European Food Safety Authority

FEEDAP UNIT

GUIDANCE OF EFSA

Administrative guidance to applicants on the preparation and presentation of applications for authorisation of additives for use in animal nutrition

Issued in September 2008
Revised in December 2009

This document is available on the EFSA website at
www.efsa.europa.eu

For further information, please contact us at FEEDADDITIVES@efsa.europa.eu

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FOREWORD

This document provides guidance on the preparation and presentation of applications for authorisation of the placing on the market and the use of feed additives under Community legislation (Regulation (EC) No 1831/2003 and Regulation (EC) No 429/2008) which are to be evaluated by the European Food Safety Authority (EFSA).

The above-mentioned regulations outline the procedure for authorisation of any feed additive and therefore need to be followed. This guidance document does not replace any of the requirements of the existing guidelines for the assessment of feed additives in animal nutrition, nor the guidelines that may be developed in the future. An overview of the authorisation process for feed additives is presented on the European Commission website.

This guidance document will be updated regularly according to the new legislation and the experience that EFSA will develop in handling applications. Therefore, applicants are advised to always consult the latest version available on the EFSA website.

SCOPE OF THE DOCUMENT

In accordance with Article 7(6) of Regulation (EC) No 1831/2003[1] on additives for use in animal nutrition, EFSA is requested 'to publish detailed guidance to assist the applicant in the preparation and presentation of its application.'

This guidance document follows the scope of Regulation (EC) No 1831/2003 and Regulation (EC) No 429/2008[2] regarding applications for authorisation of a feed additive or a new use of a feed additive (Article 4), re-evaluation of an authorised additive (Article 10), change of terms of authorisation of additives authorised under the framework of Regulation (EC) No 1831/2003 (Article 13) and renewal of authorisations (Article 14).

Regulation (EC) No1831/2003 does not cover the authorisation of products that act as direct or indirect protein sources (bioproteins) and animal feedingstuffs intended for particular nutritional purposes (within the meaning of Directive 93/74/EEC[3]), which are covered by Directive 82/471/EEC[4] and Directive 2008/38/EC,[5] respectively. Additionally, processing aids and veterinary medicinal products as defined in Directive 2001/82/EC,[6] with the exception of coccidiostats and histomonostats used as feed additives, are not covered by that Regulation.

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1 Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p.29. Last amended by Regulation (EC) No 386/2009, OJ L 118, 13.5.2009, p. 66.

2 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 presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1

3 Council Directive 93/74/EEC of 13 September 1993 on feedingstuffs intended for particular nutritional purposes. OJ L 237, 22.09.1993 p. 23

4 Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition. OJ L 213, 21.7.1982, p. 8

5 Commission Directive 2008/38/EC of 5 March 2008 establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes. OJ L 62, 6.03.2008, p. 9

6 Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products. OJ L 311, 28.11.2001 p. 1

1. Authorisation of a feed additive or a new use of a feed additive (Article 4(1) of Regulation (EC) No 1831/2003) or authorisation of existing products (Article 10(2) and 10(7) of Regulation (EC) No 1831/2003)

Any person seeking an authorisation for a feed additive or for a new use of a feed additive, as according to Article 4(1) of Regulation (EC) No 1831/2003, or an authorisation for existing products, as according to Article 10(2) and 10(7) of Regulation (EC) No 1831/2003, shall submit an application to the European Commission in compliance with Article 7 of Regulation (EC) No 1831/2003. The relative documentation and time frame are presented below.

1.1. Documentation

When submitting an application, the following documents and particulars should be provided to the corresponding institutions:

(a) European Commission

- Application form in accordance with Annex I of Regulation (EC) No 429/2008[7]
- Administrative data of the applicant(s)
- Public summary of the dossier
- Detailed summary of the dossier (scientific summary)
- List of the parts of the dossier requested to be treated as confidential (with accompanying justification) and a copy of the corresponding parts of the dossier
- Confirmation that the fee to the CRL has been paid

Those particulars must be sent to the following address:

European Commission
Health and Consumer Protection Directorate-General
Unit D2 Feed
Rue Froissart 101 00/30
B-1049 Brussels (Belgium)

(b) Community Reference Laboratory (CRL)

- Declaration form and accompanying cover letter
- Three samples of the feed additive
- Fee
- Material safety data sheet
- Certificate of identification and analysis
- Public summary of the dossier
- Detailed summary of the dossier (scientific summary)

For information on how to submit the samples, the above-mentioned documentation and pay the fee, please check the CRL website. Applicants should note that Regulation (EC) No

[7] Available at http://ec.europa.eu/food/food/animalnutrition/feedadditives/guidelines_en.htm

885/2009[8] has specific provisions regarding the submission of samples and the payment of the fee to the CRL for certain types of applications.

