
STATUTORY INSTRUMENTS

1998 No. 1047

The Feedingstuffs (Zootechnical Products) Regulations 1998

PART V

CONTROL OF ZOOTECHNICAL ADDITIVES

Manufacture of zootechnical additives

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

Duties on persons manufacturing zootechnical additives

27. A person manufacturing a zootechnical additive on a U.K. approved Chapter I.1 establishment, with a view to putting it into circulation, shall fulfil the essential conditions contained in Chapter I.1(b) of the Annex to the Establishments Directive.

Packaging of zootechnical additives

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

Labelling of zootechnical additives

29.—(1) No person shall put a zootechnical additive into circulation unless the labelling of the additive complies with the requirements of Article 14.1.A and B(a) of the Additives Directive as amended by Directive [96/51/EC](#).

(2) No person shall put a zootechnical additive into circulation if information other than that—

- (a) required by virtue of Articles 14.1.A and B(a) of the Additives Directive, as amended by Directive [96/51/EC](#), or
- (b) authorised by virtue of Article 14.2 of the Additives Directive, as amended by Directive [96/51/EC](#),

appears on the package, container or label of the additive, unless that information is clearly separated from the required and authorised information in accordance with Article 14.3 of the Additives Directive as amended by Directive [96/51/EC](#).

Wrapping, packaging and storage of zootechnical additives by intermediaries

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

Duties on intermediaries wrapping, packaging or storing zootechnical additives

31. A U.K. approved Chapter I.1 intermediary wrapping, packaging or storing a zootechnical additive shall fulfil the applicable essential conditions referred to in point 7 of Chapter I.1(b) of the Annex to the Establishments Directive.

Putting zootechnical additives into circulation

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

- (a) a U.K. approved or permitted Chapter I.1 establishment;
- (b) an E.C. approved or permitted Chapter I.1 establishment; or
- (c) an establishment located in a third country—
 - (i) if it is listed in relation to zootechnical additives under arrangements to implement the second indent of the second paragraph of Article 15(a) of the Establishments Directive,
 - or
 - (ii) pending the making of those arrangements, if it is reasonable to conclude that it would have been so listed if those arrangements had been made.

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

Duties on intermediaries putting zootechnical additives into circulation

33. A U.K. approved Chapter I.1 intermediary putting a zootechnical additive into circulation shall fulfil the applicable essential conditions referred to in point 7 of Chapter I.1(b) of the Annex to the Establishments Directive.

Supply of zootechnical additives

34.—(1) Subject to paragraph (3), no person shall supply an unauthorised zootechnical additive.

(2) Subject to paragraph (3), no person shall supply an authorised zootechnical additive other than to—

- (a) a U.K. or E.C. approved or permitted Chapter I.1 intermediary;
- (b) a person manufacturing, or intending to manufacture, a zootechnical premixture on a U.K. or E.C. approved or permitted Chapter I.2 establishment;
- (c) where the zootechnical additive is delivered at the last stage of circulation, a person manufacturing, or intending to manufacture, a compound feedingstuff on a UK or EC approved or permitted Chapter I.3(M) establishment, if the conditions specified in the first and third indented paragraphs of Article 13.4(b) of the Additives Directive, as amended by Directive [96/51/EC](#), are complied with; or
- (d) a person who intends to export it to a third country.

(3) Nothing in regulation 32(1) or paragraph (1) or (2) shall prohibit a person from supplying an unauthorised or authorised zootechnical additive to a person (in this paragraph called “the recipient”) who intends—

- (a) to use the additive, or
- (b) to incorporate the additive in a feedingstuff and then use that feedingstuff

for an Article 6.4 purpose if the use of the additive or the resulting feedingstuff, as the case may be, will constitute—

- (i) a medicinal test on animals for which the recipient has been issued with an animal test certificate, or
- (ii) a regulated procedure for which the recipient holds a personal licence and which is specified in a project licence which authorises the procedure.

Use of zootechnical additives for the purpose of animal feeding

35.—(1) Subject to paragraph (2), no person shall use a zootechnical additive for the purpose of animal feeding except an authorised zootechnical additive which—

- (a) has been incorporated in a feedingstuff, and
 - (b) was incorporated in the feedingstuff in accordance with regulation 36.
- (2) Nothing in paragraph (1) shall prohibit a person from feeding an animal—
- (a) an unauthorised zootechnical additive, or
 - (b) a feedingstuff containing an unauthorised zootechnical additive

for an Article 6.4 purpose if the use of the additive or the feedingstuff, as the case may be, will constitute—

- (i) a medicinal test on animals for which he has been issued with an animal test certificate, or
- (ii) a regulated procedure for which he holds a personal licence, and which is specified in a project licence which authorises the procedure.

