
STATUTORY INSTRUMENTS

1999 No. 1872

AGRICULTURE

**The Feeding Stuffs (Establishments
and Intermediaries) Regulations 1999**

<i>Made</i>	- - - -	<i>29th June 1999</i>
<i>Laid before Parliament</i>		<i>30th June 1999</i>
<i>Coming into force</i>	- -	<i>2nd August 1999</i>

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

PART I
GENERAL

Title, commencement and revocation

1.—(1) These Regulations may be cited as the Feeding Stuffs (Establishments and Intermediaries) Regulations 1999 and shall come into force on 2nd August 1999.

(2) The Feeding Stuffs (Establishments and Intermediaries) Regulations 1998⁽³⁾ (“the 1998 Regulations”) are hereby revoked.

Definition of “feeding stuff” and related definitions and general interpretation

2.—(1) In these Regulations—

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

(1) S.I. 1972/1811.
(2) 1972, c.68.
(3) S.I. 1998/1049.

- (c) “compound feeding stuff” means a mixture of feeding stuffs; and
- (d) “feeding stuff” means—
 - (i) a product of vegetable or animal origin in its natural state (whether fresh or preserved);
 - (ii) a product derived from the industrial processing of such a product, or
 - (iii) an organic or inorganic substance, used singly or in a mixture,whether or not containing additives, for oral feeding to any pet animal or farmed creature, but for the purposes of any definition containing the expression “Article 2.2(d)”, and of regulations 5(1)(d), 33(1)(d), 82, 83 and 94, extends to any such product or substance which is intended for oral feeding to any animal living freely in the wild;

(2) In these Regulations, save where the context otherwise requires,—

“the Act” means the Agriculture Act 1970(4);

“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;

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

“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 any establishment, not being a third country establishment, the body referred to in section 67(1), (1A) or (2) of the Act in the area of which the establishment concerned is,
- (ii) in the case of any third country establishment, the body referred to as aforesaid in the area of which a product of the establishment concerned, covered by the first indent of Article 6.4(b) of Directive 98/51, is located, or an authorised person believes is located, and
- (iii) in the case of any intermediary, the body referred to as aforesaid in the area of which the intermediary concerned 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;

“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, and includes any substance or material (other than a machine or implement) appearing to be used, or intended to be used, in the manufacture or production of any such controlled product;

“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⁽⁵⁾ as amended by amendments up to, but not including, the amendments effected by Council Directive [1999/20/EC](#)⁽⁶⁾;

“Directive 82/471” means Council Directive [82/471/EEC](#) concerning certain products used in animal nutrition⁽⁷⁾;

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

“Directive 95/53” means Council Directive [95/53/EC](#) fixing the principles governing the organisation of official inspections in the field of animal nutrition⁽⁸⁾ (with effect from 1st October 1999 as amended by Council Directive [1999/20/EC](#)⁽⁶⁾);

“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](#)⁽⁹⁾ (with effect from 1st October 1999 as amended by Council Directive [1999/20/EC](#)⁽⁶⁾);

“Directive 98/51” means Commission Directive [98/51/EC](#) laying down certain measures for implementing Council Directive [95/69/EC](#) laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector⁽¹⁰⁾;

“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 checks of the kinds specified in Article 21.1 of Directive 70/524, Articles 3, 4, 7 and 10 to 12, the second paragraph of Article 14, the second and third paragraphs of Article 15.2 and Article 17.1 of Directive 95/53, Article 13 of Directive 95/69, or which are carried out with a view to enforcement of the provisions of Article 6 of Directive 98/51;

“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 99(d);

“third country” means a country other than a member State or the United Kingdom;

“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.

(3) Except in so far as 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,

(5) OJ No. L270, 14.12.70, p. 1 (OJ/SE Vol. 18, p. 4). The next most recent amendment of Directive 70/524 was Directive [98/92/EC](#) (OJ No. L346, 22.22.98, p. 49).

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

(7) OJ No. L213, 21.7.82, p. 8, last amended by Council Directive [96/25/EC](#) (OJ No. L125, 23.5.96, p. 135).

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

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

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

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

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

- (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,
 - (d) the expressions listed in Part II of Schedule 1 have the same meaning as in Directive 95/69,
 - (e) in the expressions “representative established within the United Kingdom” and “representative established within a Member State”, “representative” and “established within” shall have the same meanings as in the expression “representative established within the European Community” in Directive 98/51, and
 - (f) any reference to a European Community Directive is a reference to that Directive as amended as at the date these Regulations are made.
- (4) In these Regulations, any reference to any things done under provisions of these Regulations shall be taken to include things done under corresponding provisions of the 1998 Regulations.

Definition of “establishment” and related definitions

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

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

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

“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 approved third country Article 2.2(a)(A) establishment” means a third country establishment listed on a register of approved establishments, maintained by a competent authority in a member State, in implementation of Article 5 of Directive 95/69 (as read with Directive 98/51), as an establishment as to which an additive, of any kind referred to in Chapter I.1(a) of the Annex, manufactured thereon, may be imported into that member State, and which has a representative established within that member State;

“EC approved third country Article 2.2(a)(P) establishment” means a third country establishment listed on a register of approved establishments, maintained by a competent authority in a member State, in implementation of Article 5 of Directive 95/69 (as read with Directive 98/51), as an establishment as to which a Directive 82/471 product, of any kind referred to in Chapter I.1(a) of the Annex, manufactured thereon, may be imported into that member State, and which has a representative established within that member State;

“EC approved third country Article 2.2(b) establishment” means a third country establishment listed on a register of approved establishments, maintained by a competent authority in a member State, in implementation of Article 5 of Directive 95/69 (as read with Directive 98/51), as an establishment as to which a premixture, which contains additives of any kind referred to in Chapter I.2(a) of the Annex, manufactured thereon, may be imported into that member State, and which has a representative established within that member State;

“EC approved third country Article 2.2(d) establishment” means a third country establishment listed on a register of approved establishments, maintained by a competent authority in a member State, in implementation of Article 5 of Directive 95/69, as an establishment as to which a compound feeding stuff, of any kind the manufacture of which is regulated by Article 2.2(d) of Directive 95/69 (as read with Directive 98/51), manufactured thereon, may be imported into that member State, and which has a representative established within that member State;

“EC permitted Article 2.2(a)(A) establishment” means an establishment located in a member State if—

- (a) 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) before 1st September 1998, an application (which is pending) in respect of the establishment, was 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 an establishment located in a member State if—

- (a) 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) before 1st September 1998, an application (which is pending) in respect of the establishment, was 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 an establishment located in a member State if—

- (a) 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) before 1st September 1998, an application (which is pending) in respect of the establishment, was 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 an establishment located in a member State if—

- (a) 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) before 1st September 1998, a declaration (consideration of which is pending) in respect of the establishment, was 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 an establishment located in a member State if—

- (a) a premixture, which contained additives 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) before 1st September 1998, a declaration (consideration of which is pending) in respect of the establishment, was 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 an establishment located in a member State if—

- (a) 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) before 1st September 1998, a declaration (consideration of which is pending) in respect of the establishment, was 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 an establishment located in a member State if—

- (a) 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) before 1st September 1998, a declaration (consideration of which is pending) in respect of the establishment, was 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 permitted third country Article 2.2(a)(A) establishment” means—

- (a) before the applicable day, a third country establishment (other than an EC approved third country Article 2.2(a)(A) 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 31st December 1998, and the establishment has, at all times since that date, had a representative established within a member State, and

- (b) on and after the applicable day, a third country establishment if—
 - (i) 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 31st December 1998 and, at all times since that date, the establishment has had a representative as aforesaid, and
 - (ii) before the applicable day, a declaration (consideration of which is pending) in respect of the establishment, has been submitted to a competent authority in the member State, in accordance with any requirements in the member State for the submission of such declarations pursuant to Article 6.3 of Directive 98/51, with a view to registration of the establishment, pursuant to that Directive, as an establishment as to which an additive of any such kind, manufactured thereon, may be imported into that member State;

