Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (Text with EEA relevance)

Article 1

Definitions

The following definitions shall apply for the purpose of this Regulation:

1. ‘pets and other non-food producing animals’ means animals belonging to species normally nourished, bred or kept, but not consumed by humans, except horses;

2. ‘minor species’ means food-producing animals other than bovines (dairy and meat animals, including calves), sheep (meat animals), pigs, chickens (including laying hens), turkeys and fish belonging to the *Salmonidae*.

Article 2

Application

1 An application for the authorisation of a feed additive, as provided for in Article 7 of Regulation (EC) No 1831/2003, shall be submitted using the form set out in Annex I.

It shall be accompanied by a dossier as provided for in Article 3 (hereinafter ‘the dossier’), containing the particulars and documents referred to in Article 7(3) of Regulation (EC) No 1831/2003.

2 Where, in accordance with Article 18 of Regulation (EC) No 1831/2003, the applicant requests certain parts of the dossier referred to in paragraph 1 to be kept confidential, he shall provide verifiable justification for each document or each part of a document that disclosure of this information might significantly harm its competitive position. Confidential parts shall be submitted separately from the rest of the dossier and shall not be included in the summary referred to in Article 7(3)(h) of Regulation (EC) No 1831/2003. The applicant shall send to the Commission a copy of the parts of the dossier requested to be treated as confidential and of the accompanying justification.

Article 3

Dossier

1 The dossier shall adequately and sufficiently demonstrate that the feed additive satisfies the conditions for authorisation provided for in Article 5 of Regulation (EC) No 1831/2003.

2 The general requirements for the preparation and presentation of the dossier shall be as set out in Annex II.

The specific requirements to be satisfied by the dossier, in the case concerned, shall be as set out in Annex III.

The minimum duration of long term studies shall be as set out in Annex IV.

3 By way of derogation from paragraph 2, the applicant may submit a dossier not satisfying the requirements provided for in paragraph 2, provided that he submits a justification for each element not complying with those requirements.

Article 4

Transitional measures

1 To applications for authorisation submitted before the date of entry into force of this Regulation the Annex to Directive 87/153/EEC shall continue to apply.

2 For applications for authorisation submitted before 11 June 2009 applicants may choose the continued application of Sections III and IV of Parts I and II of the Annex to Directive 87/153/EEC instead of points 1.3, 1.4, 2.1.3, 2.1.4, 2.2.3, 2.2.4, 3.3, 3.4, 4.1.3, 4.1.4, 4.2.3, 4.2.4, 5.3, 5.4, 6.3, 6.4, 7.3, 7.4, 8.3 and 8.4 of Annex III and instead of the provisions laid down in the column 'Minimum duration of long term efficacy studies' of the tables of Annex IV.

Article 5

Entry into force

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 April 2008.

For the Commission

Androulla VASSILIOU

Member of the Commission