

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
Article 2	Application
Article 3	Dossier
Article 4	Transitional measures
Article 5	Entry into force
	Signature

ANNEX I

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

1. APPLICATION FORM
 - 1.1. Identification and characterisation of additive
 - 1.2. Conditions of use
 - 1.2.1. Use in complete feedingstuffs
 - 1.2.2. Use in water
 - 1.2.3. Special conditions of use (if appropriate)
 - 1.3. Reference samples
 - 1.4. Modification requested (where appropriate)
 - 1.5. Enclosures:
2. ADMINISTRATIVE DATA OF APPLICANT(S)
 - (1) Applicant company or person
 - (2) Contact person (for all correspondence with Commission, Authority and CRL)...

ANNEX II

GENERAL REQUIREMENTS TO BE SATISFIED BY THE DOSSIER PROVIDED FOR IN ARTICLE 3

GENERAL ASPECTS

Safety assessment
Efficacy assessment

1. SECTION I: SUMMARY OF THE DOSSIER
 - 1.1. Public summary according to Article 7(3)(h) of Regulation (EC) No 1831/2003
 - 1.1.1. Contents
 - 1.1.2. Description
 - 1.2. Scientific summary of the dossier
 - 1.3. List of documents and other particulars

- 1.4. List of parts of the dossier requested to be treated...
2. SECTION II: IDENTITY, CHARACTERISATION AND CONDITIONS OF USE OF THE...
 - 2.1. Identity of the additive
 - 2.1.1. Name of the additive
 - 2.1.2. Proposal for classification
 - 2.1.3. Qualitative and quantitative composition (active substance/agent, other components, impurities, batch...
 - 2.1.4. Purity
 - 2.1.4.1. Additives whose authorisation is linked to a holder of authorisation...
 - 2.1.4.2. Additives whose authorisation is not linked to a holder of...
 - 2.1.5. Physical state of each form of the product
 - 2.2. Characterisation of the active substance(s)/agent(s)
 - 2.2.1. Description
 - 2.2.1.1. Chemical substances
 - 2.2.1.2. Micro-organisms
 - 2.2.2. Relevant properties
 - 2.2.2.1. Chemical substances
 - 2.2.2.2. Micro-organisms
 - 2.3. Manufacturing process, including any specific processing procedures
 - 2.3.1. Active substance(s)/agent(s)
 - 2.3.2. Additive
 - 2.4. Physico-chemical and technological properties of the additive
 - 2.4.1. Stability
 - 2.4.2. Homogeneity
 - 2.4.3. Other characteristics
 - 2.4.4. Physico-chemical incompatibilities or interactions
 - 2.5. Conditions of use of the additive
 - 2.5.1. Proposed mode of use in animal nutrition
 - 2.5.2. Information related to users/workers safety
 - 2.5.2.1. Chemical substances
 - 2.5.2.2. Micro-organisms
 - 2.5.2.3. Labelling requirements
 - 2.6. Methods of analysis and reference samples
 - 2.6.1. Methods of analysis for the active substance
 - 2.6.1.1. These methods shall meet the same requirements as those for...
 - 2.6.1.2. The detailed characterisation of the method(s) shall include the appropriate...
 - 2.6.1.3. Performance characteristics of in-house validated methods shall be verified by...
 - 2.6.1.4. The CRL may select appropriate characteristics as mentioned under Annex III...
 - 2.6.1.5. Performance criteria for methods for specific groups of substances (e.g....
 - 2.6.2. Methods of analysis for the determination of the residues of...
 - 2.6.2.1. These methods shall meet the same requirements as those for...
 - 2.6.2.2. The detailed characterisation of the method(s) shall include the appropriate...
 - 2.6.2.3. Performance characteristics of in-house validated methods shall be verified by...

