
SCOTTISH STATUTORY INSTRUMENTS

2000 No. 453

The Feeding Stuffs (Scotland) Regulations 2000

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Feeding Stuffs (Scotland) Regulations 2000 and shall come into force on 31st January 2001.

(2) These Regulations extend to Scotland only.

Interpretation

2.—(1) In these Regulations—

“the Act” means the Agriculture Act 1970;

“additive” means a substance or preparation used in animal nutrition in order to—

- (a) affect favourably the characteristics of feed materials, compound feeding stuffs or animal products;
- (b) satisfy the nutritional needs of animals or improve animal production (in particular by affecting the gastro-intestinal flora or the digestibility of feeding stuffs);
- (c) introduce into nutrition elements conducive to obtaining particular nutritional objectives or to meeting the nutritional needs of animals at a particular time; or
- (d) prevent or reduce the harmful effects caused by animal excretions or improve the animal environment,

but excludes everything excluded from coverage of the Additives Directive by Article 1.2 and 1.3 thereof;

“the Additives Directive” means Council Directive [70/524/EEC](#) concerning additives in feeding stuffs⁽¹⁾;

“the Agency” means the Food Standards Agency;

“ash” means the matter which results from the treatment of a feeding stuff in accordance with the appropriate procedure set out in the method of analysis for ash specified in Point 5 of the Annex to Directive [71/250/EEC](#)⁽²⁾;

“authorised”, in relation to any additive, or the name of any additive, save in the expressions “authorised intermediate product” and “authorised medicated premix”, and subject to paragraph (2) below, means authorised in or, as the case may be, under, the Additives Directive, and “authorisation” shall be construed accordingly;

“authorised intermediate product” and “authorised medicated premix” have the meanings given in regulation 2(1) of the Medicated Feedingstuffs Regulations 1998⁽³⁾;

“the Certain Products Directive” means Council Directive [82/471/EEC](#) concerning certain products used in animal nutrition⁽⁴⁾;

(1) O.J. No. L 270, 14.12.70, p.1 (O.J./S.E. Vol. 18, p.4).

(2) O.J. No. L 155, 12.7.71, p.13 (O.J./S.E. 1971(II), p.480).

(3) S.I.1998/1046, to which there is an amendment not relevant to these Regulations.

(4) O.J. No. L 213, 21.7.82, p.8.

“complementary feeding stuff”, subject to regulation 14(10)(a), 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;

“complete feeding stuff”, subject to regulation 14(10)(a), means a compound feeding stuff which, by reason of its composition, is sufficient to ensure a daily ration;

“compound feeding stuff”, subject to regulation 14(10)(a), means a mixture of feeding stuffs;

“the Compound Feeding Stuffs Directive” means Council Directive [79/373/EEC](#) on the marketing of compound feedingstuffs⁽⁵⁾;

“daily ration” means the average total quantity of feeding stuff, expressed on a 12% 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;

“dossier” means a dossier compiled in accordance with the relevant provisions of the Dossiers Directive and which includes–

- (a) an identification note (containing where applicable the information specified in Article 9o.1 of the Additives Directive);
- (b) any monograph supplied pursuant to Article 9n.3 of the Additives Directive; and
- (c) in the case of an additive to which Article 7a of the Additives Directive applies, the documents referred to in the indented paragraphs of the first paragraph of that Article;

“the Dossiers Directive” means Council Directive [87/153/EEC](#) fixing guidelines for the assessment of additives in animal nutrition⁽⁶⁾;

“EC approved Article 2.2(d) establishment” means an establishment listed on a register of approved establishments, maintained by a competent authority in a member State, in implementation of Article 5 of the Establishments Directive, as an establishment on which a compound feeding stuff, of any kind the manufacture of which is regulated by Article 2.2(d) of that Directive, may be manufactured with a view to putting it into circulation;

“EC approved Article 2.2(f) establishment” means an establishment listed on a register of approved establishments, maintained by a competent authority in a member State, in implementation of Article 5 of the Establishments Directive, as an establishment on which a compound feeding stuff, of any kind the production of which is regulated by Article 2.2(f) of that Directive, may be produced for the exclusive requirements of the producer’s holding;

“EC permitted Article 2.2(d) establishment” means an establishment located in a member State (other than an EC approved Article 2.2(d) establishment or an establishment which a competent authority in the member State has declined to approve as such an establishment) if–

- (a) a compound feeding stuff, of any kind the manufacture of which is regulated by Article 2.2(d) of the Establishments Directive, 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 the Establishments Directive, as an establishment on which a compound feeding stuff of any such kind may be manufactured with a view to putting it into circulation;

⁽⁵⁾ O.J. No. L 86, 6.4.79, p.30.

⁽⁶⁾ O.J. No. L 64, 7.3.87, p.19, as amended by Commission Directive [94/40/EC](#) (O.J. No. L 208, 11.8.94, p.15) and Commission Directive [95/11/EC](#) (O.J. No. L 106, 11.5.95, p.23).

“EC permitted Article 2.2(f) establishment” means an establishment located in a member State (other than an EC approved Article 2.2(f) establishment or an establishment which a competent authority in the member State has declined to approve as such an establishment) if–

- (a) a compound feeding stuff, of any kind the production of which is regulated by Article 2.2(f) of the Establishments Directive, was being produced on the establishment, for the exclusive requirements of the producer’s holding, on 1st April 1998; and
- (b) before 1st September 1998, an application (which is pending) in respect of the establishment, was made to 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 the Establishments Directive, as an establishment on which a compound feeding stuff of any such kind may be produced for the exclusive requirements of the producer’s holding;

“EEA Agreement” means the Agreement on the European Economic Area signed at Oporto on 2nd May 1992 as adjusted by the Protocol signed at Brussels on 17th March 1993(7);

“EEA State” means a State which is a Contracting Party to the EEA Agreement;

“energy value” means the energy value of a feeding stuff calculated in accordance with the relevant method specified in Schedule 1;

“establishment” has the meaning given by Article 1.3(b) of the Establishments Directive;

