STATUTORY INSTRUMENTS

1998 No. 1047

The Feedingstuffs (Zootechnical Products) Regulations 1998

PART II

APPLICATIONS FOR THE COMMUNITYAUTHORISATION 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.