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

- (a) before the applicable day, a third country establishment (other than an EC approved third country Article 2.2(a)(P) 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 31st December 1998, and the establishment has, at all times since that date, had a representative established within a member State; and
- (b) on and after the applicable day, a third country establishment if—
 - (i) a 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 31st December 1998 and, at all times since that date, the establishment has had a representative as aforesaid, and
 - (ii) before the applicable day, a declaration (consideration of which is pending) in respect of the establishment, has been submitted to a competent authority in the member State, in accordance with any requirements in the member State for the submission of such declarations pursuant to Article 6.3 of Directive 98/51, with a view to registration of the establishment, pursuant to that Directive, as an establishment as to which a Directive 82/471 product of any such kind, manufactured thereon, may be imported into that member State;

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

- (a) before the applicable day, a third country establishment (other than an EC approved third country Article 2.2(b) 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 31st December 1998, and the establishment has, at all times since that date, had a representative established within a member State, and
- (b) on and after the applicable day, a third country establishment if—
 - (i) a 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 31st December 1998 and, at all times since that date, the establishment has had a representative as aforesaid, and
 - (ii) before the applicable day, a declaration (consideration of which is pending) in respect of the establishment, has been submitted to a competent authority in the member State, in accordance with any requirements in the member State for the submission of such declarations pursuant to Article 6.3 of Directive 98/51, with a view to registration of the establishment, pursuant to that Directive, as an

establishment as to which a premixture of that kind, manufactured thereon, may be imported into that member State;

“EC permitted third country Article 2.2(d) establishment” means—

- (a) before the applicable day, a third country establishment (other than an EC approved third country Article 2.2(d) 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 31st December 1998, and the establishment has, at all times since that date, had a representative established within a member State, and
- (b) on and after the applicable day, a third country establishment if—
 - (i) a 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 31st December 1998 and, at all times since that date, the establishment has had a representative as aforesaid, and
 - (ii) before the applicable day, a declaration (consideration of which is pending) in respect of the establishment, has been submitted to a competent authority in the member State, in accordance with any requirements in the member State for the submission of such declarations pursuant to Article 6.3 of Directive 98/51, with a view to registration of the establishment, pursuant to that Directive, as an establishment as to which a compound feeding stuff of any such kind, manufactured thereon, may be imported into that member State;

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

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

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

- (a) before the applicable day, a third country establishment (other than an EC registered third country Article 7.2(b) establishment) if a premixture, which contained additives 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 1.2(a) of the Annex, was being manufactured on the establishment, with a view to putting it into circulation, on 31st December 1998, and the establishment has, at all times since that date, had a representative established within a member State, and

- (b) on and after the applicable day, a third country establishment if—
 - (i) a 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 31st December 1998 and, at all times since that date, the establishment has had a representative as aforesaid, and
 - (ii) before the applicable day, a declaration (consideration of which is pending) in respect of the establishment, has been submitted to a competent authority in the member State, in accordance with any requirements in the member State for the submission of such declarations pursuant to Article 6.3 of Directive 98/51, with a view to registration of the establishment, pursuant to that Directive, as an establishment as to which a premixture of that kind, manufactured thereon, may be imported into that member State;

“EC permitted third country Article 7.2(c)(A) establishment” means—

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

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

- (a) before the applicable day, a third country establishment (other than an EC registered third country 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 31st December 1998, and the establishment has, at all times since that date, had a representative established within a member State, and
- (b) on and after the applicable day, a third country establishment if—
 - (i) a 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 31st December 1998 and, at all times since that date, the establishment has had a representative as aforesaid, and
 - (ii) before the applicable day, a declaration (consideration of which is pending) in respect of the establishment, has been submitted to a competent authority in the member State, in accordance with any requirements in the member State for

the submission of such declarations pursuant to Article 6.3 of Directive 98/51, with a view to registration of the establishment, pursuant to that Directive, as an establishment as to which a compound feeding stuff of that kind, manufactured thereon, may be imported into that member State;

“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 (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;

“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;

“EC registered third country Article 7.2(a) establishment” means a third country 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 read with Directive 98/51), as an establishment as to which an additive, of any kind the manufacture of which is regulated by Article 7.2(a) of Directive 95/69, manufactured thereon, may be imported into that member State, and which has a representative established within that member State;

“EC registered third country Article 7.2(b) establishment” means a third country 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 read with Directive 98/51), as an establishment as to which a premixture (which contains additives 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 1.2(a) of the Annex) manufactured thereon, may be imported into that member State, and which has a representative established within that member State;

“EC registered third country Article 7.2(c)(A) establishment” means a third country 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 read with Directive 98/51), as an establishment as to 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 1.2(a) of the Annex) manufactured thereon, may be imported into that member State, and which has a representative established within that member State;

“EC registered third country Article 7.2(c)(PA) establishment” means a third country 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 read with Directive 98/51), as an establishment as to 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) manufactured thereon, may be imported into that member State, and which has a representative established within that member State;

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

“UK approved Article 2.2(a)(A) establishment” means an establishment approved, pursuant to regulation 6 or, as the case may be, 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, as the case may be, 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, as the case may be, 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, as the case may be, 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, as the case may be, 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 approved third country Article 2.2(a)(A) establishment” means a third country establishment approved pursuant to regulation 34(1)(a), or, as the case may be, 35(3), as an establishment as to which an additive, of any kind referred to in the fourth to the ninth indents of Chapter I.1(a) of the Annex, manufactured thereon, may be imported into the United Kingdom, and which has a representative established within the United Kingdom;

“UK approved third country Article 2.2(a)(P) establishment” means a third country establishment approved pursuant to regulation 34(1)(a), or, as the case may be, 35(3), as an establishment as to which a Directive 82/471 product, of any kind referred to in Chapter 1.1(a) of the Annex, manufactured thereon, may be imported into the United Kingdom, and which has a representative established within the United Kingdom;

“UK approved third country Article 2.2(b) establishment” means a third country establishment approved pursuant to regulation 34(1)(a), or, as the case may be, 35(3), as an establishment as to which a premixture (containing additives of any kind referred to in the fourth or fifth indent of Chapter 1.2(a) of the Annex but not containing a zootechnical additive) manufactured thereon, may be imported into the United Kingdom, and which has a representative established within the United Kingdom;

“UK approved third country Article 2.2(d) establishment” means a third country establishment approved pursuant to regulation 34(1)(a), or, as the case may be, 35(3), as an establishment as to which a compound feeding stuff, of any kind the manufacture of which is regulated by Article

2.2(d) of Directive 95/69, manufactured thereon, may be imported into the United Kingdom, and which has a representative established within the United Kingdom;

“UK permitted Article 2.2(a)(A) establishment” means an establishment located in the United Kingdom if—

- (a) 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) 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), was submitted in respect of the establishment;

“UK permitted Article 2.2(a)(P) establishment” means an establishment located in the United Kingdom if—

- (a) 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) 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), was submitted in respect of the establishment;

“UK permitted Article 2.2(b) establishment” means an establishment located in the United Kingdom if—

- (a) a premixture, which contained additives of any kind referred to in Chapter 1.2(a) of the Annex, was being manufactured on the establishment, with a view to putting it into circulation, on 1st April 1998, and
- (b) 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), was submitted in respect of the establishment;

“UK permitted Article 2.2(d) establishment” means an establishment located in the United Kingdom 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 1st April 1998, and either—

- (a) 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), was submitted in respect of the establishment, or
- (b) in any case where, on 1st April 1998, a compound feedingstuff intended for animals living freely in the wild was being manufactured on the establishment, before 1st October 1999, an application under regulation 5(1)(d), or a corresponding application under regulation 7(1) (which in either case is pending) relating to such manufacture, made in accordance with regulation 5(2), or, as the case may be, 7(2), is submitted in respect of the establishment, accompanied by a declaration that, had the 1998 Regulations provided for such an application, there would have been no reason to prevent one being made before 1st September 1998;

“UK permitted Article 2.2(f) establishment” means an establishment located in the United Kingdom if—

- (a) 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) 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), was submitted in respect of the establishment;

“UK permitted Article 7.2(a) establishment” means an establishment located in the United Kingdom if—

- (a) 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) 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), was submitted in respect of the establishment;

“UK permitted Article 7.2(b) establishment” means an establishment located in the United Kingdom if—

- (a) a premixture, which contained additives 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) 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), was submitted in respect of the establishment;