- 2.6.2.4. The CRL may select appropriate characteristics from the ones mentioned...
 - 2.6.2.5. Performance criteria for methods for specific groups of substances (e.g....
 - 2.6.3. Methods of the analysis relating to the identity and characterisation...
- 3. SECTION III: STUDIES CONCERNING SAFETY OF THE ADDITIVE
 - 3.1. Studies concerning the safety of use of the additive for...
 - 3.1.1. Tolerance studies for the target species
 - 3.1.1.1. The design of a tolerance test includes a minimum of...
 - 3.1.1.2. Duration of tolerance trials
 - 3.1.1.3. Experimental conditions
 - 3.1.2. Microbial studies
 - 3.2. Studies concerning the safety of use of the additive for...
 - 3.2.1. Metabolic and residue studies
 - 3.2.1.1. Metabolic studies
 - 3.2.1.2. Residue studies
 - 3.2.1.3. Metabolic and disposition studies
 - 3.2.1.4. Bioavailability of residues
 - 3.2.2. Toxicological studies
 - 3.2.2.1. Acute toxicity
 - 3.2.2.2. Genotoxicity studies including mutagenicity
 - 3.2.2.3. Sub-chronic repeated dose oral toxicity studies
 - 3.2.2.4. Chronic oral toxicity studies (including carcinogenicity studies)
 - 3.2.2.5. Reproduction toxicity studies (including prenatal developmental toxicity)
 - 3.2.2.5.1. Two generation reproduction toxicity study
 - 3.2.2.5.2. Prenatal developmental toxicity study (teratogenicity study)
 - 3.2.2.6. Other specific toxicological and pharmacological studies
 - 3.2.2.7. Determination of No Observed Adverse Effect Levels (NOAEL)
 - 3.2.3. Assessment of consumer safety
 - 3.2.3.1. Proposal of the acceptable daily intake (ADI) for the active...
 - 3.2.3.2. Tolerable upper intake level (UL)
 - 3.2.3.3. Consumer exposure
 - 3.2.3.4. Proposal for maximum residue limits (MRLs)
 - 3.2.3.5. Proposal for a withdrawal period
 - 3.3. Studies concerning the safety of use of the additive for...
 - 3.3.1. Toxicological risk assessment for user/worker safety
 - 3.3.1.1. Effects on the respiratory system
 - 3.3.1.2. Effects on the eyes and skin
 - 3.3.1.3. Systemic toxicity
 - 3.3.1.4. Exposure assessment
 - 3.3.2. Measures to control exposure
 - 3.4. Studies concerning the safety of use of the additive for...
 - 3.4.1. Phase I assessment
 - 3.4.1.1. Additives for terrestrial animals
 - 3.4.1.2. Additives for aquatic animals

Phase I — Decision tree
 - 3.4.2. Phase II assessment
 - 3.4.2.1. Phase II A

3.4.2.2. Phase IIB (more detailed ecotoxicological studies)

4. SECTION IV: STUDIES CONCERNING THE EFFICACY OF THE ADDITIVE
 - 4.1. In vitro studies
 - 4.2. Short term efficacy studies with animals
 - 4.3. Long term efficacy studies with animals
 - 4.4. Duration of long term efficacy studies with target animals
 - 4.5. Efficacy requirements for additive categories and functional groups
 - 4.6. Studies on the quality of animal products where this is...
5. SECTION V: POST-MARKET MONITORING PLAN

ANNEX III

SPECIFIC REQUIREMENTS TO BE SATISFIED BY THE DOSSIER
PROVIDED FOR IN ARTICLE 3 WITH RESPECT TO CERTAIN CATEGORIES
OF ADDITIVES OR CERTAIN PARTICULAR SITUATIONS, AS
PROVIDED FOR IN ARTICLE 7(5) OF REGULATION (EC) No 1831/2003

Regulation (EC) No 1831/2003 foresees additional assistance for
the preparation of...

List of the specific requirements for establishing dossiers for:

General conditions

1. TECHNOLOGICAL ADDITIVES
 - 1.1. Section I: summary of the dossier
 - 1.2. Section II: identity, characterisation and conditions of use of the...
 - 1.3. Section III: studies concerning the safety of the additive
 - 1.3.1. Studies concerning the safety of use of the additive to...
 - 1.3.1.1. Tolerance studies for the target species
 - 1.3.1.2. Microbial studies
 - 1.3.2. Studies concerning the safety of use of the additive for...
 - 1.3.2.1. Metabolic and residue studies
 - 1.3.2.2. Toxicological studies
 - 1.3.2.3. Assessment of consumer safety
 - 1.3.3. Studies concerning the safety of use of the additive for...
 - 1.3.4. Studies concerning the safety of use of the additive for...
 - 1.4. Section IV: studies concerning the efficacy of the additive
 - 1.5. Section V: post-market monitoring plan
2. SENSORY ADDITIVES
 - 2.1. Colourants
 - 2.1.1. Section I: summary of the dossier
 - 2.1.2. Section II: identity, characterisation and conditions of use of the...
 - 2.1.3. Section III: studies concerning the safety of the use of...
 - 2.1.4. Section IV: studies concerning the efficacy of the additive
 - 2.1.5. Section V: post-market monitoring plan
 - 2.2. Flavouring compounds
 - 2.2.1. Section I: summary of the dossier
 - 2.2.2. Section II: identity, characterisation and conditions of use of the...

