establishment)—
- (i) on which, on 1st April 1998, a premixture containing a substance used as a carrier, and containing any copper, selenium, vitamin A or vitamin D, but not containing a zootechnical additive, was being manufactured in a proportion of less than 0.2% by weight of the feeding stuff, and
  - (ii) as to which, before 1st September 1998, a request, (consideration of which is pending) has been made to the competent body to satisfy itself that those conditions are met.

## PART VIII

### CONTROL OF DIRECTIVE 82/471 PRODUCTS

#### **Manufacture of Directive 82/471 products referred to in Article 2.2(a) of Directive 95/69**

**63.** No person shall manufacture a Directive 82/471 product, of any kind referred to in Chapter I.1(a) of the Annex, with a view to putting it into circulation, except on a UK approved or permitted Article 2.2(a)(P) establishment.

#### **Further control of manufacture of Directive 82/471 products to which regulation 63 applies**

**64.** No person shall manufacture a Directive 82/471 product of any kind to which regulation 63 applies on a UK approved Article 2.2(a)(P) establishment, with a view to putting it into circulation, unless he fulfils the essential conditions contained or referred to in Chapter I.1(b) of the Annex.

#### **Wrapping, packaging and storage by intermediaries of Directive 82/471 products referred to in Article 3.1 of Directive 95/69**

**65.** No intermediary shall wrap, package or store a Directive 82/471 product of any kind referred to in Chapter I.1(a) of the Annex, other than a UK approved or permitted Article 3.1(P) intermediary.

#### **Further control of wrapping, packaging or storing by intermediaries of Directive 82/471 products to which regulation 65 applies**

**66.** No UK approved Article 3.1(P) intermediary shall wrap, package or store a Directive 82/471 product of any kind to which regulation 65 applies, unless he fulfils the essential conditions contained or referred to in point 7 of Chapter I.1(b) of the Annex.

#### **Putting into circulation by intermediaries of Directive 82/471 products to which regulation 65 applies**

**67.** No intermediary shall put into circulation a Directive 82/471 product of any kind to which regulation 65 applies, other than an EC or UK approved or permitted Article 3.1(P) intermediary.

#### **Further control of putting into circulation by intermediaries of Directive 82/471 products to which regulation 65 applies**

**68.** No EC or UK approved Article 3.1(P) intermediary shall put into circulation a Directive 82/471 product of any kind to which regulation 65 applies, unless he fulfils the essential conditions contained or referred to in point 7 of Chapter I.1(b) of the Annex.

### **Putting into circulation certain Directive 82/471 products**

**69.** No person shall put into circulation a Directive 82/471 product, of any kind referred to in Chapter I.1(a) of the Annex, except a product of any such kind manufactured on—

- (a) a UK approved or permitted Article 2.2(a)(P) establishment,
- (b) an EC approved or permitted Article 2.2(a)(P) establishment, or
- (c) an establishment located in a third country.

## **PART IX**

### **CONTROL OF COMPOUND FEEDING STUFFS**

#### **Manufacture of compound feeding stuffs referred to in Article 2.2(d) of Directive 95/69**

**70.** No person shall manufacture a compound feeding stuff of any kind the manufacture of which is regulated by Article 2.2(d) of Directive 95/69, with a view to putting it into circulation, except on a UK approved or permitted Article 2.2(d) establishment.

#### **Further control of manufacture of compound feeding stuffs to which regulation 70 applies**

**71.** No person shall manufacture a compound feeding stuff of any kind to which regulation 70 applies on a UK approved Article 2.2(d) establishment, with a view to putting it into circulation, unless he fulfils the essential conditions contained or referred to in Chapter I.4 of the Annex.

#### **Production of compound feeding stuffs referred to in Article 2.2(f) of Directive 95/69**

**72.** No person shall produce, for the exclusive requirements of his holding, a compound feeding stuff of any kind the production of which is regulated by Article 2.2(f) of Directive 95/69, except on a UK approved or permitted Article 2.2(f) establishment.

#### **Further control of production of compound feeding stuffs to which regulation 72 applies**

**73.** No person shall produce, for the exclusive requirements of his holding, a compound feeding stuff of any kind to which regulation 72 applies on a UK approved Article 2.2(f) establishment, unless he fulfils the essential conditions contained or referred to in points 1 to 6.2 of Chapter I.4 of the Annex.