Those particulars must be sent to the following address:

Community Reference Laboratory for Feed Additives
European Commission - Joint Research Centre
Institute for Reference Materials and Measurements
Retieseweg 111
B-2440 Geel (Belgium)

(c) EFSA

The following information must be sent in the form of 1 paper copy and 2 CD/DVD-ROMs:

- Administrative documents (see Part 1)
- Cover letter accompanying the technical dossier
- Copy of the application form in accordance with Annex I of Regulation (EC) No 429/2008 sent to the European Commission
- Contact details (Annex E)[9]
- Description and conditions of use of the additive (Annex A)
- Completeness check list (Annex B)
- Declaration of conformity between the electronic and paper copies of the dossier
- Technical dossier (see Part 2)
- Confidential parts of the dossier (see Part 3)

Those particulars must be sent to the following address:

European Food Safety Authority
Feed additives applications
Largo N. Palli 5/A
I-43121 Parma (Italy)

1.2. Preparation of the dossier

1) Structure of the dossier

The dossier should be clearly organised with the different parts and sections properly identified both in the paper copy and in the electronic version.

The dossier should contain three parts (Administrative documents, Technical dossier and Confidential parts of the dossier). Each part should correspond to a folder in the electronic version of the dossier.

[8] Commission Regulation (EC) No 885/2009 of 25 September 2009 amending Regulation (EC) No 378/2005 as regards reference samples, fees and the laboratories listed in Annex II. OJ L 254, 26.9.2009, p. 58

[9] The applicant must notify EFSA, the European Commission and the CRL of any change in the contact details during the evaluation process.

The dossier should follow the structure and the naming convention detailed below. When no standard file name is recommended, the name of the file should be descriptive of its contents. Please note that special characters (e.g. # . % ! ? & ( ) [ ] * +) are not allowed in the file names and that file names should contain preferably no more than 32 characters.

It is recommended that one file should be produced for each section of the dossier (except for Section I in which there are four independent files) and for each study report or appendix mentioned in the dossier. Please be aware that PDF files containing more than one section, annex, etc., will not be accepted.

Files should not be more than 20 Mb in size. If for technical reasons more than one file needs to be prepared (i.e. if the final file size is over 20 Mb), the resulting files should be named using consecutive numbers.

Should these indications not be respected, the applicant will be requested to re-submit the electronic dossier with the appropriate files size, name and structure.

Part 1: **Administrative documents**

This part of the dossier should contain all the administrative documents related to the application. The list of documents and the corresponding recommended file names (for the electronic version of the dossier) can be found below.

ADMINISTRATIVE DOCUMENTS

File name	Contents
EFSA_letter.pdf	Cover letter accompanying the dossier
Annex_I.pdf	Copy of the application form in accordance to Annex I of Regulation (EC) No 429/2008 sent to the European Commission
Contact.pdf	Contact details (Annex E)
DescriptAdd.pdf*	Description and conditions of use of the additive (Annex A)
CClist.pdf	Completeness check list (Annex B)
CoIdentity.pdf	Declaration of conformity between the electronic and paper copies of the dossier

* The description and conditions of use of the additive must be submitted in pdf and word formats.

Part 2: Technical dossier

The technical dossier included in an application for the authorisation of a feed additive within the framework of the Regulation (EC) No 1831/2003 should be compiled according to the legislative requirements and according to the format proposed in this guidance document. It should consist of the elements specified in Article 7 of Regulation (EC) No 1831/2003 and detailed in Annex II and Annex III of Regulation (EC) No 429/2008. The technical dossier should follow the sections, numbering and headings presented in Regulation (EC) No 429/2008. When preparing the dossier, applicants should also consider the following EFSA guidance documents:

