
STATUTORY INSTRUMENTS

1998 No. 1047

The Feedingstuffs (Zootechnical Products) Regulations 1998

PART II

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

Transitional applications

6.—(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 the Additives Directive, as amended by Directive [96/51/EC](#), in the case of an application relating to a BI zootechnical additive;
- (b) Article 9h.2 of the Additives Directive, 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 the Additives Directive, 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 the Additives Directive, 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 the Additives Directive 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 the Additives Directive, as amended by Directive [96/51/EC](#), in the case of a BI zootechnical additive;
- (b) Article 9h.2 of the Additives Directive, as amended by Directive [96/51/EC](#), in the case of a BII zootechnical additive; and
- (c) Article 9i.2 of the Additives Directive, as amended by Directive [96/51/EC](#), in the case of a BIII zootechnical additive.

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 the Additives Directive, 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 the Additives Directive 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 as specified 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 the Additives Directive 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, means the fee specified opposite the application in question in Part I of Schedule 2, and it shall be payable by the person who submits a dossier to the Minister in connection with that application pursuant to regulation 6(3), 7(1) or 8(1).

(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 6(3), 7(1) or 8(1), unless the application is accompanied by the relevant fee.