- 2.2.2.1. Characterisation of active substance(s)/agent(s)
 - 2.2.2.2. Method of production and manufacture
 - 2.2.2.3. Methods of analysis
 - 2.2.3. Section III: studies concerning the safety of the additive
 - 2.2.3.1. Studies concerning the safety of use of the additive for...
 - 2.2.3.2. Studies concerning the safety of use of the additive for...
 - 2.2.3.3. Studies concerning the safety of use of the additive for...
 - 2.2.3.4. Studies concerning the safety of use of the additive for...
 - 2.2.4. Section IV: studies concerning the efficacy of the additive
 - 2.2.5. Section V: post-market monitoring plan
- 3. NUTRITIONAL ADDITIVES
 - 3.1. Section I: summary of the dossier
 - 3.2. Section II: identity, characterisation and conditions of use of the...
 - 3.3. Section III: studies concerning the safety of the additives
 - 3.3.1. Studies concerning the safety of use of the additive for...
 - 3.3.1.1. Tolerance of the target species
 - 3.3.1.2. Microbial studies
 - 3.3.2. Studies concerning the safety of use of the additive for...
 - 3.3.2.1. Metabolic and residue studies
 - 3.3.2.2. Toxicological studies
 - 3.3.2.3. Assessment of consumer safety
 - 3.3.3. Studies concerning the safety of use of the additive for...
 - 3.3.4. Studies concerning the safety of use of the additive for...
 - 3.4. Section IV: studies concerning the efficacy of the additive
 - 3.5. Section V: post-market monitoring plan
- 4. ZOOTECHNICAL ADDITIVES
 - 4.1. Zootechnical additives other than enzymes and micro-organisms
 - 4.1.1. Section I: summary of the dossier.
 - 4.1.2. Section II: identity, characterisation and conditions of use of the...
 - 4.1.3. Section III: studies concerning the safety of the additives
 - 4.1.3.1. Studies concerning the safety of use of the additive for...
 - 4.1.3.2. Studies concerning the safety of use of the additive for...
 - 4.1.3.3. Studies concerning the safety of the additive for users/workers
 - 4.1.3.4. Studies concerning the safety of the additive for the environment...
 - 4.1.4. Section IV: studies concerning the efficacy of the additive
 - 4.1.5. Section V: post-market monitoring plan
 - 4.2. Zootechnical additives: enzymes and micro-organisms
 - 4.2.1. Section I: summary of the dossier
 - 4.2.2. Section II: identity, characterisation and conditions of use of the...
 - 4.2.3. Section III: studies concerning the safety of the additives
 - 4.2.3.1. Studies concerning the safety of use of the additive for...
 - 4.2.3.2. Studies concerning the safety of the additive use for consumer...
 - 4.2.3.3. Studies concerning the safety of the additive for users/workers
 - 4.2.3.4. Studies concerning the safety of the additive for the environment...
 - 4.2.4. Section IV: studies concerning the efficacy of the additives
 - 4.2.5. Section V: post-market monitoring plan
- 5. COCCIDIOSTATS AND HISTOMONOSTATS

