
STATUTORY INSTRUMENTS

1999 No. 1871

The Feedingstuffs (Zootechnical Products) Regulations 1999

PART II

**APPLICATIONS FOR THE COMMUNITY
AUTHORISATION OF ZOOTECHNICAL ADDITIVES**

Transitional applications

5.—(1) An eligible person who wishes the United Kingdom to act as the rapporteur in connection with an application for the Community authorisation of a BI, BII or BIII zootechnical additive may submit an application for such authorisation, accompanied by a monograph and identification note relating to the additive, to the Minister.

(2) Where documentation is submitted to the Minister pursuant to paragraph (1), he shall process this in accordance with the requirements of—

- (a) Article 9g.2 of Directive 70/524/EEC, as amended by Directive 96/51/EC, in the case of an application relating to a BI zootechnical additive;
- (b) Article 9h.2 of Directive 70/524/EEC, as amended by Directive 96/51/EC, in the case of an application relating to a BII zootechnical additive; and
- (c) Article 9i.2 of Directive 70/524/EEC, as amended by Directive 96/51/EC, in the case of an application relating to a BIII zootechnical additive.

(3) A person who applies for the Community authorisation of a BI zootechnical additive for which the United Kingdom is acting as rapporteur may submit a dossier relating to the additive to the Minister in accordance with the requirements of Article 9g.4 of Directive 70/524/EEC, as amended by Directive 96/51/EC.

(4) Where a dossier relating to a BI zootechnical additive is submitted to the Minister pursuant to paragraph (3), he shall (subject to regulation 9)—

- (a) forward it to the Commission, and
- (b) forward a copy of it to each Member State,

if he is satisfied as specified in paragraph (5).

(5) The Minister is satisfied in accordance with this paragraph if he is satisfied that—

- (a) the dossier submitted pursuant to paragraph (3) has been compiled in accordance with the applicable provisions of Directive 87/153/EEC, and
- (b) the zootechnical additive to which the dossier relates meets the conditions laid down in Article 3a of Directive 70/524/EEC as amended by Directive 96/51/EC.

(6) If, in relation to a dossier submitted pursuant to paragraph (3), the Minister is not satisfied about both of the matters specified in paragraph (5), he shall reject the dossier, or postpone taking the action specified in paragraph (4) in relation to it, until such time as he is satisfied about both of those matters.

(7) Where the Minister rejects a dossier submitted to him pursuant to paragraph (3), or postpones taking the action specified in paragraph (4) in relation to it, he shall inform the Commission and each Member State of the rejection or postponement, and shall notify them of the reasons for the rejection or postponement.

(8) If requested to do so by the Commission, the Minister shall forward a copy of all or part of a dossier relating to a BI zootechnical additive submitted to him pursuant to paragraph (3) to each member of the Scientific Committee for Animal Nutrition.

(9) In paragraph (1) “eligible person” means a person who is entitled to apply for the Community authorisation of a BI, BII or BIII zootechnical additive, as the case may be, in accordance with the provisions of—

- (a) Article 9g.2 of Directive 70/524/EEC, as amended by Directive 96/51/EC, in the case of a BI zootechnical additive;
- (b) Article 9h.2 of Directive 70/524/EEC, as amended by Directive 96/51/EC, in the case of a BII zootechnical additive; and
- (c) Article 9i.2 of Directive 70/524/EEC, as amended by Directive 96/51/EC, in the case of a BIII zootechnical additive.

Preliminary ordinary applications

6.—(1) A person who, in the specified circumstances, wishes the Minister to act in accordance with the following provisions of this regulation in connection with an application for the Community authorisation of a zootechnical additive may submit an application for the Community authorisation of the additive and a dossier relating to the additive to the Minister.

- (2) Where documentation is submitted to the Minister pursuant to paragraph (1), he shall—
- (a) forward it to the Commission, and
 - (b) forward a copy of it to each Member State,

if he is satisfied as specified in paragraph (3) and has received the appropriate fee in accordance with paragraph (4).

- (3) The Minister is satisfied in accordance with this paragraph if he is satisfied that—
- (a) the dossier submitted pursuant to paragraph (1) has been compiled in accordance with the applicable provisions of Directive 87/153/EEC, and
 - (b) the zootechnical additive to which the dossier relates meets the conditions laid down in Article 3a of Directive 70/524/EEC as amended by Directive 96/51/EC.

(4) If the Minister is satisfied in accordance with paragraph (3), the Minister shall notify the person who has submitted the documentation pursuant to paragraph (1) of the Minister’s intention, subject to receipt of the appropriate fee, to forward the dossier to the Commission and the other Member States in accordance with paragraph (2), and upon receipt of such notice such person shall pay the appropriate fee to the Minister and any unpaid sum shall be recoverable as a debt.

