
STATUTORY INSTRUMENTS

1999 No. 1871

The Feedingstuffs (Zootechnical Products) Regulations 1999

PART VI

CONTROL OF ZOOTECHNICAL ADDITIVES

Manufacture of zootechnical additives

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

Duties on persons manufacturing zootechnical additives

34. A person manufacturing a zootechnical additive on a UK 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 Directive 95/69/EC.

Packaging of zootechnical additives

35. No person shall market a zootechnical additive unless the additive is packaged in accordance with the requirements of Article 10 of Directive 70/524/EEC.

Labelling of zootechnical additives

36.—(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 Directive 70/524/EEC as amended by Directive 96/51/EC or, with effect from 1st October 1999, complies with those provisions as amended as aforesaid, and as amended further by Council Directive 1999/20/EC(1).

(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 Directive 70/524/EEC, as amended by Directive 96/51/EC or, with effect from 1st October 1999, as so amended and as amended further by Council Directive 1999/20/EC, or
- (b) authorised by virtue of Article 14.2 of Directive 70/524/EEC, 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 Directive 70/524/EEC as amended by Directive 96/51/EC.

Wrapping, packaging and storage of zootechnical additives by intermediaries

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

(1) OJNo. L80, 25.3.99, p. 20.

Duties on intermediaries wrapping, packaging or storing zootechnical additives

38. A UK 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 Directive 95/69/EC.

Putting zootechnical additives into circulation

39.—(1) Subject to paragraph (2) and regulation 41(3), no person shall put a zootechnical additive into circulation other than an authorised zootechnical additive manufactured on—

- (a) a UK approved or permitted Chapter I.1 establishment;
- (b) an EC approved or permitted Chapter I.1 establishment;
- (c) a UK approved or permitted third country Chapter I.1 establishment; or
- (d) an EC approved or permitted third country Chapter I.1 establishment.

(2) Subject to regulation 41(3), no intermediary shall put an authorised zootechnical additive into circulation unless he is a UK or EC approved or permitted Chapter I.1 intermediary.

Duties on intermediaries putting zootechnical additives into circulation

40. A UK 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 Directive 95/69/EC.

Supply of zootechnical additives

41.—(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 UK or EC approved or permitted Chapter I.1 intermediary;
- (b) a person manufacturing, or intending to manufacture, a zootechnical premixture on a UK or EC 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 Directive 70/524/EEC, 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 39(1) or paragraphs (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

42.—(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 43.

(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

43.—(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 UK or EC approved or permitted Chapter I.2 establishment, or
- (ii) a UK or EC approved or permitted third country Chapter I.2 establishment,

and in accordance with the requirements specified, or in the case of a third country establishment, requirements equivalent to those specified, in the first paragraph of Article 13.3 of Directive 70/524/EEC, as amended by Directive 96/51/EC, and he incorporates the premixture in the feedingstuff in accordance with regulation 59; or

(b) the incorporation is carried out on a UK 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 Directive 70/524/EEC, 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 Directive 70/524/EEC as amended by Directive 96/51/EC.

Mixing of zootechnical additives

44.—(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 Directive 70/524/EEC.

(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 Directive 70/524/EEC, and

(b) does not contravene the provisions contained in Article 6.3 of Directive 70/524/EEC.

(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.

Importation of zootechnical additives

45. No person shall import into the United Kingdom, from a third country, a zootechnical additive manufactured in a third country, unless it was manufactured on a UK approved or permitted third country Chapter I.1 establishment, or an EC approved or permitted third country Chapter I.1 establishment.

Provision of samples

46. 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 Directive 70/524/EEC as amended by Directive 96/51/EC.

Monitoring of undesirable interactions

47.—(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 Directive 70/524/EEC, 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 European Community of the person responsible for putting the zootechnical additive into circulation where the zootechnical additive originates in a third country.

Provision of information

48. 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 Directive 70/524/EEC as amended by Directive 96/51/EC.