#### **Manufacture of compound feeding stuffs containing premixtures of additives referred to in Chapter II(b) of the Annex to Directive 95/69**

**74.** No person shall manufacture a compound feeding stuff containing a premixture which contains additives of any kind referred to in Chapter II(b) of the Annex, but does not contain a zootechnical additive, with a view to putting it into circulation, except on a UK registered or permitted Article 7.2(c)(PA) establishment.

#### **Further control of manufacture of compound feeding stuffs to which regulation 74 applies**

**75.** No person shall manufacture a compound feeding stuff of the kind to which regulation 74 applies on a UK registered Article 7.2(c)(PA) establishment, with a view to putting it into circulation, unless he fulfils the essential conditions contained or referred to in Chapter II(c) of the Annex.

**Production of compound feeding stuffs containing premixtures of additives referred to in Chapter II(b) of the Annex to Directive 95/69**

76. No person shall produce, for the exclusive requirements of his holding, a compound feeding stuff containing a premixture which contains additives of any kind referred to in Chapter II(b) of the Annex, but does not contain a zootechnical additive, except on a UK registered or permitted Article 7.2(d)(PA) establishment.

**Further control of production of compound feeding stuffs to which regulation 76 applies**

77. No person shall produce, for the exclusive requirements of his holding, a compound feeding stuff of the kind to which regulation 76 applies on a UK registered Article 7.2(d)(PA) establishment, unless he fulfils the essential conditions contained or referred to in Chapter II(c) of the Annex.

**Manufacture of compound feeding stuffs containing additives referred to in Chapter II(a) of the Annex to Directive 95/69**

78. No person shall manufacture, with a view to putting it into circulation, a compound feeding stuff which contains an additive of any kind (other than copper, selenium, vitamin A and vitamin D) referred to in Chapter II(a) of the Annex, but does not contain an additive of any kind referred to in Chapter I.2(a) of the Annex, except on a UK registered or permitted Article 7.2(c)(A) establishment.

**Further control of manufacture of compound feeding stuffs to which regulation 78 applies**

79. No person shall manufacture a compound feeding stuff of the kind to which regulation 78 applies on a UK registered Article 7.2(c)(A) establishment, with a view to putting it into circulation, unless he fulfils the essential conditions contained or referred to in Chapter II(c) of the Annex.

**Production of compound feeding stuffs containing additives referred to in Chapter II(a) of the Annex to Directive 95/69**

80. No person shall produce, for the exclusive requirements of his holding, a compound feeding stuff which contains an additive of any kind (other than copper, selenium, vitamin A and vitamin D) referred to in Chapter II(a) of the Annex, but does not contain an additive of any kind referred to in Chapter I.2(a) of the Annex, except on a UK registered or permitted Article 7.2(d)(A) establishment.

**Further control of production of compound feeding stuffs to which regulation 80 applies**

81. No person shall produce, for the exclusive requirements of his holding, a compound feeding stuff of the kind to which regulation 80 applies on a UK registered Article 7.2(d)(A) establishment, unless he fulfils the essential conditions contained or referred to in Chapter II(c) of the Annex.

## PART X

### ENFORCEMENT

**Official checks and enforcement**

82.—(1) Subject to paragraph (2), it shall be the duty of the competent body to enforce these Regulations and carry out official checks for that purpose.

(2) Nothing in these Regulations shall be taken as authorising any competent body in Scotland to institute proceedings for an offence.

### **Powers of authorised persons**

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

- (a) carrying out official checks, and
- (b) ascertaining whether an offence under regulation 91(a) 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 controlled product has been manufactured or produced, or is being kept for the purpose of being put into circulation, incorporated in another product 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 controlled product which the occupier of the premises has in his possession.

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

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

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

(4) Every warrant granted under this regulation shall continue in force for a period of one month.

(5) In the application of paragraph (3) to Scotland, any reference to a justice of the peace includes a reference to the sheriff and to a magistrate.

