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)

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...

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 PART ICULAR 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...

ANNEX IV

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

(**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).