- 5.1. Section I: summary of the dossier
 - 5.2. Section II: identity, characterisation and conditions of use of the...
 - 5.3. Section III: studies concerning the safety of the additives
 - 5.3.1. Studies concerning the safety of use of the additive for...
 - 5.3.2. Studies concerning the safety of use of the additive for...
 - 5.3.3. Studies concerning the safety of use of the additive for...
 - 5.3.4. Studies concerning the safety of use of the additive for...
 - 5.4. Section IV: studies concerning the efficacy of the additive
 - 5.5. Section V: post-market monitoring plan
6. EXTRAPOLATION FROM MAJOR TO MINOR SPECIES
- 6.1. Section I: summary of the dossier
 - 6.2. Section II: identity, characterisation and conditions of use of the...
 - 6.3. Section III: studies concerning the safety of the use of...
 - 6.3.1. Studies concerning the safety of use of the additive for...
 - 6.3.1.1. Tolerance of the target species
 - 6.3.2. Studies concerning the safety of use of the additive for...
 - 6.3.2.1. Metabolic studies
 - 6.3.2.2. Residue studies
 - 6.3.2.3. Assessment of consumer safety
 - 6.3.3. Studies concerning the safety of use of the additive for...
 - 6.3.4. Studies concerning the safety of use of the additive for...
 - 6.4. Section IV: studies concerning the efficacy of the additive
 - 6.5. Section V: post-market monitoring plan
7. PETS AND OTHER NON FOOD-PRODUCING ANIMALS
- 7.1. Section I: summary of the dossier
 - 7.2. Section II: identity, characterisation and conditions of use of the...
 - 7.3. Section III: studies concerning the safety of the additive
 - 7.3.1. Studies concerning the safety of use of the additive for...
 - 7.3.2. Studies concerning the safety of use of the additive for...
 - 7.3.3. Studies concerning the safety of use of the additive for...
 - 7.3.4. Studies concerning the safety of use of the additive for...
 - 7.4. Section IV: studies concerning the efficacy of the additive
 - 7.5. Section V: post-market monitoring plan
8. ADDITIVES ALREADY AUTHORISED FOR USE IN FOOD
- 8.1. Section I: summary of the dossier
 - 8.2. Section II: identity, characterisation and conditions of use of the...
 - 8.3. Section III: studies concerning the safety of the additives
 - 8.3.1. Studies concerning the safety of use of the additive for...
 - 8.3.2. Studies concerning the safety of use of the additive for...
 - 8.3.2.1. Food additives for which an ADI is not specified
 - 8.3.2.2. Food additives with an established ADI or UL
 - 8.3.2.3. Food additives for which no ADI is allocated
 - 8.3.3. Studies concerning the safety of use of the additive for...
 - 8.3.4. Studies concerning the safety of use of the additive for...
 - 8.4. Section IV: studies concerning the efficacy of the additive
 - 8.5. Section V: post-market monitoring plan
9. MODIFICATION OF THE AUTHORISATIONS
10. RENEWAL OF AUTHORISATIONS

- 10.1. Section I: summary of the dossier
 - 10.2. Section II: identity, characterisation and conditions of use of the...
 - 10.3. Section III: studies concerning the safety of the additives
11. RE-EVALUATION OF CERTAIN ADDITIVES ALREADY AUTHORISED UNDER DIRECTIVE 70/524/EEC
- 11.1. Section I: summary of the dossier
 - 11.2. Section II: identity, characterisation and conditions of use of the...
 - 11.3. Section III: studies concerning the safety of the additives
 - 11.4. Section IV: studies concerning the efficacy of the additive
 - 11.5. Section V: post-market monitoring plan

ANNEX IV

Categories and definitions of target animals and indication of the minimum duration of efficacy studies

- 1. Table. Animal categories: Pigs
- 2. Table. Animal categories: Poultry
- 3. Table. Animal categories: Bovines (domestic bovine animals including bubalus and...)
- 4. Table. Animal categories: Sheep
- 5. Table. Animal categories: Goats
- 6. Table. Animal categories: Fish
- 7. Table. Animal categories: Rabbits
- 8. Table. Animal Categories: horses

Status: This is the original version (as it was originally adopted).

- (1) [OJ L 268, 18.10.2003, p. 29](#). Regulation as amended by Commission Regulation (EC) No 378/2005 ([OJ L 59, 5.3.2005, p. 68](#)).
- (2) [OJ L 64, 7.3.1987, p. 19](#). Repealed by Regulation (EC) No 1831/2003.
- (3) [OJ L 358, 18.12.1986, p. 1](#). Directive as amended by Directive 2003/65/EC of European Parliament and the Council ([OJ L 230, 16.9.2003, p. 32](#)).
- (4) [OJ L 270, 14.12.1970, p. 1](#). Directive as last amended by Commission Regulation (EC) No 1800/2004 ([OJ L 317, 16.10.2004, p. 37](#)).