“the Establishments Directive” means Council Directive [95/69/EC](#) which laid down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector and which amended [70/524/EEC](#), [74/63/EEC](#), [79/373/EEC](#) and [82/471/EEC](#)(8);

“fat” means the extract obtained following the treatment of a feeding stuff in accordance with the appropriate procedure set out in the method of analysis for oils and fats specified in Part IV of the Annex to Directive [71/393/EEC](#)(9);

“feeding stuff”, subject to regulation 14(10)(a), has the meaning attributed to it by section 66(1) as modified by regulation 20(1)(a);

“feeding stuff intended for a particular nutritional purpose” means a compound feeding stuff, the composition or method of manufacture of which distinguishes it from other feeding stuffs and from the type of products covered by the Medicated Feedingstuffs Directive, and in respect of which any indication is given that it is intended for a particular nutritional purpose;

“feed material”, subject to regulation 14(10)(b), means–

- (a) any product of vegetable or animal origin, in its natural state, (whether fresh or preserved);
- (b) any product derived from such a product by industrial processing; or
- (c) any organic or inorganic substance,

specified in Parts II or III of Schedule 2 (whether or not containing any additive) and for use in oral feeding to pet animals or farmed creatures, directly as such, or after processing, in the preparation of a compound feeding stuff or as a carrier of a premixture;

(7) The reference for the EEA Agreement is O.J. No. L 1, 3.1.94, p.1. The reference for the protocol signed on 17th March 1993 is O.J. No. L 1, 3.1.94, p.571.

(8) O.J. No. L 332, 30.12.95, p.15, as amended by Council Directive [98/92/EC](#) (O.J. No. L 346, 22.12.98, p.49) and Council Directive [1999/20/EC](#) (O.J. No. L 80, 25.3.99, p.20).

(9) O.J. No. L 279, 20.12.71, p.7 (O.J./SE 1971 (III) p.987. Part IV was replaced entirely by Annex 1 to Directive [84/4/EEC](#) (O.J. No. L 15, 18.1.84, p.28). That Annex was in turn replaced entirely by Part B of the Annex to Directive [98/64/EC](#) (O.J. L 257, 19.9.98, p.14).

materials, amending Directives [70/524/EEC](#), [74/63/EEC](#), [82/471/EEC](#) and [93/74/EEC](#) and repealing Directive [77/101/EEC](#)(**10**);

“fibre” means the organic matter calculated following the treatment of a feeding stuff in accordance with the procedure set out in the method of analysis for fibre specified in Point 3 of Annex 1 to Directive [73/46/EEC](#)(**11**);

“identification note” has the same meaning as in the Additives Directive;

“intermediary” has the meaning given by Article 1.3(c) of the Establishments Directive;

“mammalian meat and bone meal” has the meaning given in Article 4(1) of the Bovine Spongiform Encephalopathy (No. 2) Order 1996(**12**);

“the Medicated Feedingstuffs Directive” means Council Directive [90/167/EEC](#) laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community(**13**);

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

“MFS prescription” has the meaning given in regulation 2(1) of the Medicated Feedingstuffs Regulations 1998;

“micro-organism” has the meaning given by Article 2(aa) of the Additives Directive;

“milk replacer feed” means a compound feeding stuff administered in dry form, or after reconstitution with a given quantity of liquid, for feeding young animals as a supplement to, or substitute for, post-colostrum milk or for feeding calves intended for slaughter;

“mineral feeding stuff” means a complementary feeding stuff which is composed mainly of minerals and which contains at least 40% by weight of ash;

“minimum storage life” means, in relation to a compound feeding stuff, the date until which, under proper storage conditions, that feeding stuff retains its specific properties;

“molassed feeding stuff” means a complementary feeding stuff prepared from molasses and which contains at least 14% by weight of total sugar expressed as sucrose;

“moisture” means water and other volatile material determined in accordance with the procedure set out in the method of analysis for moisture specified in Part I of the Annex to Directive [71/393/EEC](#)(**14**);

“monograph” has the same meaning as in the Additives Directive;

“name”, in relation to any additive specified in any of Parts I to VIII of the Table to Schedule 3, means the name specified for that additive in that Table, and, in relation to any other additive means, its authorised name;

“national list” means the list of establishments published in London by the Agency, for the purposes of Article 6.1 of the Establishments Directive;

“oil” means the extract obtained following the treatment of a feeding stuff in accordance with the appropriate procedure set out in the method of analysis for oils and fats specified in Part IV of the Annex to Directive [71/393/EEC](#);

“particular nutritional purpose” means the purpose of satisfying any nutritional requirement of pet animals or productive livestock, the process of assimilation or absorption of which, or the metabolism of which, may be temporarily impaired, or is temporarily or permanently impaired,

(10) O. J. No. L 125, 23.5.96, p.35.

(11) O.J. No. L 83, 30.3.73, p.21. Point 3 of Annex 1 was replaced entirely by the Annex to Directive [92/89/EEC](#) (O.J. No. L 344, 26.11.92, p.35).

(12) S.I. [1996/3183](#); the relevant amending instrument is S.I. [1999/921](#).

(13) O.J. No. L92, 7.4.90, p. 42.

(14) O.J. No. L 279, 20.12.71, p.7 (O.J./SE 1971 (III), p.987), amended by Article 1 of Directive [73/47/EEC](#) (O.J. No. L 83, 30.3.73, p.35).

and which may therefore benefit from ingestion of a feeding stuff capable of achieving that purpose;

“pet animal” has the same meaning as in the Additives Directive;

“pet food” means a feeding stuff for pet animals and “compound pet food” shall be construed accordingly;

“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;

“protein”, except in paragraphs 12(2), 13, 28(2) and 29 of Part I of Schedule 4, and subject to paragraph (3) below, means the matter obtained as a result of treatment of a feeding stuff in accordance with the procedure set out in the method of analysis for protein specified in Point 2 of Annex 1 to Directive [72/199/EEC\(15\)](#);

“protein equivalent of biuret, diureidoisobutane, urea or urea phosphate” in relation to an amount of biuret, diureidoisobutane, urea and urea phosphate nitrogen, means that amount multiplied by 6.25;