“UK permitted Article 7.2(c)(A) establishment” means an establishment located in the United Kingdom if—

- (a) 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) 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), was submitted in respect of the establishment;

“UK permitted Article 7.2(c)(PA) establishment” means an establishment located in the United Kingdom if—

- (a) 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) 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), was submitted in respect of the establishment;

“UK permitted Article 7.2(d)(A) establishment” means an establishment located in the United Kingdom if—

- (a) 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) 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), was submitted in respect of the establishment;

“UK permitted Article 7.2(d)(PA) establishment” means an establishment located in the United Kingdom if—

- (a) 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) 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), was submitted in respect of the establishment;

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

- (a) before 1st October 1999, a third country establishment (other than a UK approved third country Article 2.2(a)(A) 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 31st December 1998, and the establishment has, at all times since that date, had a representative established within the United Kingdom, and
- (b) on and after 1st October 1999, a third country establishment if—
 - (i) 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 31st December 1998 and, at all times since that date, the establishment has had a representative as aforesaid, and
 - (ii) before 1st October 1999, a declaration under (or required to be treated as under) regulation 33(1)(a), or a corresponding declaration under (or required to be treated as under) regulation 35(1), (consideration of which in either case is pending), made in compliance with (or required to be treated as made in compliance with) regulation 33(2), or, as the case may be, 35(2), and not containing a negative reply to a question specified in regulation 33(2)(g) or, as the case may be, 35(2)(g), has been submitted in respect of the establishment;

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

- (a) before 1st October 1999, a third country establishment (other than a UK approved third country Article 2.2(a)(P) 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 31st December 1998, and the establishment has, at all times since that date, had a representative established within the United Kingdom, and
- (b) on and after 1st October 1999, a third country establishment if—

- (i) a 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 31st December 1998 and, at all times since that date, the establishment has had a representative as aforesaid, and
- (ii) before 1st October 1999, a declaration under (or required to be treated as under) regulation 33(1)(b), or a corresponding declaration under (or required to be treated as under) regulation 35(1), (consideration of which in either case is pending), made in compliance with (or required to be treated as made in compliance with) regulation 33(2), or, as the case may be, 35(2), and not containing a negative reply to a question specified in regulation 33(2)(g) or, as the case may be, 35(2)(g), has been submitted in respect of the establishment;

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

- (a) before 1st October 1999, a third country establishment (other than a UK approved third country Article 2.2(b) 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 31st December 1998, and the establishment has, at all times since that date, had a representative established within the United Kingdom, and
- (b) on and after 1st October 1999, a third country establishment if—
 - (i) a 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 31st December 1998 and, at all times since that date, the establishment has had a representative as aforesaid, and
 - (ii) before 1st October 1999, a declaration under (or required to be treated as under) regulation 33(1)(c), or a corresponding declaration under (or required to be treated as under) regulation 35(1), (consideration of which in either case is pending), made in compliance with (or required to be treated as made in compliance with) regulation 33(2), or, as the case may be, 35(2), and not containing a negative reply to a question specified in regulation 33(2)(g) or, as the case may be, 35(2)(g), has been submitted in respect of the establishment;

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

- (a) before 1st October 1999, a third country establishment (other than a UK approved third country Article 2.2(d) 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 31st December 1998, and the establishment has, at all times since that date, had a representative established within the United Kingdom, and
- (b) on and after 1st October 1999, a third country establishment if—
 - (i) a 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 31st December 1998 and, at all times since that date, the establishment has had a representative as aforesaid, and
 - (ii) before 1st October 1999, a declaration under (or required to be treated as under) regulation 33(1)(d), or a corresponding declaration under (or required to be treated as under) regulation 35(1), (consideration of which in either case is pending), made in compliance with (or required to be treated as made in compliance with) regulation 33(2), or, as the case may be, 35(2), and not containing a negative reply to a question specified in regulation 33(2)(g) or, as the case may be, 35(2)(g), has been submitted in respect of the establishment;

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

- (a) before 1st October 1999, a third country establishment (other than a UK registered third country 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 31st December 1998, and the establishment has, at all times since that date, had a representative within the United Kingdom, and
- (b) on and after 1st October 1999, a third country establishment 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 31st December 1998 and, at all times since that date, the establishment has had a representative as aforesaid, and
 - (ii) before 1st October 1999, a declaration under (or required to be treated as under) regulation 33(1)(e), or a corresponding declaration under (or required to be treated as under) regulation 35(1), (consideration of which in either case is pending), made in compliance with (or required to be treated as made in compliance with) regulation 33(2), or, as the case may be, 35(2), and not containing a negative reply to a question specified in regulation 33(2)(g) or, as the case may be, 35(2)(g), has been submitted in respect of the establishment;

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

- (a) before 1st October 1999, a third country establishment (other than a UK registered third country Article 7.2(b) establishment) if a premixture, which contained additives 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 31st December 1998, and the establishment has, at all times since that date, had a representative established within the United Kingdom, and
- (b) on and after 1st October 1999, a third country establishment if—
 - (i) a 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 31st December 1998 and, at all times since that date, the establishment has had a representative as aforesaid, and
 - (ii) before 1st October 1999, a declaration under (or required to be treated as under) regulation 33(1)(f), or a corresponding declaration under (or required to be treated as under) regulation 35(1), (consideration of which in either case is pending), made in compliance with (or required to be treated as made in compliance with) regulation 33(2), or, as the case may be, 35(2), and not containing a negative reply to a question specified in regulation 33(2)(g) or, as the case may be, 35(2)(g), has been submitted in respect of the establishment;

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

- (a) before 1st October 1999, a third country establishment (other than a UK registered third country 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 31st December 1998, and the establishment has, at all times since that date, had a representative established within the United Kingdom, and
- (b) on and after 1st October 1999, a third country establishment if—

- (i) a 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 31st December 1998 and, at all times since that date, the establishment has had a representative as aforesaid, and
- (ii) before 1st October 1999, a declaration under (or required to be treated as under) regulation 33(1)(h), or a corresponding declaration under (or required to be treated as under) regulation 35(1), (consideration of which in either case is pending), made in compliance with (or required to be treated as made in compliance with) regulation 33(2), or, as the case may be, 35(2), and not containing a negative reply to a question specified in regulation 33(2)(g) or, as the case may be, 35(2)(g), has been submitted in respect of the establishment;

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

- (a) before 1st October 1999, a third country establishment (other than a UK registered third country 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 zotechnical additive, was manufactured on the establishment, with a view to putting it into circulation, on 31st December 1998, and the establishment has, at all times since that date, had a representative established within the United Kingdom, and
- (b) on and after 1st October 1999, a third country establishment if—
 - (i) a 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 31st December 1998 and, at all times since that date, the establishment has had a representative as aforesaid, and
 - (ii) before 1st October 1999, a declaration under (or required to be treated as under) regulation 33(1)(g), or a corresponding declaration under (or required to be treated as under) regulation 35(1), (consideration of which in either case is pending), made in compliance with (or required to be treated as made in compliance with) regulation 33(2), or, as the case may be, 35(2), and not containing a negative reply to a question specified in regulation 33(2)(g) or, as the case may be, 35(2)(g), has been submitted in respect of the establishment;

“UK registered Article 7.2(a) establishment” means an establishment registered, pursuant to regulation 20, or, as the case may be, 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, as the case may be, 21, as an establishment on which a premixture, which contains additives 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)(A) establishment” means an establishment registered, pursuant to regulation 20 or, as the case may be, 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, as the case may be, 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, as the case may be, 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, as the case may be, 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;

“UK registered third country Article 7.2(a) establishment” means a third country establishment registered pursuant to regulation 34(1)(b), or, as the case may be, 35(3), as an establishment as to which an additive, of any kind the manufacture of which is regulated by Article 7.2(a) of Directive 95/69, manufactured thereon, may be imported into the United Kingdom, and which has a representative established within the United Kingdom;

“UK registered third country Article 7.2(b) establishment” means a third country establishment registered pursuant to regulation 34(1)(b), or, as the case may be, 35(3), as an establishment as to which a premixture (containing additives 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 1.2(a) of the Annex) manufactured thereon, may be imported into the United Kingdom, and which has a representative established within the United Kingdom;

