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)

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)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[(1)], and in particular Article 7(4) and (5) thereof,

After consulting the European Food Safety Authority in accordance with Article 7(4) and (5) of Regulation (EC) No 1831/2003,

Whereas:

(1) It is necessary to establish implementing rules concerning the procedure for the authorisation of feed additives under Regulation (EC) No 1831/2003, including rules for the preparation and the presentation of the applications and for the assessment and the authorisation of such additives. These rules are intended to replace the provisions laid down in the Annex to Council Directive 87/153/EEC[(2)] fixing guidelines for the assessment of additives in animal nutrition.

(2) Those rules should provide for the requirements to be satisfied by the dossier accompanying the application. They should, in particular, set out the scientific data to be submitted for the identification and the characterisation of the additive concerned and the studies to be submitted to demonstrate its efficacy and its safety for humans, animals and the environment in view of the verification and assessment of the applications for authorisation by the European Food Safety Authority (the Authority).

(3) Depending on the nature of the additive or its requested conditions of use, the extent of the studies necessary to evaluate its properties or its effects may vary. Operators should, therefore, be granted some flexibility with respect to the kind of studies and material to be submitted to demonstrate the safety and the efficacy of the additive concerned. Operators making use of that flexibility should have to justify their choice in the dossier.

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EC) No 429/2008. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(4) The Authority should have the possibility to request supplementary information, where appropriate, in order to determine whether the additive complies with the conditions for authorisation referred to in Article 5 of Regulation (EC) No 1831/2003.

(5) It is indispensable to apply appropriate quality standards when developing dossiers for additives intended for use in feed or water to ensure that the results of laboratory tests are not disputed.

(6) Where necessary, specific requirements should be established for each category of additives referred to in Article 6(1) of Regulation (EC) No 1831/2003.

(7) To stimulate efforts to obtain authorisations for minor species while keeping the necessary level of safety, specific conditions should be provided for taking into account the possibility of extrapolating the results of the studies carried out on major species to minor species.

(8) Implementing rules concerning applications for authorisation should take into account different requirements for food-producing animals and other animals, for which aspects regarding the safety evaluation for the human consumer are not relevant.

(9) Recourse to procedures involving the use of laboratory animals for experimental or other scientific purposes and animal testing according to Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of the animals used for experimental and other scientific purposes[(3)] should be kept to a minimum.

(10) To avoid repeating studies unnecessarily, simplified procedures should be provided for the authorisation of additives already authorised for use in food.

(11) As regards additives already authorised without a time limit under Council Directive 70/524/EEC[(4)], where appropriate, the possibility should be provided for the applicant to demonstrate efficacy, where studies are not available, by any other material which is available to demonstrate efficacy, in particular material concerning the long history of use of the additive concerned.

(12) Rules should be provided for applications for modifications of authorisations in accordance with Article 13(3) of Regulation (EC) No 1831/2003.

(13) Rules should also be provided for applications for the renewal of authorisation under Article 14 of Regulation (EC) No 1831/2003.

(14) With respect to the provisions concerning the safety and efficacy studies to be carried out in support of the application, it is necessary to provide for a transitional period during which the present rules continue to apply. Applications submitted before the entry into force of this Regulation should continue to be treated in accordance with the Annex to Directive 87/153/EEC. With respect to applications submitted during a certain period after entry into force, taking into account the long period of time required for some studies, applicants should have a choice between the rules provided for in this Regulation and the Annex to Directive 87/153/EEC. The implementing rules have been

***Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EC) No 429/2008. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

drawn up on the basis of present scientific and technical knowledge and they should be adapted if necessary to any new developments.

(15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

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.

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EC) No 429/2008. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

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

***Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EC) No 429/2008. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

ANNEX I

APPLICATION FORM REFERRED TO IN ARTICLE 2(1) AND ADMINISTRATIVE DATA

1. APPLICATION FORM
EUROPEAN COMMISSIONHEALTH AND CONSUMER PROTECTIONDIRECTORATE-GENERAL

(Address)

Date: ….

Subject : Application for authorisation of a feed additive in accordance with Regulation (EC) No 1831/2003.

Authorisation of a feed additive or a new use of a feed additive (Article 4(1) of Regulation (EC) No 1831/2003)

Authorisation of an existing product (Article 10(2) or 10(7) of Regulation (EC) No 1831/2003)

Modification of an existing authorisation (Article 13(3) of Regulation (EC) No 1831/2003)

Renewal of a feed additive authorisation (Article 14 of Regulation (EC) No 1831/2003)

Urgent authorisation (Article 15 of Regulation (EC) No 1831/2003)

(Please indicate clearly by ticking one of the boxes)

The Applicant(s) and/or his/their Representative(s) in the Community (Article 4(3) of Regulation (EC) No 1831/2003), under the conditions required in Article 7(3)(a) of Regulation (EC) No 1831/2003 (name, address….)

…

…

submit(s) the present application in order to obtain an authorisation for the following product as a feed additive:

1.1. Identification and characterisation of additive

Additive name (characterisation of the active substance(s) or agent(s) as defined in the subsections 2.2.1.1 and 2.2.1.2 of Annex II):

…

…

Trade name (if appropriate for the authorisations linked to the holder):

…

…

under the category/ies and functional group/s of additives[(5)] (list):

…