“put into circulation” has the same meaning as in the Feed Materials Directive but, in regulation 14(3), (4) and (7), also means import into Scotland from a country which is neither an EEA State nor part of an EEA State;

“registered veterinarian” has the same meaning as in the Medicated Feedingstuffs Directive;

“starch” means the matter obtained as the result of treatment of a feeding stuff in accordance with the procedure set out in the method of analysis for starch specified in Point 1 of Annex 1 to Directive [72/199/EEC\(16\)](#);

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

“UK approved Article 2.2(d) establishment”, “UK approved Article 2.2(f) establishment”, “UK permitted Article 2.2(d) establishment” and “UK permitted Article 2.2(f) establishment” have, subject to regulation 14(5), the meanings respectively given to them by regulation 3 of the Feedingstuffs (Establishments and Intermediaries) Regulations 1999(17), as read with regulation 2(4) of those Regulations;

“zootechnical additive” means an additive belonging to one or more of the groups of additives specified in Part I of Annex C to the Additives Directive;

“zootechnical feeding stuff” means a feeding stuff that contains a zootechnical additive or zootechnical premixture; and

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

(2) The additives appearing in the Section headed “Radionuclide Binders”, and as numbers 3 and 4 in the Section headed “Micro-organisms”, in the Annex to Commission Regulation ([EC](#)) [No. 2785/98\(18\)](#), shall be deemed for the purposes of these Regulations to be “authorised” within the meaning of that term as defined in paragraph (1) above.

(3) For the purposes of paragraphs 12(1) and 28(1) of Part I of Schedule 4, “protein” has the meaning given to it by article 4(1) of the Bovine Spongiform Encephalopathy (No.2) Order 1996.

(4) In these Regulations, “botanical purity” shall be construed in accordance with paragraph 2 of Section II of Part A of the Annex to the Feed Materials Directive.

(15) O.J. No. L 123, 29.5.72, p.6 (O.J./SE 1966-1972 supplement, p.74). Point 2 of Annex 1 has been replaced by the Annex to Directive [93/28/EEC](#) (O.J. No. L 179, 22.7.93, p.8).

(16) O.J. No. L 123, 29.5.72, p.6 (O.J./S.E. 1966-1972 supplement, p.74). Point 1 of Annex 1 has been replaced entirely by the Annex to Directive [1999/79/EC](#) (O.J. No. L 209, 7.8.99, p.25).

(17) S.I. [1999/1872](#) to which there are modifications not relevant to these Regulations.

(18) O.J. No. L 347, 23.12.98, p.21.

(5) Any reference in these Regulations to a numbered regulation or Schedule shall, unless the context otherwise requires, be construed as a reference to the regulation or Schedule bearing that number in these Regulations.

(6) Any reference in these Regulations to a numbered section shall, unless the reference is to a section of a specified Act, be construed as a reference to the section bearing that number in the Act.

(7) Any reference in these Regulations to a European Community Directive or Regulation shall be construed as a reference to that Directive or, as the case may be, Regulation, as amended as at the date these Regulations are made.

Prescribed material

3.—(1) These Regulations apply to material of the following description, that is to say any material usable as a feeding stuff, and any material usable as a feed material, premixture or additive in such a feeding stuff.

(2) The description in paragraph (1) above is a prescribed description for the purposes of sections 68(1) and 69(1); and in these Regulations material so described is referred to as the “prescribed material”.

(3) In the application of section 68 with respect to the prescribed material, subsection (2) shall be disregarded.

Matters required or permitted to be contained in a statutory statement or otherwise declared

4. The particulars, information and instructions required, and the particulars, information and instructions permitted, to be contained in a statutory statement or, as the case may be, otherwise declared, shall be as specified in, and shall comply with, the provisions of Schedule 4 (save in respect of additives and premixtures not contained in feeding stuffs) and Schedule 5 (in respect of additives and premixtures not contained in feeding stuffs).

Forms of statutory statement

5.—(1) Subject to the provisions relating to small quantities of feeding stuffs in the second paragraph of Article 16.6 of the Additives Directive, and Article 5 of the Compound Feeding Stuff Directive, and paragraph (2) below, the statutory statement—

- (a) in the case of any prescribed material delivered in a package or other container, shall—
 - (i) take the form of a label attached to that package or container; or
 - (ii) be clearly marked directly thereon; and
- (b) in the case of such material delivered in bulk, shall take the form of a document relating to and accompanying each consignment.

(2) In the case of any feed material sold in a quantity not exceeding 10 kg, and supplied directly to the final user thereof, the statutory statement may be provided in the form of a notice in writing.

(3) The particulars, information and instructions required or permitted to be contained in the statutory statement shall—

- (a) be clearly separate from any other information;
- (b) subject to paragraphs (5) and (6) below, be in English; and
- (c) be legible and indelible.

(4) For the purposes of section 69 (marking of material prepared for sale), prescribed material which is contained in a package or other container shall be labelled or marked in the manner prescribed in relation to such material in paragraph (1) or, where applicable, (2), above, and such

material in bulk shall be marked by the display in as close proximity to the material as may be practicable of a document relating thereto.

(5) In the case of any compound feeding stuff or feed material which is intended for export to a member State, the statutory statement shall be in one or more official Community languages, as determined by that member State.

(6) In the case of any feeding stuff, not being a zootechnical feeding stuff, which is intended for export to an EEA State which is not a member State, the statutory statement shall comply with the requirements of Article 18 of the Additives Directive as if the EEA State were a member State.

Register of marks

6.—(1) As respects any feed material, the matters required by section 69(1) to be marked on that material may be denoted by a mark, the meaning of which can be ascertained by reference to a register kept in accordance with this regulation.

(2) In the case of any compound feeding stuff, not being of a standard formulation on general sale by the seller concerned, which is specially manufactured or mixed to the order of a purchaser—

- (a) there shall be an indication in a document, label or notice, which is readily apparent and unequivocally associated with the material, of the type of feeding stuff, and of the name or trade name, and of the address or registered office, of the manufacturer; and
- (b) the other matters required by section 69(1) to be marked on the material may be denoted by a mark, the meaning of which can be ascertained by reference to a register kept in accordance with this regulation.