“UK registered third country Article 7.2(c)(A) establishment” means a third country establishment registered pursuant to regulation 34(1)(b), or, as the case may be, 35(3), as an establishment as to 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 1.2(a) of the Annex) manufactured thereon, may be imported into the United Kingdom, and which has a representative established within the United Kingdom;

“UK registered third country Article 7.2(c)(PA) establishment” means a third country establishment registered pursuant to regulation 34(1)(b), or, as the case may be, 35(3), as an establishment as to 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, manufactured thereon, may be imported into the United Kingdom, and which has a representative established within the United Kingdom;

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 an intermediary whose facilities are located in a member State, who—

- (a) 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) before 1st September 1998 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 an intermediary whose facilities are located in a member State, who—

- (a) 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) before 1st September 1998 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 product of any such kind;

“EC permitted Article 3.1(PA) intermediary” means an intermediary whose facilities are located in a member State, who—

- (a) 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) before 1st September 1998 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 an intermediary whose facilities are located in a member State, who—

- (a) 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) before 1st September 1998 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;

“EC permitted Article 8.1(PA) intermediary” means an intermediary whose facilities are located in a member State, who—

- (a) on 1st April 1998 was wrapping, packaging, storing or putting into circulation a premixture which contained additives 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; and
- (b) before 1st September 1998 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 (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;

“UK approved Article 3.1(A) intermediary” means an intermediary approved, pursuant to regulation 13 or, as the case may be, 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, as the case may be, 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, as the case may be, 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 an intermediary whose facilities are located in the United Kingdom, who—

- (a) 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) before 1st September 1998, submitted 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 an intermediary whose facilities are located in the United Kingdom, who—

- (a) 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) before 1st September 1998, submitted 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 an intermediary whose facilities are located in the United Kingdom, who—

- (a) 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) before 1st September 1998, submitted 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 an intermediary whose facilities are located in the United Kingdom, who—

- (a) 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) before 1st September 1998, submitted 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 an intermediary whose facilities are located in the United Kingdom, who—

- (a) on 1st April 1998, was wrapping, packaging, storing or putting into circulation a premixture, which contained additives 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; and
- (b) before 1st September 1998, submitted 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, as the case may be, 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, as the case may be, 28, as an intermediary who may wrap, package, store and put into circulation a premixture which contains additives 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.

PART II

APPROVAL OF ESTABLISHMENTS LOCATED IN THE UNITED KINGDOM

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 or, where the establishment in respect of which the application is made is situated wholly or partly in Wales, in either that language or the Welsh language,
 - (c) be signed by or on behalf of the applicant,
 - (d) contain the name (or business name) and address of the applicant,
 - (e) identify the establishment in respect of which the application is made, and
 - (f) identify the establishment activity which the applicant is exercising or, as the case may be, intends to exercise, on that establishment.

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, as read with Articles 8 and 9 of, and the Annex to, Directive 98/51, 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 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 or, where the establishment in respect of which the application is made is situated wholly or partly in Wales, in either that language or the Welsh language,
- (c) be signed by or on behalf of the applicant,
- (d) contain the name (or business 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, and
 - (g) 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 41, 58, 75, 83 or 85, 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 41, 58, 75, 83 or 85, 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 or, where the facilities in respect of which the application is made are situated wholly or partly in Wales, in either that language or the Welsh language,
- (c) be signed by or on behalf of the applicant,
- (d) contain the name (or business 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, and
- (f) identify the facilities in respect of which the application is made.

(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, as read with Articles 8 and 9 of, and the Annex to, Directive 98/51, 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 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 or, where the facilities in respect of which the application is made are situated wholly or partly in Wales, in either that language or the Welsh language,
- (c) be signed by or on behalf of the applicant,
- (d) contain the name (or business 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, and
- (g) 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 95/96, 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 45, 49, 62, 66, 77 or 79, 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 45, 49, 62, 66, 77 or 79, 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 LOCATED IN THE UNITED KINGDOM

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 (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;
- (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 or, where the establishment to which the declaration relates is situated wholly or partly in Wales, in either that language or the Welsh language,
- (c) be signed by or on behalf of the person submitting the declaration,
- (d) contain the name (or business name) and address of that person,
- (e) identify the establishment to which the declaration relates,
- (f) identify the establishment activity which the person submitting the declaration is exercising or, as the case may be, intends to exercise, on that establishment, and

(g) 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)(g), 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 1999⁽¹¹⁾ 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, as read with Articles 8 and 9 of, and the Annex to, Directive 98/51, 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 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 or, where the establishment to which the declaration relates is situated wholly or partly in Wales, in either that language or the Welsh language,
- (c) be signed by or on behalf of the person submitting the declaration,
- (d) contain the name (or business name) and address of that person,
- (e) identify the establishment to which the declaration relates,
- (f) identify the new establishment activity which the person submitting the declaration is exercising or, as the case may be, intends to exercise, on that establishment,
- (g) state under which sub-paragraph of paragraph (1) the declaration is submitted, and
- (h) contain a statement that the establishment complies, and an undertaking that when the new establishment activity is exercised on it it will comply, with the applicable conditions.

(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) Regulations 1999 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.

(11) [S.I. 1999/1871](#).

(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 43, 60, 87, 89, 91 or 93, 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 43, 60, 87, 89, 91 or 93, 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 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 (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.

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

- (a) be in writing,
- (b) be in the English language or, where the facilities in respect of which the declaration is submitted are situated wholly or partly in Wales, in either that language or the Welsh language,
- (c) be signed by or on behalf of the person submitting the declaration,
- (d) contain the name (or business name) and address of that person,
- (e) identify the 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, and
- (g) 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)(g), 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 1999 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, as read with Articles 8 and 9 of, and the Annex to, Directive 98/51, 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 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 or, where the facilities in respect of which the declaration is made are situated wholly or partly in Wales, in either that language or the Welsh language,
 - (c) be signed by or on behalf of the person submitting the declaration,
 - (d) contain the name (or business name) and address of that person,
 - (e) identify the 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) state under which sub-paragraph of paragraph (1) the declaration is submitted, and
 - (h) 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)(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 1999 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 47, 51, 64 or 68, 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 47, 51, 64 or 68, 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

APPROVAL OR REGISTRATION OF ESTABLISHMENTS LOCATED IN THIRD COUNTRIES

Declarations leading to the approval or registration of establishments located in third countries

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

- (a) the manufacture of 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;
 - (e) 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;
 - (f) the manufacture of a premixture, containing additives 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;
 - (g) 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; or
 - (h) 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.
- (2) A declaration submitted under paragraph (1) shall—
- (a) be in writing,
 - (b) be in the English language,
 - (c) be signed by or on behalf of the person submitting the declaration,
 - (d) contain the name (or business name) and address of that person,
 - (e) identify the establishment to which the declaration relates,

- (f) identify the establishment activity which is being exercised or, as the case may be, it is intended to exercise, on that establishment,
- (g) if made by 30th September 1999, state—
 - (i) whether the establishment activity was being exercised on the establishment on 31st December 1998, and
 - (ii) if so, whether an eligible person would have been in a position to submit a declaration equivalent to one under paragraph (1) in relation to the establishment activity, at a date after 30th December 1998 but before 1st May 1999, had paragraph (1) been in force at that date;
- (h) contain a statement that the establishment complies, and an undertaking that when the establishment activity is exercised on it it will comply, with the applicable conditions, and
- (i) contain an undertaking of the kind described in the second indent of Article 6.2 of Directive 98/51.

Approval or registration of establishments located in third countries

34.—(1) Where a declaration complying with regulation 33(2) is submitted under paragraph (1) of that regulation, the Minister shall—

- (a) where the declaration is submitted under sub-paragraph (a), (b), (c) or (d) of that paragraph—
 - (i) approve the establishment as an establishment as to which any product manufactured thereon, in the course of carrying out the establishment activity to which the sub-paragraph concerned relates, may be imported into the United Kingdom, and
 - (ii) in accordance with Article 5.1 of Directive 95/69, as read with Articles 8 and 9 of, and the Annex to, Directive 98/51, enter the establishment on a register, which the Minister shall maintain, under an individual approval number which identifies the establishment, as an establishment approved in relation to the establishment activity concerned, and
- (b) where the declaration is submitted under sub-paragraph (e), (f), (g) or (h) of that paragraph—
 - (i) register the establishment as an establishment as to which any product manufactured thereon, in the course of carrying out the establishment activity to which the sub-paragraph concerned relates, may be imported into the United Kingdom, and
 - (ii) in accordance with Article 10.1 of Directive 95/69, as read with Articles 8 and 9 of, and the Annex to, Directive 98/51, enter the establishment on a list, which the Minister shall maintain, under an individual registration number which identifies the establishment, as an establishment approved in relation to the establishment activity concerned.