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

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

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

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

- (a) any substance or article appearing to him to be used, or intended to be used, in the manufacture or production of any controlled product;

- (b) any product appearing to him to be a controlled product manufactured, wrapped, packaged, stored or put into circulation, or intended to be put into circulation; or
  - (c) any product appearing to him to be a controlled product used, or intended to be used, for the purpose of animal feeding, in the like manner as that laid down—
    - (i) in the case of Great Britain, in paragraphs 1 to 4, 6, 7, 9 and 10 of Part II of Schedule 1 to the Feeding Stuffs (Sampling and Analysis) Regulations 1982<sup>(9)</sup> as read with Part I of that Schedule, or
    - (ii) in the case of Northern Ireland, in paragraphs 1 to 4, 6, 7, 9 and 10 of Part II of Schedule 1 to the Feeding Stuffs (Sampling and Analysis) Regulations (Northern Ireland) 1982<sup>(10)</sup> as read with Part I of that Schedule.
- (9) The provisions of the Feeding Stuffs (Sampling and Analysis) Regulations 1982 or, as the case may be, the Feeding Stuffs (Sampling and Analysis) Regulations (Northern Ireland) 1982<sup>(10)</sup> referred to in paragraph (8), shall have effect, for the purposes of that paragraph, as if—
- (a) for all references in those provisions to “a feeding stuff” or to “feeding stuffs” there were substituted references to “a controlled product” or “controlled products” respectively, and
  - (b) in paragraph 1 of those provisions, the expression “, except where section 68(2)(b) of the Act applies” were omitted.
- (10) Where, for the purpose of taking a sample pursuant to paragraph (8), an authorised person takes some of it from each of one or more containers of the substance or, as the case may be, the article or product, which are exposed for sale by retail, and none of which weighs more than six kilograms, the owner of the container or containers may require the authorised person to purchase the container or containers on behalf of the competent body for whom he acts.
- (11) An authorised person entering premises by virtue of this regulation, or of a warrant issued under it, shall have the right—
- (a) to require any person carrying on, or appearing to be carrying on, a business which consists of or includes the manufacture, production, wrapping, packaging, storage, putting into circulation, or use of a controlled product, or any person employed in connection with such a business, to produce any record (in whatever form it is held) relating to or arising out of the exercise in the course of that business of any such activity, and which is in his possession or under his control, and
  - (b) to inspect and take copies of any record, or of any entry in any record, produced in pursuance of the preceding sub-paragraph.
- (12) An authorised person exercising the power conferred by paragraph (11) in respect of a record held by means of a computer—
- (a) shall be entitled at any reasonable time to have access to, and inspect and check the operation of, any computer and associated apparatus or material which is or has been, or which it appears is or has been, in use in connection with the record in question;
  - (b) may require—
    - (i) the person by whom or on whose behalf the computer is or has been so used, or
    - (ii) any person having charge of, or otherwise concerned with the operation of, the computer, apparatus or material,
 to afford the authorised person such reasonable assistance as he may require for that purpose; and

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<sup>(9)</sup> S.I. 1982/1144, to which there are amendments not relevant to these Regulations.

<sup>(10)</sup> S.R. 1982/338, to which there are amendments not relevant to these Regulations.

<sup>(10)</sup> S.R. 1982/338, to which there are amendments not relevant to these Regulations.

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

(13) An authorised person entering premises by virtue of this regulation, or of a warrant issued under it, shall have the right to seize and detain any product which he has reasonable cause to believe to be a controlled product in relation to which, or by means of which, it appears that 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.

### **Division of samples**

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

- (a) cause each part to be marked, sealed and fastened up in the like manner as that laid down—
  - (i) in the case of Great Britain, in Part V of Schedule 1 to the Feeding Stuffs (Sampling and Analysis) Regulations 1982, as read with Part I of that Schedule, or
  - (ii) in the case of Northern Ireland, in Part V of Schedule 1 to the Feeding Stuffs (Sampling and Analysis) Regulations (Northern Ireland) 1982, as read with Part I of that Schedule;
- (b) send one part for analysis to—
  - (i) in Great Britain, the agricultural analyst for the area of the competent body which authorised the authorised person to carry out the official check in the course of which the sample was taken, and
  - (ii) in Northern Ireland, an agricultural analyst in Northern Ireland;
- (c) send another part to the person subject to the official check; and
- (d) retain and preserve the remaining part as an officially sealed reference sample.

### **Supply of part of sample to manufacturer**

**85.** If the person who manufactured a substance or, as the case may be, article or product, of which an authorised person has taken a sample, is not a person to whom part of the sample is required to be sent under regulation 84, that regulation shall have effect as if, for the reference to three parts, there were substituted a reference to four parts, and the authorised person shall send the fourth part to the manufacturer, unless he does not know the manufacturer's name, or any address of his in the United Kingdom, and is unable, after making reasonable enquiries, to ascertain the name or, as the case may be, any such address, before the expiration of fourteen days from the date when the sample was taken.