(3) The register shall show those matters to which the mark relates, being matters required to be contained in a statutory statement relating to the material to which the mark relates, and the date of entry of those particulars in the register, and entries relating to material of a kind mentioned in paragraph (2) above shall include the name and address of the purchaser, the date of the order and the amount ordered.

(4) The register shall be kept as a separate record in book form, marked on the outside “Register of marks under section 69(6) of the Agriculture Act 1970” and shall be kept on the premises where the material is held for the purpose of selling it in the course of trade for use as a feeding stuff, save that, if the material is not in the premises of the person who has the material for sale, the register shall be kept on those premises.

(5) The period for which the register is to be preserved in accordance with section 69(7) shall be six months, commencing on the first day on which none of the materials referred to in the register remains on the premises, for sale as aforesaid.

(6) The register shall be kept by the seller concerned.

Limits of variation

7.—(1) In the application of section 74 with respect to the prescribed material, the limits of variation mentioned in subsection (1) shall, in relation to any mis-statement in a statutory statement, document or mark, as to the nature, substance or quality of a feeding stuff or, as the case may be, feed material, where the mis-statement relates to—

- (a) any analytical constituent specified in the first column of—
 - (i) Part A of Schedule 6 (where the feeding stuff is a compound feeding stuff not intended for pets);
 - (ii) Part B of Schedule 6 (where the feeding stuff is a compound pet food); or
 - (iii) Part C of Schedule 6 (in the case of a feed material);

(b) any vitamin or trace element specified in the first column of Part D of that Schedule, or
(c) the energy value of any feeding stuff specified in the first column of Part E of that Schedule,
be as set out with respect to that constituent or, as the case may be, vitamin, trace element or feeding stuff, in the corresponding entry in the second column of the relevant Part of that Schedule.

(2) Particulars with respect to any material which are contained in a statutory statement, or in any document, or which are marked on, or denoted by a mark on, the material, shall not, for the purposes of Part IV of the Act or of these Regulations, be treated as false by reason of any mis statement therein as to the nature, substance or quality of the material, if—

- (a) the material was first sold, or otherwise put into circulation, in a member State;
- (b) the mis-statement did not, at the time of putting into circulation, exceed any limits of variation prescribed in relation thereto in that member State; and
- (c) any such limits were in accordance with any applicable European Community Directive.

Assigned meanings

8. In the application of section 70 with respect to the prescribed material, there shall be assigned to the expressions “complementary feeding stuff”, “complete feeding stuff”, “compound feeding stuff”, “feeding stuff”, “milk replacer feed”, “mineral feeding stuff” and “molassed feeding stuff” in each case the meaning given by regulation 2(1) to the expression concerned.

Manner of packaging and sealing compound feeding stuffs, additives and premixtures

9.—(1) Subject to paragraphs (2) and (3) below, no person shall sell a compound feeding stuff, or any additive or premixture, unless it is in a bag or container, and that bag or container is sealed in such a way that, when the bag or container is opened, the seal is damaged and cannot be re-used.

(2) Compound feeding stuffs may be sold in bulk, in unsealed bags or in unsealed containers, in the case of—

- (a) deliveries between producers or sellers of compound feeding stuffs;
- (b) deliveries from producers of compound feeding stuffs to packaging enterprises;
- (c) compound feeding stuffs obtained by mixing grain or whole fruit;
- (d) blocks or licks;
- (e) small quantities not exceeding 50 kg in weight, which are intended for the final user and are taken directly from a bag or container which, before opening, complied with the sealing provision in paragraph (1) above.

(3) Compound feeding stuffs may be sold in bulk, in unsealed containers, but not in unsealed bags, in the case of—

- (a) direct deliveries from the producer to the final user;
- (b) molassed feeding stuffs consisting of less than three feed materials;
- (c) pelleted feeding stuffs.

Control of feed materials

10.—(1) No person shall put into circulation any feed material of a description specified in column (3) of Part II of Schedule 2, under a name other than that specified in the corresponding entry in column (2) of that Part.

(2) No person shall put into circulation any feed material of a description specified in column (1) of Part III of Schedule 2, except under a name or description, or a name and description (other

than one specified in that column or in column (2) of Part II of that Schedule) sufficiently specific to indicate the nature of the material.

(3) No person shall—

- (a) put into circulation any feed material of a description specified in column (3) of Part II of Schedule 2, and which has a name specified in the corresponding entry in column (2) of that Part which includes a common name or term specified in column (4) of Part I of that Schedule; or
- (b) sell, or have in possession with a view to sale, any compound feeding stuff containing any such feed material,

unless, in either case, the feed material was prepared by the process specified, in relation to the common name or term, in column (2), and described in column (3), of Part I of that Schedule.

(4) No person shall put into circulation any feed material, or sell, or have in possession with a view to sale, any compound feeding stuff containing any feed material, unless—

- (a) in the case of any feed material of a description specified in column (3) of Part II of Schedule 2—
 - (i) the botanical purity by weight of the feed material is not less than the percentage (if any) specified in relation to it in column (3) of Part II of that Schedule or, if none is specified, is not less than 95%; and
 - (ii) the feed material complies with the requirements of paragraph 1 of Section II of Part A of the Annex to the Feed Materials Directive; and
- (b) in the case of any feed material of a description specified in column (1) of Part III of that Schedule—
 - (i) the botanical purity by weight of the feed material is not less than 95%; and
 - (ii) the feed material complies with the requirements of paragraph 1 of Section II as aforesaid.

(5) No person shall use any feed material to bind another feed material, if the quantity of the feed material so used exceeds 3% of the total weight of the feed material bound.

(6) Without prejudice to sections 73 and 73A, no person shall import into Scotland from any country which is neither a member State nor another part of the United Kingdom, supply (otherwise than on sale) or have in possession with a view to so supplying, any feed material, unless it is wholesome, and is not deleterious or dangerous to farmed creatures, to pet animals or, through consumption of the products of any animal fed with the feed material, to human beings.

(7) No person shall put into circulation any feed material in a manner likely to mislead.