(2) The Minister shall, for the purposes of paragraph (1) treat, a declaration submitted in anticipation of regulation 33(1) as submitted thereunder and complying with regulation 33(2) if the declaration either—

- (a) complies with all the requirements set out in regulation 33(2), or
- (b) if made after 30th December 1998 but before 1st May 1999, complies with all those requirements other than the requirement set out in regulation 33(2)(g)(ii).

Amendment of approvals or registrations

35.—(1) An eligible person may submit to the Minister a declaration relating to an approved or, as the case may be, registered, third country establishment on which it is intended to exercise an establishment activity (“the new establishment activity”)—

(a) in addition to an establishment activity for the exercise of which the establishment is already approved or, as the case may be, 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 (or business name) and address of that person,

(e) identify the establishment to which the declaration relates,

(f) identify the new establishment activity which is being exercised or, as the case may be, it is intended to exercise, on that establishment,

(g) if made by 30th September 1999, state—

(i) whether the new establishment activity was being exercised on the establishment on 31st December 1998, and

(ii) if so, whether an eligible person would have been in a position to submit a declaration equivalent to one under paragraph (1) in relation to the new establishment activity, at a date after 30th December 1998 but before 1st May 1999, had paragraph (1) been in force at that date;

(h) state under which sub-paragraph of paragraph (1) the declaration is submitted,

(i) contain a statement that the establishment complies, and an undertaking that when the new establishment activity is exercised on it it will comply, with the applicable conditions; and

(j) contain an undertaking of the kind prescribed in the second indent of Article 6.2 of Directive 98/51.

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

(4) Where, pursuant to paragraph (3), the Minister approves or, as the case may be, registers an establishment, he shall amend the register or, as the case may be, list, maintained by him under regulation 34(1)(a) or, as the case may be, (b), to show all the establishment activities in relation to which the establishment is approved or, as the case may be, registered, under regulation 34(1)(a) or, as the case may be, (b), under paragraph (3).

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

(a) complies with all the requirements set out in paragraph (2), or

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

Cancellation of approvals or registrations

36.—(1) The Minister shall cancel an approval or, as the case may be, registration, relating to the exercise of an establishment activity on an approved or, as the case may be, registered, third country establishment if, as a result of official checks, or an on-the spot inspection carried out pursuant to Article 5.1 of Directive 98/51, and after following the procedure in regulation 37, he is not satisfied that the person exercising on the establishment the activity concerned (“the manufacturer”), is fulfilling, in relation to that activity, the essential conditions or that the representative of that establishment established within the United Kingdom is fulfilling the essential representative conditions.

(2) Where, pursuant to paragraph (1), the Minister cancels an approval or, as the case may be, a registration, he shall amend the register or, as the case may be, list, maintained by him under regulation 34(1)(a) or, as the case may be, (b), by deleting from it the entry in respect of the establishment activity in relation to which approval or, as the case may be, registration, has been cancelled.

Procedure relating to the cancellation of approvals or registrations

37.—(1) Where, in the circumstances described in regulation 36(1), the Minister proposes to cancel an approval or, as the case may be, registration, relating to the exercise of an establishment activity on an approved or, as the case may be, registered, third country establishment, he shall not cancel it unless—

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

Obligation of competent bodies to supply certain information to the Minister of Agriculture, Fisheries and Food

38. Where any competent body comes into possession of information which it considers will assist the Minister to exercise his functions under regulations 36 and 37, it shall as soon as practicable provide that information to him in writing.

Interpretation of Part VI

39. In this Part—

“the applicable Chapter” means—

- (a) in the case of a declaration made pursuant to regulation 33(1)(a) or 33(1)(b), Chapter I.1(b) of the Annex;
- (b) in the case of a declaration made pursuant to regulation 33(1)(c), Chapter I.2(b) of the Annex;
- (c) in the case of a declaration made pursuant to regulation 33(1)(d), Chapter I.4 of the Annex; and
- (d) in the case of a declaration made pursuant to regulation 33(1)(e), (f), (g) or (h), Chapter II(c) of the Annex;

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

“approved third country establishment” means a third country establishment approved by the Minister pursuant to regulation 34(1)(a) or, as the case may be, 35(3);

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

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

“essential representative conditions”, in relation to a representative established within the United Kingdom of a third country establishment, has the same meaning as the expression “essential condition applicable to their activities” in Article 6(4)(b) of Directive 98/51 has in relation to him;

“establishment activity” means an activity specified in sub-paragraph (a), (b), (c), (d), (e), (f), (g) or (h) of regulation 33(1); and

“registered third country establishment” means a third country establishment registered by the Minister pursuant to regulation 34(1)(b) or, as the case may be, 35(3).

PART VII

CONTROL OF ADDITIVES

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

40. 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 40 applies

41. No person shall manufacture an additive of any kind to which regulation 40 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

42. 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 42 applies

43. No person shall manufacture an additive of any kind to which regulation 42 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

44. 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 44 applies

45. No UK approved Article 3.1(A) intermediary shall wrap, package or store an additive of any kind to which regulation 44 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

46. 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 46 applies

47. No UK registered Article 8.1(A) intermediary shall wrap, package or store an additive of any kind to which regulation 46 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 44 applies

48. No intermediary shall put into circulation an additive of any kind to which regulation 44 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 44 applies

49. No EC or UK approved Article 3.1(A) intermediary shall put into circulation an additive of any kind to which regulation 44 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 46 applies

50. No intermediary shall put into circulation an additive of any kind to which regulation 46 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 46 applies

51. No EC or UK registered Article 8.1(A) intermediary shall put into circulation an additive of any kind to which regulation 46 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

52.—(1) No person shall 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, 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, a UK approved or permitted third country Article 2.2(a)(A) establishment or an EC approved or permitted third country Article 2.2(a)(A) establishment.

(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, a UK registered or permitted third country Article 7.2(a) establishment or an EC registered or permitted third country Article 7.2(a) establishment.

Supply of certain additives

53.—(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,
 - (iii) a UK approved or permitted third country Article 2.2(a)(A) establishment, or
 - (iv) an EC approved or permitted third country Article 2.2(a)(A) establishment; and
- (b) the additive concerned—
 - (i) is supplied to—

-
- (A) a UK approved or permitted Article 2.2(b) establishment,
 - (B) a UK approved Chapter I.2 establishment, as defined in regulation 3 of the

- Feedingstuffs (Zootechnical Products) Regulations 1999(12),
- (C) a UK permitted Chapter I.2 establishment, as defined as aforesaid,
 - (D) an EC approved or permitted Article 2.2(b) establishment,
 - (E) a UK approved or permitted Article 3.1(A) intermediary,
 - (F) an EC approved or permitted Article 3.1(A) intermediary,
 - (G) a UK registered or permitted Article 7.2(c)(PA) establishment, engaged in the manufacture of compound feeding stuffs for pet animals,
 - (H) an EC registered or permitted Article 7.2(c) (PA) establishment, engaged as aforesaid,
 - (I) a UK registered or permitted Article 7.2(d) (PA) establishment, engaged as aforesaid, or
 - (J) 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

54. 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 a UK or EC approved or permitted Article 2.2(b) establishment, a UK approved or permitted third country Article 2.2(b) establishment or an EC approved or permitted third country Article 2.2(b) establishment, and he incorporates the premixture in accordance with regulation 71,
- (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—
 - (i) a UK approved Chapter I.2 establishment, as defined in regulation 3 of the Feedingstuffs (Zootechnical Products) Regulations 1999,
 - (ii) a UK permitted Chapter I.2 establishment as defined as aforesaid,

- (iii) an EC approved or permitted Article 2.2(b) establishment,
 - (iv) a UK approved or permitted third country Chapter I.2 establishment, as defined as aforesaid,
 - (v) an EC approved or permitted third country Article 2.2(b) establishment;
- and he incorporates the premixture in accordance with regulation 59 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.