### **Statement to accompany sample**

**86.** There shall be sent with the part of the sample sent to the agricultural analyst pursuant to regulation 84, a statement signed by the authorised person that the sample was taken in the manner referred to in regulation 83(8).

### **Analysis by the Agricultural Analyst**

**87.** The agricultural analyst shall analyse the part of the sample sent to him under regulation 84, and send a certificate of the analysis, completed in the form set out in Schedule 2, and in accordance with the notes set out in that Schedule, to the authorised person, who shall send a copy to—

- (a) the person who was subjected to the official check concerned, and
- (b) any person to whom he has sent a part of the sample pursuant to regulation 85.

### **Alternative arrangements for carrying out analyses**

**88.** If the agricultural analyst to whom a sample is sent for analysis under regulation 84 determines that an effective analysis of the sample cannot be made by him or under his direction, he shall send it to the agricultural analyst for another area or, in Northern Ireland, to another agricultural analyst in Northern Ireland, together with any documents received by him with the sample, and thereupon regulation 87 shall apply, as if the sample had originally been sent to that other agricultural analyst.

### **Further analysis of samples**

**89.**—(1) Where a part of a sample sent to an agricultural analyst pursuant to regulation 84 has been analysed, and it is intended to institute proceedings, or proceedings have been commenced, against a person for an offence under regulation 91(a), and it is intended to adduce, on behalf of the prosecution, evidence of the result of the analysis of that part of the sample, the defendant, for the purpose of obtaining a second opinion, may request the authorised person to send the retained part of the sample for analysis to—

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

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

- (a) the authorised person shall—
  - (i) send the retained part of the sample for analysis to the Government Chemist or, as the case may be, the Chief Agricultural Analyst, and
  - (ii) supply the defendant with a copy of the Government Chemist's or, as the case may be, the Chief Agricultural Analyst's, certificate of analysis of that part of the sample; and
- (b) the Government Chemist or, as the case may be, the Chief Agricultural Analyst, shall analyse the part of the sample sent to him under sub-paragraph (a) above and shall send a certificate of the analysis, completed in the form set out in Schedule 2, and in accordance with the notes set out in that Schedule, to the authorised person.

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

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

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

- (4) In this regulation “defendant” includes a prospective defendant.



### Methods of analysis

**90.** For the purpose of analysing a part of a sample taken in the course of the carrying out of official checks, any scientifically valid method of analysis shall be used by the agricultural analyst concerned or, as the case may be, by the Government Chemist or the Chief Agricultural Analyst.

### Offences

**91.** It shall be an offence for a person—

- (a) without reasonable excuse, to contravene any of the regulations 33 to 81;
- (b) intentionally to obstruct an authorised person in the exercise of any power conferred by regulation 83, or
- (c) without reasonable excuse to fail to comply with any requirement made of him, pursuant to regulation 83, by an authorised person.

### Punishment of offences

**92.—(1)** A person contravening, without reasonable excuse, any of regulations 33, 35, 37, 39, 41, 43, 45, 46, 47, 48, 50, 52, 54, 56, 58, 60, 61, 62, 63, 65, 67, 69, 70, 72, 74, 76, 78 or 80 shall be liable—

- (a) on summary conviction, to a fine not exceeding the statutory maximum,
- (b) on conviction on indictment, to a fine.

(2) A person contravening, without reasonable excuse, any of regulations 34, 36, 38, 40, 42, 44, 49, 51, 53, 55, 57, 59, 64, 66, 68, 71, 73, 75, 77, 79 or 81 shall be liable on summary conviction to a fine not exceeding level 5 on the standard scale.

(3) A person contravening regulation 91(b) shall be liable on summary conviction to a fine not exceeding level 3 on the standard scale.

(4) A person contravening, without reasonable excuse, regulation 91(c) shall be liable on summary conviction to a fine not exceeding level 3 on the standard scale.

### Time limit for prosecutions

**93.—(1)** Proceedings for an offence under any of the regulations specified in regulation 92(2) may, subject to paragraph (2), 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(11) (date of commencement of proceedings) shall apply for the purposes of this regulation as it applies for the purposes of that section.

**Offences by Scottish partnerships**

94. 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**

95. Where a person responsible for putting a controlled product into circulation is charged with an offence under these Regulations, in respect of a controlled 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 specifications for manufacture and assembly of the product were available, or had been provided, to that other person and that the person responsible for putting the product into circulation had instructed that other person to manufacture or assemble the product in accordance with those specifications,
- (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 with the exercise of reasonable care have known, that that instruction had not been complied with.