(8) In paragraph 4(a) above “description” shall be taken to exclude any botanical purity requirement.

Applications for Community authorisation of additives and of new uses for additives

11.—(1) Any person resident, or having a place of business in Scotland who wishes the United Kingdom to act as the rapporteur in connection with—

- (a) an application for the Community authorisation of an additive which is not a zootechnical additive; or
- (b) an application for the Community authorisation of a new use of an already authorised additive which is not a zootechnical additive,

may submit to the Agency an application for the Community authorisation of the additive or the new use of the additive, as the case may be, and a dossier relating to the additive, or the new use, as the case may be.

- (2) Where documentation is submitted to the Agency pursuant to paragraph (1) above, it shall—
- (a) forward it to the Commission; and
 - (b) forward a copy of it to each member State,

in accordance with Article 4.3 of the Additives Directive, if it is satisfied as specified in paragraph (3) below.

- (3) The Agency is satisfied in accordance with this paragraph if it is satisfied that—
- (a) the dossier submitted pursuant to paragraph (1) above has been compiled in accordance with the applicable provisions of the Dossiers Directive; and
 - (b) the additive to which the dossier relates, or the new use to which it relates, as the case may be, appears to meet the conditions laid down in Article 3a of the Additives Directive.

(4) If, in relation to a dossier submitted pursuant to paragraph (1) above, the Agency is not satisfied about both of the matters specified in paragraph (3) above, it shall reject the documentation, or postpone taking the action specified in paragraph (2) above in relation to the documentation, until such time as it is satisfied about both of those matters.

(5) Where the Agency rejects documentation submitted to it pursuant to paragraph (1) above, or postpones taking the action specified in paragraph (2) above in relation to it, it shall inform the Commission, the applicant and each member State of the rejection or postponement, and shall notify them of the reasons for the rejection or postponement.

(6) If requested to do so by the Commission, the Agency shall forward a copy of all or part of a dossier relating to any additive for which an application has been submitted to it pursuant to paragraph (1) above, to each member of the Scientific Committee for Animal Nutrition.

Confidential information relating to additives

12.—(1) Subject to paragraphs (2) and (3) below, no person shall publish or disclose any confidential information obtained by that person in the performance of functions under regulation 11, without the previous consent in writing of the person who, in accordance with that regulation, has made an application for Community authorisation of, or, as the case may be, for a new use of, the additive concerned.

(2) Nothing in paragraph (1) above shall restrict the publication or disclosure of such information for the purpose of the exercise of functions under regulation 11.

(3) Nothing in paragraph (1) above shall prevent the publication or disclosure of confidential information of a type specified in Article 7.2 of the Additives Directive.

(4) In this regulation, “confidential information” means information of the type specified in Article 7.1 of the Additives Directive.

(5) A publication or disclosure in contravention of paragraph (1) above shall be punishable as if it were a disclosure prohibited by section 83.

Control of additives in feeding stuffs

13.—(1) No person shall use an additive for the purpose of animal nutrition unless any incorporation thereof in a feeding stuff accords with paragraph (2) to (4) below.

(2) Subject to regulation 23 and paragraph (8) below, no person shall carry out a relevant activity in relation to an additive, unless—

- (a) where the additive is not contained in a feeding stuff—
 - (i) the additive is—

- (aa) permitted to be contained in material intended for use as a feeding stuff pursuant to paragraph 5(1) of Schedule 3; or
 - (bb) specified in any of Parts I to VIII of the Table to Schedule 3(19); or
 - (ii) the relevant activity relates to an additive authorised under any European Community Regulation specified in Part IX of that Table;
 - (b) where the additive is contained in a feeding stuff, it is covered by sub-paragraph (a) above and, where applicable, the feeding stuff or, as the case may be, the relevant activity, complies with the relevant requirements specified in Schedule 3 or, as the case may be, with the relevant conditions required to be observed for compliance with the European Community Regulation concerned.
- (3) In paragraph (2) above, “relevant activity”, in relation to an additive, means any one or more of the following:–
- (a) the putting into circulation for use as a feeding stuff of any material containing the additive;
 - (b) the use as a feeding stuff of any material containing the additive;
 - (c) the putting of the additive into circulation, for incorporation in a feeding stuff;
 - (d) the incorporation of the additive in a feeding stuff.
- (4) Without prejudice to paragraph (2) above, no person shall incorporate any additive into a feed material, unless–
- (a) (where the additive is listed in any of Parts I to VIII of the Table to Schedule 3) the expression “all feeding stuffs” appears, opposite to that additive, whether or not accompanied by qualifying words, in the column headed “Conditions” in the Part concerned;
 - (b) (where the additive is otherwise authorised) it is indicated in the European Community Regulation concerned that such incorporation is permitted; or
 - (c) the additive is permitted to be contained in material pursuant to paragraph 5(1) of that Schedule.
- (5) Paragraphs (1) to (4) above shall not apply to any added substance which is–
- (a) for use in accordance with an MFS prescription issued by a registered veterinarian, pursuant to regulation 29 of the Medicated Feedingstuffs Regulations 1998(20);
 - (b) an authorised medicated premix;
 - (c) an authorised intermediate product; or
 - (d) a zootechnical additive.
- (6) Subject to paragraph (8) below, no person shall put into circulation, for use as a feeding stuff, any complementary feeding stuff which, when diluted as specified by the manufacturer for feeding to animals, contains any additive specified in any of Parts I to VIII of the Table to Schedule 3, or which is authorised by any European Community Regulation specified in Part IX of that Table, at a level exceeding that specified for that additive in the Part concerned or, as the case may be, in the European Community Regulation, in relation to complete feeding stuffs.
- (7) No person shall–
- (a) mix in a premixture or feeding stuff, with an additive which is not a zootechnical additive, another additive which is not a zootechnical additive, unless such mixing is in accordance with Article 9q2 of the Additives Directive; or

(19) Parts I to VIII relate only to additives covered by European Community Directives. Part IX relates only to additives covered by European Community Regulations.

(20) S.I. 1998/1046, to which there is an amendment not relevant to these Regulations.