Importation of certain additives referred to in Article 2.2(a) of Directive 95/69

55. No person shall import into the United Kingdom from a third country, an additive of any kind referred to in the fourth to the ninth indents of Chapter I.1(a) of the Annex, manufactured in a third country, unless the additive was manufactured on a UK approved or permitted third country Article 2.2(a)(A) establishment, or an EC approved or permitted third country Article 2.2(a)(A) establishment.

Importation of additives referred to in Article 7.2(a) of Directive 95/69

56. No person shall import into the United Kingdom from a third country, an additive of any kind the manufacture of which is regulated by Article 7.2(a) of Directive 95/69, manufactured in a third country, unless the additive was manufactured on a UK registered or permitted third country Article 7.2(a) establishment, or an EC registered or permitted third country Article 7.2(a) establishment.

PART VIII

CONTROL OF PREMIXTURES

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

57. 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 57 applies

58. No person shall manufacture a premixture of the kind to which regulation 57 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

59. No person shall manufacture a premixture, which contains additives 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, 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 59 applies

60. No person shall manufacture a premixture of the kind to which regulation 59 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

61. 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 61 applies

62. No UK approved Article 3.1(PA) intermediary shall wrap, package or store a premixture of the kind to which regulation 61 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

63. No intermediary shall wrap, package or store a premixture which contains additives 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, 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 63 applies

64. No UK registered Article 8.1(PA) intermediary shall wrap, package or store a premixture of the kind to which regulation 63 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 61 applies

65. No intermediary shall put into circulation a premixture of the kind to which regulation 61 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 61 applies

66. No EC or UK approved Article 3.1(PA) intermediary shall put into circulation a premixture of the kind to which regulation 61 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 63 applies

67. No intermediary shall put into circulation a premixture of the kind to which regulation 63 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 63 applies

68. No EC or UK registered Article 8.1(PA) intermediary shall put into circulation a premixture of the kind to which regulation 63 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

69.—(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, a UK approved or permitted third country Article 2.2(b) establishment or an EC approved or permitted third country Article 2.2(b) establishment.

(2) No person shall put into circulation a premixture which contains additives 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, 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, a UK registered or permitted third country Article 7.2(b) establishment or an EC registered or permitted third country Article 7.2(b) establishment.

Supply of certain premixtures

70.—(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,
- (c) a UK approved or permitted third country Article 2.2(b) establishment, or
- (d) an EC approved or permitted third country Article 2.2(b) establishment.

(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

71.—(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 which prejudice to regulations 86 and 87, 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 additives of any kind referred to in Chapter 1.2(a) of the Annex, was being manufactured in a proportion of less than 0.2% by weight of the feeding stuff, and
 - (ii) as to which—
 - (aa) before 1st September 1998, a request, (consideration of which is pending) was made to the competent body to satisfy itself that those conditions are met, or
 - (bb) in any case where the additives which the premixture contained included a zootechnical additive, before 1st October 1999 a request (consideration of which is pending) has been made to the competent body to satisfy itself that those conditions are met, accompanied by a declaration that, had the 1998 Regulations provided for such a request, there would have been no reason to prevent one being made before 1st September 1998.

Importation of certain premixtures referred to in Article 2.2(b) of Directive 95/69

72. No person shall import into the United Kingdom from a third country, a premixture which contains additives of any kind referred to in the fourth or fifth indents of Chapter I.2(a) of the Annex, manufactured in a third country, but does not contain a zootechnical additive, unless the premixture was manufactured on a UK approved or permitted third country Article 2.2(b) establishment, or an EC approved or permitted third country Article 2.2(b) establishment.

Importation of premixtures referred to in Article 7.2(b) of Directive 95/69

72. No person shall import into the United Kingdom from a third country, a premixture which contains additives 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 1.2(a) of the Annex, manufactured in a third country, unless the premixture was manufactured on a UK registered or permitted third country Article 7.2(b) establishment, or an EC registered or permitted third country Article 7.2(b) establishment.

PART IX

CONTROL OF DIRECTIVE 82/471 PRODUCTS

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

74. 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 74 applies

75. No person shall manufacture a Directive 82/471 product of any kind to which regulation 74 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

76. 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 76 applies

77. No UK approved Article 3.1(P) intermediary shall wrap, package or store a Directive 82/471 product of any kind to which regulation 76 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 76 applies

78. No intermediary shall put into circulation a Directive 82/471 product of any kind to which regulation 76 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 76 applies

79. 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 76 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

80. 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,
- (c) a UK approved or permitted third country Article 2.2(a)(P) establishment, or
- (d) an EC approved or permitted third country Article 2.2(a)(P) establishment.

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

81. No person shall import into the United Kingdom from a third country, a Directive 82/471 product of any kind referred to in Chapter I.1(a) of the Annex, manufactured in a third country, unless it was manufactured on a UK approved or permitted third country Article 2.2(a)(P) establishment, or an EC approved or permitted third country Article 2.2(a)(P) establishment.

PART X

CONTROL OF COMPOUND FEEDING STUFFS

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

82. 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 82 applies

83. No person shall manufacture a compound feeding stuff of any kind to which regulation 82 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

84. 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 84 applies

85. No person shall produce, for the exclusive requirements of his holding, a compound feeding stuff of any kind to which regulation 84 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

86. 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 86 applies

87. No person shall manufacture a compound feeding stuff of the kind to which regulation 86 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

88. 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 88 applies

89. No person shall produce, for the exclusive requirements of his holding, a compound feeding stuff of the kind to which regulation 88 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

90. 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 90 applies

91. No person shall manufacture a compound feeding stuff of the kind to which regulation 90 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

92. 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 92 applies

93. No person shall produce, for the exclusive requirements of his holding, a compound feeding stuff of the kind to which regulation 92 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.

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

94. No person shall import into the United Kingdom from a third country, a compound feeding stuff of any kind the manufacture of which is regulated by Article 2.2(d) of Directive 95/69, manufactured in a third country, unless it was manufactured on a UK approved or permitted third country Article 2.2(d) establishment, or an EC approved or permitted third country Article 2.2(d) establishment.

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

95. No person shall import into the United Kingdom from a third country, a compound feeding stuff containing a premixture which contains additives of any kind referred to in Chapter II(b) of the Annex, manufactured in a third country, but does not contain a zootechnical additive, unless it was manufactured on a UK registered or permitted third country Article 7.2(c)(PA) establishment, or an EC registered or permitted third country Article 7.2(c)(PA) establishment.

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

96. No person shall import into the United Kingdom from a third country, 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 1.2(a) of the Annex, manufactured in a third country, unless it was manufactured on a UK registered or permitted third country Article 7.2(c)(A) establishment, or an EC registered or permitted third country Article 7.2(c)(A) establishment.

PART XI

ENFORCEMENT

Official checks and enforcement

97.—(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

98.—(1) An authorised person may exercise the powers specified in this regulation for the purposes of—

- (a) carrying out official checks, and
- (b) ascertaining whether an offence under regulation 107(a) or (b) has been or is being committed.

(2) An authorised person shall have the right at all reasonable times, and on producing, if requested to do so, some duly authenticated document showing his authority, to enter—

- (a) any premises on which he has reasonable cause to believe that a controlled product has been, or is being, 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 appearing to be 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 or under his control.

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

- (a) that admission to the premises has been refused, or a refusal is apprehended, and that notice of the intention to apply for a warrant has been given to the occupier; or

- (b) that an application for admission, or the giving of such a notice, would defeat the object of the entry, or that the case is one of urgency, or that the premises are unoccupied or the occupier temporarily absent,

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

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

(5) In the application of paragraph (3)—

- (a) to Scotland, any reference to a justice of the peace includes a reference to the sheriff and to a magistrate, and
- (b) to Northern Ireland, the reference to a sworn information in writing includes a reference to a sworn complaint in writing.