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

96.—(1) Subject to paragraph (2), for the purposes of this Part of these Regulations, sections 79(4) to (8), 80(1), 81, 82 and 110, of the Act shall have effect, as if these Regulations were made under section 74A(4) of the Act.

(2) For the purposes of paragraph (1)—

- (a) in relation to Northern Ireland—
  - (i) section 79(4) to (6) of the Act shall have effect as if, for the references therein to the Government Chemist, there were substituted references to the Chief Agricultural Analyst, and
  - (ii) section 79(5) of the Act shall have effect as if the expression “(3)(b)” were omitted,
- (b) section 82(1) of the Act shall have effect as if, for the words “any of the following provisions of this Act, namely, sections 68(1A), 4(b) and (c), 69(4)(c), 70(2), 71(2)(b), 73, 73A and 74A” there were substituted the words “the Feeding Stuffs (Establishments and Intermediaries) Regulations 1998”, and
- (c) section 110(1) of the Act shall have effect as if, for the words “this Act or any order or scheme made thereunder” there were substituted the words “the Feeding Stuffs (Establishments and Intermediaries) Regulations 1998”.

**Service of certificates, notices and parts of samples**

97. Any certificate, notice or part of a sample, required to be served on a person under any provision of these Regulations, may be served—

- (a) by delivering it to him;

- (b) by leaving it at the usual or last known place of abode or business of that person, or, in a case where an address for service has been given by that person, at that address;
- (c) by sending it in a prepaid registered letter, or by the recorded delivery service, addressed to that person at his usual or last-known place of abode or business or, in a case where an address for service has been given by that person, at that address; or
- (d) in the case of a body corporate, by delivering it to the secretary or clerk of the body corporate at its registered or principal office, or by sending it in a prepaid registered letter, or by the recorded delivery service, addressed to the secretary or clerk of that body corporate at that office.

9th April 1998

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

1st April 1998

*Sewel*  
Parliamentary Under Secretary of State, Scottish  
Office

*Status: This is the original version (as it was originally made).*

**SCHEDULE 1**

regulation 2(2)

**PART I**

**EXPRESSIONS HAVING THE SAME MEANING AS IN DIRECTIVE 70/524**

antibiotics  
coccidiostats and other medicinal substances  
growth promoters  
incorporate  
last stage of circulation  
supply

**PART II**

**EXPRESSIONS HAVING THE SAME MEANING AS IN DIRECTIVE 95/69**

ceased  
corresponding activity  
essential conditions  
exclusive requirements  
facilities  
holding  
manufacture  
on the spot verification  
produce  
reasonable time

**SCHEDULE 2**

regulations 87 and 89(3)

**FORM OF CERTIFICATE OF ANALYSIS  
CERTIFICATE OF ANALYSIS OF SAMPLE OF PRODUCT ANALYSED PURSUANT  
TO THE FEEDING STUFFS (ESTABLISHMENTS AND INTERMEDIARIES)  
REGULATIONS 1998 (1)**

I, the undersigned, agricultural analyst for the (2) /agricultural analyst in Northern Ireland/  
Government Chemist/Chief Agricultural Analyst, in pursuance of the provisions of the Feeding  
Stuffs (Establishments and Intermediaries) Regulations 1998, hereby certify that I received on the  
day of 19 , from (3) one part of a sample of  
(4) for analysis; which was duly sealed and fastened up and marked (5)  
and was accompanied by a (6) and also by a signed statement  
that the sample was taken in the manner referred to in regulation 83(8) of those Regulations; and  
that the said part has been analysed by me, or under my direction, and I declare the results of  
analysis to be as follows:—

(7)

(8)

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

Signature of analyst/Government Chemist/Chief Agricultural Analyst

Address

Date

## NOTES

(1) Statements made in certificates are to be confined to matters which are necessary to verify compliance with the Feeding Stuffs (Establishments and Intermediaries) Regulations 1998.

(2) Insert the name of the local authority where appropriate, and delete as applicable.

(3) Insert the name of the authorised person who submitted the sample for analysis; and also the mode of transit, for example “by hand”, “by registered post”, “by rail”, as the case may be.

(4) Insert the name or description applied to the material.

(5) Insert the distinguishing mark on the sample and the date of sampling shown thereon.