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

(6) Where the Minister rejects the documentation submitted to him pursuant to paragraph (1), or postpones taking the action specified in paragraph (2) in relation to it, he shall inform the person who has submitted the application pursuant to paragraph (1), the Commission and each Member State of the rejection or postponement, and shall notify them of the reasons for the rejection or postponement.

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

(8) For the purposes of this regulation—

(a) the “specified circumstances” apply where—

- (i) the person in question is, at the time these Regulations come into force, putting the additive in question into circulation,
- (ii) he is not an eligible person under regulation 5 in relation to that additive,
- (iii) he wishes to be able to continue putting the additive into circulation lawfully on or after 1st October 1999, and
- (iv) he submits the documentation required pursuant to paragraph (1) to the Minister and this is received by the Minister before 1st October 1999; and

(b) “the appropriate fee” means the fee specified in relation to an application under regulation 6(1) in Part I of Schedule 3.

(9) The Minister shall, subject to paragraph (10), treat any documentation submitted to him in anticipation of paragraph (1) as submitted pursuant thereto, and accordingly references in this regulation to anything submitted pursuant to that paragraph shall be taken to include anything required by this paragraph to be so treated.

(10) Paragraph (9) shall only apply where the person who has submitted the documentation in question has, following the coming into force of that paragraph, notified the Minister that he wishes the documentation to be treated as specified in that paragraph.

Ordinary applications

7.—(1) A person who wishes the United Kingdom to act as the rapporteur in connection with—

- (a) an application for the Community authorisation of a zootechnical additive, or
- (b) an application for the Community authorisation of a new use of an already authorised zootechnical additive,

may submit 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, to the Minister.

(2) Where documentation is submitted to the Minister pursuant to paragraph (1), he shall (subject to regulation 9)—

- (a) forward it to the Commission, and
- (b) forward a copy of it to each Member State,

in accordance with Article 4.3 of Directive 70/524/EEC, as amended by Directive 96/51/EC, if he is satisfied as specified in paragraph (3) below.

(3) The Minister is satisfied in accordance with this paragraph if he is satisfied that—

- (a) the dossier submitted pursuant to paragraph (1) has been compiled in accordance with the applicable provisions of Directive 87/153/EEC, and
- (b) the zootechnical additive to which the dossier relates, or the new use to which the dossier relates, as the case may be, meets the conditions laid down in Article 3a of Directive 70/524/EEC as amended by Directive 96/51/EC.

(4) If, in relation to a dossier submitted pursuant to paragraph (1), the Minister is not satisfied about both of the matters specified in paragraph (3), he shall reject the documentation, or postpone

taking the action specified in paragraph (2) in relation to the documentation, until such time as he is satisfied about both of those matters.

(5) Where the Minister rejects documentation submitted to him pursuant to paragraph (1), or postpones taking the action specified in paragraph (2) in relation to it, he shall inform the Commission 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 Minister shall forward a copy of all or part of a dossier relating to a zootechnical additive for which an application has been submitted to him pursuant to paragraph (1) to each member of the Scientific Committee for Animal Nutrition.

Renewal applications

8.—(1) A person who wishes the United Kingdom to act as the rapporteur in connection with an application to renew a Community authorisation relating to a zootechnical additive may submit an application to renew the Community authorisation relating to the additive and a dossier relating to the additive to the Minister.

(2) Where documentation is submitted to the Minister pursuant to paragraph (1), he shall (subject to regulation 9)—

- (a) forward it to the Commission, and
- (b) forward a copy of it to each Member State,

if he is satisfied in paragraph (3).

(3) The Minister is satisfied in accordance with this paragraph if he is satisfied that—

- (a) the dossier submitted pursuant to paragraph (1) has been compiled in accordance with the applicable provisions of Directive 87/153/EEC, and
- (b) the zootechnical additive to which the dossier relates continues to meet the conditions laid down in Article 3a of Directive 70/524/EEC as amended by Directive 96/51/EC.

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

(5) Where the Minister rejects documentation submitted to him pursuant to paragraph (1), or postpones taking the action specified in paragraph (2) in relation to it, he shall inform the Commission 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 Minister shall forward a copy of all or part of a dossier relating to a zootechnical additive for which an application has been submitted to him pursuant to paragraph (1) to each member of the Scientific Committee for Animal Nutrition.

Fees

9.—(1) In this regulation, “the relevant fee”, in relation to any application under regulation 5(3), 7(1)(a) or (b) or 8(1), means the fee specified opposite the application in question in Part I of Schedule 3, and it shall be payable by the person who submits a dossier to the Minister in connection with that application pursuant to the regulation concerned.

(2) Any relevant fee shall be paid at the time that the dossier is submitted to the Minister.

(3) Any unpaid sum due by way of a relevant fee, or any part of such fee, shall be recoverable as a debt.

(4) The Minister need not process any application made under regulation 5(3), 7(1) or 8(1), unless the application is accompanied by the relevant fee.