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

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

- (a) any material appearing to him to be a 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 on those premises, and prepare, a sample of—

- (a) any material appearing to him to be a controlled product manufactured, produced, wrapped, packaged, stored or put into circulation, or intended to be put into circulation; or
- (b) any material 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 prescribed—

- (i) in the case of Great Britain, in Part II of Schedule 1 to the Feeding Stuffs (Sampling and Analysis) Regulations 1999(13), or
- (ii) in the case of Northern Ireland, in Part II of Schedule 1 to the Feeding Stuffs (Sampling and Analysis) Regulations (Northern Ireland) 1999(14),

and paragraph 10 of Part II of Schedule 1 to the Regulations concerned shall have effect for the purposes of the certificate referred to in regulations 102 and 104(2).

(9) For the purposes of this Part of these Regulations, the provisions of regulation 3 and Schedule 1 to the Feeding Stuffs (Sampling and Analysis) Regulations 1999 or, as the case may be,

(13) S.I. 1999/1663, amended by S.I. 1999/1871.

(14) S.R. 1999/296.

of regulation 3 and Schedule 1 to the Feeding Stuffs (Sampling and Analysis) Regulations (Northern Ireland) 1999(14), shall have effect as if—

- (a) for all references to “feeding stuff” or to “feeding stuffs” there were substituted references to “controlled product” or “controlled products” respectively, and
- (b) in paragraph 1 of Part II of Schedule 1 to the Regulations concerned, the expression “, except where section 68(2)(b) of the Act applies” were omitted.

(10) 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 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

- (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

99. 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 in the like manner as that prescribed—
 - (i) in the case of Great Britain, in Part III of Schedule 1 to the Feeding Stuffs (Sampling and Analysis) Regulations, 1999, or
 - (ii) in the case of Northern Ireland, in Part III of Schedule 1 to the Feeding Stuffs (Sampling and Analysis) Regulations (Northern Ireland) 1999;
- (b) send one part for analysis to—
 - (i) in Great Britain, 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

100. If the person who manufactured any material of which an authorised person has taken a sample is not a person to whom part of the sample is required to be sent under regulation 99, 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

101. There shall be sent, with the part of the sample sent to the agricultural analyst pursuant to regulation 99, a statement signed by the authorised person that the sample was taken in the manner referred to in regulation 98(8).

Analysis by the Agricultural analyst

102. The agricultural analyst shall analyse the part of the sample sent to him under regulation 99, 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 100.

Alternative arrangements for carrying out analyses

103. If the agricultural analyst to whom a sample is sent for analysis under regulation 99 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 102 shall apply, as if the sample had originally been sent to that other agricultural analyst.

Further analysis of samples

104.—(1) Where a part of a sample sent to an agricultural analyst pursuant to regulation 99 has been analysed, and it is intended to institute proceedings, or proceedings have been commenced, against a person for an offence under regulation 107(a) or (b), and it is intended to adduce, on behalf

of the prosecution, evidence of the result of the analysis of that part of the sample, the defendant, for the purpose of obtaining a second opinion, may request the authorised person to send the retained part of the sample for analysis to—

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

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

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

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

- (a) the cost of performing them, nor
- (b) the appropriate fee for the performance of any similar function under section 78 of the Act, the authorised person may, in the absence of agreement by the defendant to pay the fee, refuse to comply with the request made under paragraph (1).

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

Default powers of the Minister of Agriculture, Fisheries and Food

105. For the purposes of this Part of these Regulations, if the Minister is of opinion that, in any area within Great Britain, these Regulations have been—

- (a) insufficiently enforced or administered, or
- (b) if applicable, enforced without sufficient regard to the requirements of Directive 95/53,

he may himself appoint one or more persons to exercise in that area the powers exercisable there by authorised persons; and any expenses certified by him as having been incurred by him under this regulation, in respect of that area, shall be repaid to him, on demand, by the competent body.

Methods of analysis

106.—(1) Subject to paragraph (2) below for the purpose of determining, by means of analysis of a part of a sample taken in the course of the carrying out of official checks, whether a substance—

- (a) of a class or description listed (in the case of Great Britain) in column 1 of Annex I to Part II of Schedule 2 to the Feeding Stuffs (Sampling and Analysis) Regulations 1999 or (in the case of Northern Ireland) in column 1 of Annex I to Part II of Schedule 2 to the Feeding Stuffs (Sampling and Analysis) Regulations (Northern Ireland) 1999, or
- (b) to which the method of analysis specified (in the case of Great Britain) in Annex II, or in Annex III, to Part II of Schedule 2 to the Feeding Stuffs (Sampling and Analysis)

Regulations 1999 relates, or (in the case of Northern Ireland) to which the method specified in Annex II, or in Annex III, to Part II of Schedule 2 to the Feeding Stuffs (Sampling and Analysis) Regulations (Northern Ireland) 1999 relates,

is present or active therein, or what quantity or proportion of such a substance is present or active therein, the provisions specified in Part I of Schedule 2 to the Regulations concerned, under the heading “GENERAL PROVISIONS” shall have effect, in the like manner as they have effect under the Regulations concerned in relation to feeding stuffs, and

- (i) in relation to a substance of a class or description listed (whether by itself or by reference to its activity) in column 1 of Annex I to Part II of Schedule 2 to the Regulations concerned, the relevant method of analysis set out in the Community provision in force specified in the corresponding entry in columns 2 and 3 of that Annex shall be used; and
- (ii) in relation to a substance to which the method specified in Annex II, or the method specified in Annex III, to Part II of Schedule 2 to the Regulations concerned relates, the method of analysis applicable to that substance shall be used,

and where more than one method is set out in columns 2 and 3 of Annex I to Part II of Schedule 2 to the Regulations concerned in relation to the same substance, the notes to that Annex shall have effect to specify which is the relevant method.

(2) After 31st October 1999, paragraph (1) above shall cease to apply to the following substances listed in column 1 of Annex I to Part II of Schedule 2 to the Regulations concerned—

- (a) menadione (vitamin K₃);
- (b) theobromine;
- (c) vitamin A; and
- (d) volatile mustard oil,

and shall cease to apply to starch insofar as it falls to be analysed by the pancreatic method as mentioned in the notes to that Annex.

(3) For the purpose of determining, by means of analysis as aforesaid, whether a substance other than one to which paragraph (1) applies is present or active in the part of a sample concerned, or what quantity or proportion of such a substance is present or active therein—

- (a) if there is an applicable standard of the kind specified in the first indent of Article 18.3 of Directive 95/33, analysis shall be carried out in accordance with that standard, and
- (b) where analysis cannot be so carried out, it shall be carried out in accordance with any scientifically valid method the application of which does not infringe any general principle of the Treaty establishing the European Community.

Offences

107. It shall be an offence for a person—

- (a) without reasonable excuse, to contravene any of regulations 40 to 96;
- (b) in connection with these Regulations to make a statement which he knows to be false in a material particular, or recklessly to make a statement which is false in a material particular;
- (c) intentionally to obstruct an authorised person in the exercise of any power conferred by regulation 98, or
- (d) without reasonable excuse to fail to comply with any requirement made of him, pursuant to regulation 98, by an authorised person.

Punishment of offences

108.—(1) A person contravening, without reasonable excuse, any of regulations 40, 42, 44, 46, 48, 50, 52, 53, 54, 55, 56, 57, 59, 61, 63, 65, 67, 69, 70, 71, 72, 73, 74, 76, 78, 80, 81, 82, 84, 86, 88, 90, 92, 94, 95, 96 or 107(b) 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 41, 43, 45, 47, 49, 51, 58, 60, 62, 64, 66, 68, 75, 77, 79, 83, 85, 87, 89, 91 or 93 shall be liable on summary conviction to a fine not exceeding level 5 on the standard scale.

(3) A person contravening regulation 107(c) or (d) shall be liable on summary conviction to a fine not exceeding level 3 on the standard scale.

Time limit for prosecutions

109.—(1) Proceedings for an offence under regulation 107(b) or any of the regulations specified in regulation 108(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(15) (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

110. 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

111. 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

112.—(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 1999”, 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 1999”.

Service of certificates, notices and parts of samples

113. 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.