(6) Insert description of any document accompanying the sample.

(7) Insert relevant results, including—

(a) identification of the type of product concerned (e.g. compound feeding stuff, complete feeding stuff, additive etc.);

(b) the name or names of any additive, premixture, undesirable substance or Directive 82/471 product comprising or contained in the product;

(c) the level of any undesirable substance or product contained in any product which is a compound feeding stuff, expressed as mg/kg of the feeding stuff, referred to a moisture content of 12% ; and

(d) the amount of any additive comprising or contained in the product, having regard to any maximum or minimum level specified in respect of the additive in Directive 70/524 and referred to a complete feeding stuff with a moisture content of 12%.

(8) Indicate the method of analysis used. If analysis cannot be carried out because no suitable method exists then the certificate should be noted accordingly.

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## EXPLANATORY NOTE

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

1. These Regulations, which extend to the United Kingdom, implement—

- (a) 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](#) (OJNo. L332, 30.12.95, p.15), and
- (b) Article 1:10 of Council Directive [96/51/EC](#) amending Directive [70/524/EEC](#) concerning additives in feeding stuffs (OJ No. L235, 17.9.96, p.39),

in relation to feeding stuffs which do not contain antibiotics, coccidiostats and other medicinal substances or growth promoters.

2. The Regulations introduce new requirements, in accordance with Directive [95/69/EC](#), under which—

- (a) “establishments” in the United Kingdom (as defined in Article 1.3 of Directive [95/69](#)) must be approved/registered by the competent authorities (local authorities in Great Britain and the Department of Agriculture for Northern Ireland in Northern Ireland) for the manufacture with a view to putting them into circulation of certain feed additives, premixtures, products regulated by Council Directive [82/471/EEC](#) and compound feeding stuffs,
- (b) “intermediaries” based in the United Kingdom (also defined in Article 1.3 of Directive [95/69](#)) must be approved/registered by the same competent authorities for the wrapping, packaging, storing and “putting into circulation” (see definition in Article 1.3 of Directive [95/69](#)) of certain feed additives, premixtures and products regulated by Directive [82/471/EEC](#), and
- (c) intermediaries based in a member state other than the United Kingdom, and putting into circulation in the United Kingdom products of the kinds referred to in (b) above, must be approved/registered by the competent authorities in the member state concerned,

(regulations 33 to 44, 48 to 59, 63 to 68 and 70 to 81).

3. In general terms, the approval requirement applies to the exercise of activities which, under Directive [95/69/EC](#), are considered potentially hazardous to animals, humans or the environment, whereas the registration provisions govern products considered less sensitive. In both cases, however, establishments and intermediaries must comply with detailed “quality control” requirements specified in the Annex to Directive [95/69](#), and that is a precondition before approval (which can only be given following an inspection by the competent authority) can be given. The obligation to comply with those requirements continues once approval/registration has been obtained.

4. Application for approval/registration must be made to the competent authority, and the application must contain specified information. The competent authority must keep a register/list of approved/registered establishments and intermediaries and must update them as necessary. Applicants may apply for approval/registration in respect of activities additional to or replacing any for which they are already approved/registered, and the competent authority can cancel approval/registration in cases where an activity is no longer being exercised, or where the quality control requirements are not being met (regulations 5 to 32).

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

6. In implementation of Article 13 of Directive [70/524/EEC](#), as substituted by Directive 96/51, the Regulations also contain provisions regulating, in relation to establishments and intermediaries requiring approval/registration—

- (a) the putting into circulation of certain additives, premixtures containing those additives and compound feeding stuffs containing such premixtures (regulations 45 and 60);
- (b) the supply of certain additives, alone or in premixtures (regulations 45 and 61), and
- (c) the incorporation of certain additives, and premixtures containing such additives, in compound feeding stuffs (regulations 47 and 62).

7. The Regulations provide for their enforcement by the competent authority and contain detailed provisions for that purpose, including provision for the taking of samples of products controlled by the Regulations, analysis of such samples, offences and penalties (regulations 82 to 97).

8. The provisions of Directive 95/69 and Article 1:10 of Directive 96/51 implemented by these Regulations are implemented, so far as relevant to feeding stuffs containing antibiotics, coccidiostats and other medicinal substances or growth promoters, by the Feedingstuffs (Zootechnical Products) Regulations 1998, save that the requirements in Directive 95/69 relating to registration do not apply to these products.

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