(b) mix a micro-organism with a zootechnical additive, unless such mixture is permitted as specified in Article 9q4 of the Additives Directive.

(8) Paragraph (2) above, in so far as it regulates “putting into circulation”, and paragraph (6) above, shall not apply in relation to any additive which is excluded from the application of the Additives Directive by Article 22 thereof.

(9) No person shall use as a feeding stuff any material containing an additive (not being one permitted to be contained in material pursuant to paragraph 5(1) of, or referred to in any of Parts I to VIII of, the Table to Schedule 3, or which is otherwise authorised) which is deleterious to farmed creatures, to pet animals, to human beings or to the environment.

Control of feeding stuffs and feed materials containing undesirable substances

14.—(1) No person shall sell, or have in possession with a view to sale, for use as a feeding stuff, or use as a feeding stuff, any material specified in column 2 of Part I of Schedule 7, which contains any substance specified in column 1 of that Part in excess of the level specified in relation thereto in column 3 thereof.

(2) No person shall sell, or have in possession with a view to sale, for use as a feeding stuff, or use as a feeding stuff, any complementary feeding stuff if—

- (a) when it is diluted as specified by the manufacturer for feeding to animals, it contains any substance specified in column 1 of Part I of Schedule 7, in excess of the level specified for that substance in column 3 of that Part in relation to complete feeding stuffs; and
- (b) there is no provision relating to any complementary feeding stuff in the corresponding entry in column 2 of that Part.

(3) No person shall put into circulation any feed material specified in column 2 of Chapter A of Part II of Schedule 7, which contains any substance specified in column 1 of that Part in excess of the level specified in relation thereto in column 3 thereof.

(4) Without prejudice to paragraph (3) above, and subject to paragraph (5) below, no person shall put into circulation any feed material specified in column 2 of Chapter A of Part II of Schedule 7, or in column 2 of Chapter B of that Part, which contains any substance specified in relation to the material in question in the corresponding entry in column 1 of the Chapter in question, in excess of the level specified in column 3 of Part I of that Schedule in relation to the corresponding feed material unless—

- (a) the feed material put into circulation—
 - (i) is intended for use only on—
 - (aa) a UK approved or permitted Article 2.2(d) establishment;
 - (bb) a UK approved or permitted Article 2.2(f) establishment;
 - (cc) an EC approved or permitted Article 2.2(d) establishment; or
 - (dd) an EC approved or permitted Article 2.2(f) establishment; and
 - (ii) is accompanied by a document stating—
 - (aa) that it is intended for use by such establishments,
 - (bb) that it may not be fed unprocessed to livestock, and
 - (cc) the amount of the specified substance contained in the material; or
- (b) the feed material is intended for supply by way of export to a third country.

(5) For the purposes of paragraph (4) above, no UK or EC establishment shall be considered an approved establishment unless—

- (a) in the case of a UK establishment, it is included in the most recently published national list (if any);
- (b) in the case of an EC establishment, it is included in the most recently published list (if any) equivalent in the member State concerned to the national list.

(6) No person shall mix with any feeding stuff or feed material, any feed material specified in column 2 of Chapter A of Part II of Schedule 7, if the feed material so specified contains any substance specified in the corresponding entry in column 1 of that Part in excess of the level specified in relation thereto in column 3 thereof.

(7) No person shall put into circulation any feed material unless it is—

- (a) sound and genuine; and
- (b) of merchantable quality.

(8) For the purposes of paragraph (7) above, and without prejudice to the provisions of paragraph (3) above, a feed material is not sound, genuine and of merchantable quality if (were it to be incorporated into any compound feeding stuff specified in column 2 of Part I of Schedule 7) the level of any substance specified in column 1 of that Part, and contained in the feed material, would exceed the level specified for that substance in column 3 of that Part in relation to the compound feeding stuff in question.

(9) Where a person has or has had in the possession or control of that person, for the purposes of a trade or business, any feeding stuff or feed material and becomes aware—

- (a) in the case of a feeding stuff, that it does not comply with any requirement of paragraphs (1) or (2) above; or
- (b) in the case of a feed material, that it does not comply with any requirement of paragraphs (3), (4), (7) or (8) above,

that person shall immediately notify the Agency, and an inspector appointed under section 67(3) by the authority which, by virtue of section 67(2), has the duty to enforce Part IV of the Act in relation to the feeding stuff or feed material in question.

(10) For the purposes of the foregoing provisions of this regulation—

- (a) “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 pet animals, to farmed creatures or to animals living freely in the wild, and “complementary feeding stuff”, “complete feeding stuff” and “compound feeding stuff” shall be construed accordingly; and
- (b) “feed material” means a product or substance within the definition of “feed materials” in Article 2(b) of Council Directive [1999/29/EC](#) on undesirable substances and products in animal nutrition⁽²¹⁾.

Control of compound feeding stuffs containing prohibited materials

15.—(1) No person shall sell, or have in possession with a view to sale, for use as a compound feeding stuff, or use as a compound feeding stuff, any material which contains—

- (a) faeces, urine or separated digestive tract contents resulting from the emptying or removal of the digestive tract, irrespective of any form of treatment or admixture;

(21) O.J. No. L 115, 4.5.99, p.32.

- (b) hide treated with tanning substances, including its waste;
- (c) seeds or other plant propagating materials which, after harvest, have undergone specific treatment with plant protection products for their intended propagation, or derived by-products;
- (d) wood, sawdust or other materials derived from wood treated with wood protection products;
- (e) sludge from sewage plants treating waste waters;
- (f) solid urban waste, such as household waste;
- (g) untreated waste from eating places, except food stuffs of vegetable origin considered unsuitable for human consumption for reasons of freshness; or
- (h) packaging and parts of packaging from products used in agriculture or the food industry.

(2) For the purposes of paragraph (1) above, except sub-paragraph (e), “waste” shall mean material of any applicable category listed in Annex 1 to Council Directive [75/442/EEC](#)(**22**) on waste, which is discarded or intended or required to be discarded.