Incorporation of zootechnical additives

36.—(1) Subject to paragraph (3), no person shall incorporate an unauthorised zootechnical additive into a feedingstuff.

(2) Subject to paragraph (3), no person shall incorporate an authorised zootechnical additive into a feedingstuff other than a compound feedingstuff.

(3) Nothing in paragraphs (1) or (2) shall prohibit a person (“the relevant person”) from incorporating—

- (a) an unauthorised zootechnical additive in a feedingstuff, or
- (b) an authorised zootechnical additive in a feedingstuff other than a compound feedingstuff where it is intended that the resulting feedingstuff will be fed to an animal for an Article 6.4 purpose and the use of the feedingstuff will constitute a use specified in paragraph (4).

(4) For the purpose of the previous paragraph the following uses are specified—

- (a) a medicinal test on animals for which the relevant person has been issued with an animal test certificate, or
- (b) a regulated procedure for which the relevant person holds a personal licence and which is specified in a project licence that authorises the procedure.

(5) No person shall incorporate an authorised zootechnical additive into a compound feedingstuff unless—

- (a) the additive has been prepared beforehand in the form of a premixture—
 - (i) on a U.K. or E.C. approved or permitted Chapter I.2 establishment, or
 - (ii) on an establishment located in a third country:

- (A) if it is listed in relation to zootechnical premixtures under arrangements to implement the second indent of the second paragraph of Article 15(a) of the Establishments Directive, or
- (B) pending the making of those arrangements, if it is reasonable to conclude that it would have been so listed if those arrangements had been made, and in accordance with the requirements specified, or in the case of an establishment located in a third country, requirements equivalent to those specified, in the first paragraph of Article 13.3 of the Additives Directive, as amended by Directive 96/51/EC, and he incorporates the premixture in the feedingstuff in accordance with regulation 51; or
- (b) the incorporation is carried out on a U.K. approved or permitted Chapter I.3(M) establishment and the conditions specified in the first and third indented paragraphs of Article 13.4(b) of the Additives Directive, as amended by Directive 96/51/EC, are complied with;

and, in either case, the additive is incorporated in accordance with the applicable provisions of the relevant Chapter entry covering the additive in Annex B to the Additives Directive as amended by Directive 96/51/EC.

Mixing of zootechnical additives

37.—(1) Subject to paragraph (3), no person shall mix a zootechnical additive with an additive which is not a zootechnical additive in a premixture or feedingstuff unless the mixing of the additives is permitted in accordance with the provisions contained in Article 6.2 of the Additives Directive.

(2) Subject to paragraph (3), no person shall mix a zootechnical additive with another zootechnical additive in a premixture or feedingstuff unless the mixing of the additives—

- (a) is permitted in accordance with the provisions contained in Article 6.2 of the Additives Directive, and
- (b) does not contravene the provisions contained in Article 6.3 of the Additives Directive.

(3) Nothing in paragraphs (1) or (2) shall prohibit a person from mixing a zootechnical additive with another zootechnical additive, or any other additive, where it is intended that—

- (a) the resulting mixture of additives, or
- (b) a premixture or feedingstuff containing the mixture of additives, will be fed to an animal for an Article 6.4 purpose, and the use of the mixture of additives, or the premixture or the feedingstuff containing the mixture, as the case may be, will constitute—
 - (i) a medicinal test on animals for which he has been issued with an animal test certificate, or
 - (ii) a regulated procedure for which he holds a personal licence and which is specified in a project licence that authorises the procedure.

Provision of samples

38. The person responsible for putting a Community authorised zootechnical additive into circulation shall make a standard sample and a reference sample available to the enforcement authority in accordance with the requirements of Article 9p.1 and 2 of the Additives Directive as amended by Directive 96/51/EC.

Monitoring of undesirable interactions

39.—(1) Where there is found to be an unforeseen undesirable interaction between a Community authorised zootechnical additive and another additive or veterinary medicine the relevant person shall comply with the requirements of Article 21a of the Additives Directive, as amended by Directive [96/51/EC](#), relating to the gathering of all the relevant information, and the forwarding on of such information to the enforcement authority.

(2) For the purposes of paragraph (1) the relevant person is—

- (a) the person responsible for putting the zootechnical additive into circulation where the zootechnical additive does not originate in a third country, and
- (b) the representative within the Community of the person responsible for putting the zootechnical additive into circulation where the zootechnical additive originates in a third country.

Provision of information

40. A person responsible for putting a zootechnical additive into circulation shall comply with the requirements relating to the provision of information contained in Article 9s of the Additives Directive as amended by Directive [96/51/EC](#).