29th June 1999

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

29th June 1999

Calum MacDonald
Parliamentary Under Secretary of State, Scottish
Office

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SCHEDULE 1

Regulation 2(3)(c) and (d)

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
pet animal
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 102 and 104(2)

FORM OF CERTIFICATE OF ANALYSIS
CERTIFICATE OF ANALYSIS OF SAMPLE OF PRODUCT ANALYSED PURSUANT TO THE
FEEDING STUFFS (ESTABLISHMENTS AND INTERMEDIARIES) REGULATIONS 1999(1)

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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 1999, 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 98(8) of those Regulations; that (7) 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:—(8)

- (A) specific method(s) is/are prescribed in the Feeding Stuffs (Establishments and Intermediaries) Regulations 1999 for the analysis of (list substance(s) and that/these method(s) was/were used in the analysis

and/or

No specific method(s) is/are prescribed in the Feeding Stuffs (Establishments and Intermediaries) Regulations 1999 for the analysis of (9) and the method(s) used complied with regulation 106(3) of those Regulations (10).

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 1999.
- (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 details of particulars contained in any accompanying document or particulars marked on, or, indicated by a mark applied to, the material, or as the case may be.
- (8) 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 for the purposes of Directive 70/524, and referred to a complete feeding stuff with a moisture content of 12%.
- (9) List substance(s).
- (10) Delete as applicable and indicate the method of analysis used. If analysis cannot be carried out because no suitable method exists then the certificate should be noted accordingly.

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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) the requirements of Council Directive [95/53/EC](#) fixing the principles governing the organisation of official inspections in the field of animal nutrition (OJNo. L265, 8.11.95, p. 17);
 - (b) Council Directive [95/69/EC](#) laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector and amending Directives [70/524/EEC](#), [74/63/EEC](#), [79/373/EEC](#) and [82/471/EEC](#) (OJ No. L332, 30.12.95, p. 15);
 - (c) 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);
 - (d) Articles 6, 8 and 9 of Commission Directive [98/51/EC](#) laying down certain measures for implementing Council Directive [95/69/EC](#) laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector (OJ No. L208, 24.7.98, p. 43); and Article 3 of Council Directive [1999/20/EC](#) (OJ No. L80, 25.3.1999, p. 20) amending Directives [70/524/EEC](#) concerning additives in feedingstuffs, [82/471/EEC](#) concerning certain products used in animal nutrition, [95/53/EC](#) fixing the principles governing the organisation of official inspections in the field of animal nutrition and [95/69/EC](#) laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector;

in relation to feeding stuffs, and related products, which do not contain zootechnical additives (i.e. antibiotics, coccidiostats and other medical substances or growth promoters).

2. In implementation of Directive [95/69/EC](#), the Regulations re-enact requirements previously contained in Regulations revoked by these Regulations—the Feeding Stuff (Establishments and Intermediaries) Regulations 1998 (“the 1998 Regulations”—[S.I. 1998/1049](#)) under which—

- (a) “establishments” (as defined in Article 1.3 of Directive [95/69/EC](#)) in the United Kingdom must be approved/registered by the relevant competent body (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/EC](#)) must be approved/registered by the same competent bodies for the wrapping, packaging, storing and “putting into circulation” (see definition in Article 1.3 of Directive [95/69/EC](#)) 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 sub-paragraph (b), must be approved/registered by the competent authorities in the member State concerned,
- (regulations 40 to 51, 57 to 68, 74 to 79 and 82 to 93).

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/EC, and that is a precondition before approval (which can only be given following an inspection by the competent body) can be given. The obligation to comply with those requirements continues once approval/registration has been obtained.

4. Application for approval/registration (which may now be made in the Welsh language in certain circumstances) must be made to the competent body, and the application must contain specified information. The competent body 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 body 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 until their application is processed, provided they applied before 1st September 1998—(see the definitions in regulations 3 and 4 commencing with “EC permitted Article” or “UK permitted Article”).

6. By way of rectification of omissions in the 1998 Regulations, the Regulations—

- (a) extend, to manufacturers of compound feeding stuffs for animals living freely in the wild, the rules relating to approval of establishments manufacturing compound feeding stuffs containing contaminants above prescribed levels; (see the definitions in regulation 2(1) of “complementary feeding stuff”, “complete feeding stuff”, “compound feeding stuff” and “feeding stuff”, and the provisions referred to in the last mentioned definition); and
- (b) include provisions in regulation 71(2)(c) (re-enacting with amendments regulation 62(2)(c) in the 1998 Regulations) the effect of which provisions is that the premixture governed by regulation 71(2)(c) now extend to those which include zootechnical additives.

7. In implementation of Article 13 of Directive 70/524/EEC, as substituted by Directive 96/51/EC, the Regulations also re-enact provisions in the 1998 Regulations regulating, in relation to establishments and intermediaries requiring approval/registration—

- (a) the putting into circulation of certain additives, premixtures containing those additives and products regulated by Directive 82/471 (regulations 52, 69 and 80);
- (b) the supply of certain additives, alone or in premixtures (regulations 53 and 70), and
- (c) the incorporation of certain additives, and premixtures containing such additives, in compound feeding stuffs (regulations 54 and 71).

8. The Regulations provide for their enforcement by the competent body 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 97 to 113).

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

- (a) among the provisions referred to in paragraph 8 there are added a number which, for the purposes of these Regulations, and in relation to products covered by the instruments referred to in paragraph 1, give effect to certain of the requirements of Directive 95/53/EC, including those relating to sampling and analysis and the manner of carrying out, and the frequency of, enforcement checks to be carried out by competent authorities;

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- (b) in accordance with Article 6 of Directive 98/51/EC (transitional provisions), the Regulations introduce, in relation to establishments located in third countries and their UK based representatives, as regards the products referred to in sub-paragraph (a), requirements similar to those described in paragraphs 2(a) and 3 to 5, the main differences being that—
- (i) approval/registration is granted by the Minister of Agriculture, Fisheries and Food and is for the importation into the United Kingdom of the products concerned. (It is made an offence to import those products into the United Kingdom, unless such approval/registration has been obtained or the transitional arrangements described in sub-paragraph (iv) apply, or importation is permitted by virtue of parallel arrangements operating in another member State—regulations 55, 56, 72, 73, 81, 94, 95 and 96);
 - (ii) application for approval/registration, including amendment applications, is made by the UK based representative to the Minister, who will maintain the register/list of approved/registered third country establishments, and have the power to withdraw approvals/registrations where there is non-compliance by an establishment or its representative with quality control requirements (regulations 33 to 39);
 - (iii) no prior inspection by the competent body (local authorities in Great Britain and the Department of Agriculture for Northern Ireland in Northern Ireland) is necessary before approval (or registration) is granted;
 - (iv) the applicable transitional provisions operate in the case of third country establishments manufacturing the product concerned on 1st December 1998, and which at all times since have had a representative established in the European Community. Importation from such establishments may lawfully continue after the Regulations come into force, (provided the necessary application is made by 30th September 1999), until the application is processed. (See the definitions in regulations 3 and 4 commencing with “EC permitted third country” and “UK permitted third country”);
- (c) certain provisions in the 1998 Regulations applied to establishments “located in a third country”. In the corresponding provisions in these Regulations there is substituted for that expression reference to the relevant type of approved, permitted or registered third country establishment provided for in these Regulations (regulations 52(1) and (2), 53(1)(a)(iii) and (iv), 54(a), 54(b)(iv) and (v), 69(1) and (2), 70(1)(c) and (d) and 80(c) and (d));
- (d) in implementation of Articles 8 and 9 of Directive 98/51/EC, the Regulations prescribe the formats of the register and approval numbers provided for in Article 5 of Directive 95/69/EC and of the list and registration numbers provided for in Article 10 of that Directive (regulations 6(2)(b), 13(3)(B), 20(b), 27(b), 34(1)(a)(ii) and 34(1)(b)(ii));
- (e) the Regulations create a new offence of making a false statement in connection with the Regulations (regulation 107(b)); and
- (f) the Regulations omit from those definitions in regulations 3 and 4 which also appear in the 1998 Regulations all wording which is now spent.

10. The provisions referred to in paragraph 1 implemented by these Regulations are implemented, so far as relevant to feeding stuffs containing zootechnical additives, by the Feedingstuffs (Zootechnical Products) Regulations 1999, but the requirements in Directive 95/69/EC and 98/51/EC relating to registration do not apply to those products.