Control of certain protein sources

16.—(1) Subject to paragraphs (3) and (4) below, no person shall sell, or have in possession with a view to sale, for use as a feeding stuff or as a protein source in a feeding stuff, any material belonging to a product group specified in column 1 of Schedule 8, unless that material—

- (a) is named as a permitted product in column 2 of that Schedule; and
- (b) complies with all the specifications and requirements contained in and imposed in relation thereto by columns 3 to 6 of that Schedule.

(2) Subject to paragraph (3) below, no person shall sell, or have in possession with a view to sale, for use as a feeding stuff, or use as a feeding stuff, any product obtained from yeasts of the “Candida” variety cultivated on n-alkanes.

(3) Paragraphs (1) and (2) above shall not apply in relation to any material or product excluded from application of the Certain Products Directive by Article 16 thereof.

(4) Paragraph (1) above shall not apply in the circumstances authorised for derogation by Article 3.2 of the Certain Products Directive.

Control of the iron content of milk replacer feeds

17. No person shall sell, or have in possession with a view to sale, any milk replacer feed intended for calves of up to 70 kilograms live weight, which has an iron content of less than 30 milligrams per kilogram of the complete feeding stuff at a moisture content of 12%.

Control of ash insoluble in hydrochloric acid in compound feeding stuffs

18.—(1) No person shall sell, or have in possession with a view to sale—

- (a) any compound feeding stuff composed mainly of rice by-products in which the level of ash insoluble in hydrochloric acid exceeds 3.3% of its dry matter; or
- (b) subject to paragraph (2) below, any other compound feeding stuff in which the level of ash insoluble in hydrochloric acid exceeds 2.2% of its dry matter.

(2) Paragraph (1)(b) above shall not apply to the sale of any compound feeding stuff which—

(22) O.J. No. L 194, 25.7.75, p.39 as amended by Council Directive [91/156/EEC](#) (O.J. No. L 78, 26.3.91, p.32) and Council Directive [91/692/EEC](#) (O.J. No. L 377, 31.12.91, p.48) and by Commission Decision [96/350/EC](#) (O.J. No. L 135, 6.6.96, p.32).

- (a) contains permitted mineral binders named or described in Commission Regulation (EC) No. 2439/1999 on the conditions for authorisation of additives belonging to the group “binders, anti-caking agents and coagulants” in feedingstuffs⁽²³⁾;
- (b) is a mineral feeding stuff;
- (c) contains more than 50% of sugar beet chips or sugar beet pulp; or
- (d) is intended for farmed fish and has a fish meal content of more than 15%,

if the level of ash insoluble in hydrochloric acid is declared in the statutory statement as a percentage of the feeding stuff as such.

Control of feeding stuffs intended for particular nutritional purposes, and supplementary provisions relating to statutory statement

19.—(1) No person shall sell, or have in possession with a view to sale, any feeding stuff intended for a particular nutritional purpose unless—

- (a) the particular nutritional purpose in question is specified in column 1 of Chapter A of Schedule 9;
- (b) the feeding stuff possesses the essential nutritional characteristics specified opposite that particular nutritional purpose in column 2 of that Chapter;
- (c) the feeding stuff is intended for animals specified opposite that particular nutritional purpose in column 3 of that Chapter;
- (d) it is recommended that the feeding stuff be used for a period of time falling within the range specified opposite that particular nutritional purpose in column 5 of that Chapter;
- (e) in relation to the feeding stuff, the requirements specified in paragraphs 1, 2 and 8 of Chapter B of Schedule 9 are complied with; and
- (f) the composition of the feeding stuff is such that it is capable of achieving the particular nutritional purpose for which it is intended.

(2) Schedule 10 shall have effect as specified in Schedule 4.

Modification of the Agriculture Act 1970 in relation to all feeding stuffs

20.—(1) In the application of section 66 with respect to the prescribed material—

- (a) in subsection (1)—
 - (i) for the definition of “feeding stuff” there shall be substituted the following definition—

““feeding stuff” means—

 - (a) a product of vegetable or animal origin in its natural state (whether fresh or preserved);
 - (b) a product derived from the industrial processing of such a product; or
 - (c) an organic or inorganic substance, used singly or in a mixture, whether or not containing additives for oral feeding to pet animals or farmed creatures;”;
 - (ii) for the definition of “pet animal” there shall be substituted the following definition—

““pet animal” has the same meaning as in Council Directive 70/524/EEC concerning additives in feeding stuffs as amended;”;

and

⁽²³⁾ O.J. No. L 297, 18.11.1999, p.8, amended by Commission Regulation (E.C.) No. 739/2000 (O.J. No. L 87, 8.4.00, p.14).

(iii) before the definition of “prescribed” there shall be inserted the following definition—

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

(b) in subsection (2), for paragraph (b)(24) there shall be substituted—

“(b) material shall be treated—

- (i) as imported or sold for use as a feeding stuff whether it is imported or, as the case may be, sold, to be used by itself, or as an ingredient, additive or premixture in something which is to be so used; and
- (ii) as used as a feeding stuff whether it is so used by itself, or as an ingredient, additive or premixture in something which is to be so used.”.

(2) In their application with respect to the prescribed material, in each of sections 73(1) and 73A(1), for the words “animals of any description prescribed for the purpose of the definition of “feeding stuff” in section 66(1) of this Act” there shall be substituted the words “any farmed creatures”.

(3) In the application of section 85 with respect to the prescribed material—

- (a) paragraph (a) shall be disregarded in relation to delivery outside the United Kingdom; and
- (b) paragraph (b) shall be disregarded.

Modification of the Agriculture Act 1970 in relation to imported feeding stuffs

21. In the application of section 69(1) with respect to the prescribed material, the words “and in either case before it is removed from the premises,” shall be disregarded in relation to feeding stuffs which have been imported.

Exemption from these Regulations

22. Insofar as provisions of these Regulations implement the Compound Feeding Stuffs Directive, they shall not apply in the circumstances specified in Article 14(c) of that Directive.

Further exemption from these Regulations

23. The provisions of regulation 13(2) (in so far as they regulate the putting into circulation of additives and material containing additives), and the provisions of regulation 13(7)(a), shall not apply in the circumstances specified in Article 9q5 of the Additives Directive.

Enforcement of provisions made under section 2(2) of the European Communities Act 1972

24. Insofar as any provision of these Regulations is made under section 2(2) of the European Communities Act 1972, that provision shall be enforced as if it was made under those provisions of Part IV of the Act under which the other provisions of these Regulations are made, and the provisions of that Part of the Act shall apply accordingly.

Modification of section 74A(3) of the Agriculture Act 1970

25.—(1) For the purposes of the provisions specified in paragraph (2) below, section 74A(3) shall have effect as if, for the words “regulations under subsection (1) above, or fails to comply with

(24) Section 66(2) was amended by the Feeding Stuffs Regulations 1995 (S.I. 1995/1412).

any other provision of the regulations,” there were substituted the words “any provision specified in regulation 25(2) of the Feeding Stuffs (Scotland) Regulations 2000”.

(2) The provisions specified for the purposes of paragraph (1) above are regulations 10(1), (2), (3)(a), (4) (in relation to putting into circulation), (6) and (7), 13(3)(a), (c) and (d), (4), (6) and (7) and 14(3), (4), (6), (7) and (9).

Revocations

26. Except insofar as they made modifications to the Act, the Feeding Stuffs Regulations 1995(25), the Feeding Stuffs (Amendment) Regulations 1996(26), the Feeding Stuffs (Amendment) Regulations 1998(27), the Feeding Stuffs (Amendment) (No. 2) Regulations 1998(28) and the Feeding Stuffs (Amendment) Regulations 1999(29) are hereby revoked.

Modification of the Feeding Stuffs (Sampling and Analysis) Regulations 1999

27. In the Feeding Stuffs (Sampling and Analysis) Regulations 1999(30)–

- (a) paragraph 5(1) of Part II of Schedule 1 shall have effect as if the words “section 76(1)(b) of the Act” read “section 76(7) of the Act, as that section is modified by regulation 10 of the Feeding Stuffs (Enforcement) Regulations 1999”(31);
- (b) the references in paragraph 3(e)(ii) of Part I of Schedule 2, and paragraph 11(a) of Part II of Schedule 3, to “the Feeding Stuffs Regulations 1995”, shall have effect as if they read “the Feeding Stuffs (Scotland) Regulations 2000”; and
- (c) the second entry for Starch (polarimetric method), in Annex I of Part II to Schedule 2, shall have effect as if, for the provisions relating to that entry in columns 2 and 3, there were substituted the following provisions:–

“Point 1 of Annex I to Directive 72/199/EEC (as replaced entirely by the Annex to Directive 1999/79/EC)(4)	O.J. No. L123, 29.5.72, p.6. (O.J./S.E. 1966-1972 supplement p.74). O.J. No. L209, 7.8.1999, p.23.”
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Modification of the Feeding Stuffs (Establishments and Intermediaries) Regulations 1999

28.—(1) The provisions of the Feeding Stuffs (Establishments and Intermediaries) Regulations 1999 specified in paragraph (2) below shall have effect as if, after the words “the Feeding Stuffs (Sampling and Analysis) Regulations 1999”, wherever they occur, there were added the words “, as amended by the Feedingstuffs (Zootechnical Products) Regulations 1999(32) and as modified by the Feeding Stuffs (Scotland) Regulations 2000,”.

(2) The provisions referred to in paragraph (1) above are regulations 98(8) and (9), 99 and 106(1).

Modification of the Feeding Stuffs (Enforcement) Regulations 1999

29. In the Feeding Stuffs (Enforcement) Regulations 1999–

- (a) in regulation 7(2) and (4), the references to “the Feeding Stuffs Regulations 1995”, shall have effect as if they read “the Feeding Stuffs (Scotland) Regulations 2000”;

(25) S.I. [1995/1412](#).

(26) S.I. [1996/1260](#).

(27) S.I. [1998/104](#).

(28) S.I. [1998/2072](#)

(29) S.I. [1999/1528](#).

(30) S.I. [1999/1663](#), to which there is an amendment not relevant to these Regulations.

(31) S.I. [1999/2325](#), to which there are modifications not relevant to these Regulations.

(32) S.I. [1999/1871](#), to which there are modifications not relevant to these Regulations.

- (b) in regulation 8, the reference to the Feeding Stuffs (Sampling and Analysis) Regulations 1999 shall have effect as if it were a reference to those Regulations as amended by the Feedingstuffs (Zootechnical Products) Regulations 1999 and as modified by these Regulations;
- (c) section 67 shall have effect for the purpose specified in regulation 7(2) of the Feeding Stuffs (Enforcement) Regulations 1999 as if for subsection (8) there were substituted the following subsection (instead of the subsection substituted by regulation 9 of those Regulations):-
- “(8) If the Scottish Ministers are of the opinion that, in the area of an enforcement authority, the Feeding Stuffs (Scotland) Regulations 2000 or section 73 or 73A of this Act have been-
- (a) insufficiently enforced or administered by the authority, or
 - (b) enforced or administered by it without sufficient regard to the requirements of Council Directive [95/53/EC](#)(**33**) fixing the principles governing the organisation of official inspections in the field of animal nutrition, as amended by Council Directive [1999/20/EC](#)(**34**),
- they may appoint one or more inspectors to exercise the powers exercisable by inspectors appointed by the authority, and any expenses certified by an inspector appointed by the Scottish Ministers as having been reasonably incurred by that inspector under this subsection shall be repaid on demand by that authority.”; and
- (d) regulation 10 shall, in so far as it modifies section 76, be read as if, in that section as so modified-
- (i) in subsections (8), (9) and (10), the references to the Feeding Stuffs (Sampling and Analysis) Regulations 1999 were references to those Regulations as amended by the Feedingstuffs (Zootechnical Products) Regulations 1999, and as modified by these Regulations; and
 - (ii) for the references in subsection 17 to the Feeding Stuffs Regulations 1995 there were substituted references to these Regulations.

Edinburgh
28th December 2000

SUSAN C DEACON
A member of the Scottish Executive

(33) O.J. No. L 265, 8.11.95, p.17.

(34) O.J. No. L 80, 25.3.99, p.20.