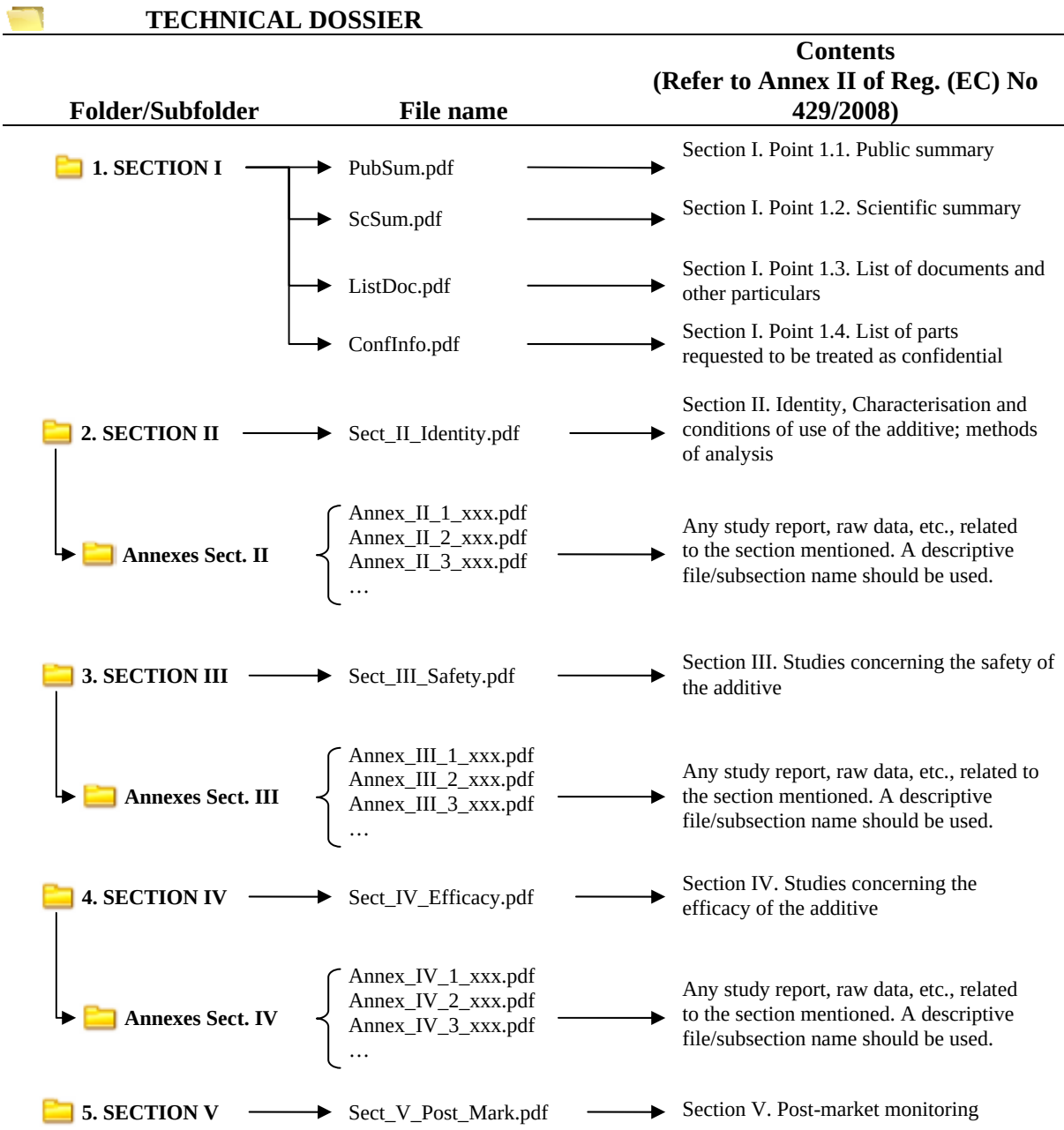
- Guidance for the preparation of dossiers by categories of feed additives: technological, sensory, nutritional, zootechnical, coccidiostats and histomonostats
- Technical guidance: Additives already authorised for use in food

- Technical guidance: Tolerance and efficacy studies in target animals
- Technical guidance: Consumer safety
- Technical guidance: User safety
- Technical guidance: Environmental risk assessment
- Technical guidance: Extrapolation of data from major species to minor species
- Technical guidance: Microbial studies
- Technical guidance: Compatibility of zootechnical microbial additives with other additives showing antimicrobial activity
- Technical guidance: Update of the criteria used in the assessment of bacterial resistance to antibiotics of human or veterinary importance
- Guidance for the re-evaluation of certain additives already authorised under Directive 70/524/EEC
- Qualified presumption of safety (QPS) for micro-organisms used as feed additives (or as source of feed additives)
- Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified micro-organisms and their derived products intended for food and feed use

The dossier should contain all the information required for a complete assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5 of Regulation (EC) No 1831/2003. The dossier should include detailed reports of all studies done and all the raw data of those experimental studies. References and copies of all published scientific data relevant to the evaluation of the dossier should be included. Other documents which provide background information but have no direct relationship with the dossier and can help the Panel members to assess the efficacy or safety of the additive may be included in the appropriate sections. Those reviewing the dossiers should not be required to undertake any additional literature reviews nor assemble or process data to evaluate the dossiers.

Data that the applicant considers confidential may be evidenced (e.g., different font color) in the technical dossier but should not be removed from the technical dossier.

The recommended file names for the electronic version of the technical dossier are shown below.



Part 3: Confidential parts of the dossier

Applicants should submit a copy of the parts of the dossier that they wish to be treated as confidential (see Section I, paragraph 1.4 of Regulation (EC) No 429/2008) to EFSA and to the European Commission as a separate part of the technical dossier. However, technical dossier (Part 2) should contain all the information (not confidential and confidential). Please remember that however data that the applicant considers confidential may be evidenced in the technical dossier (Part 2) but should not be removed from the technical dossier.

The recommended file names for this part of the dossier are shown below. Annexes containing confidential information (in whole or in part) should also be included in the confidential parts of the dossier.

CONFIDENTIAL PARTS

File name	Contents
Sect_II_Identity_Conf.pdf	Confidential information from Section II
Sect_III_Safety_Conf.pdf	Confidential information from Section III
Sect_IV_Efficacy_Conf.pdf	Confidential information from Section IV
Sect_V_Post_Mark_Conf.pdf	Confidential information from Section V
Annex_XX.1_xxx_conf.pdf	Confidential information from any study report, raw data, etc., related to a section mentioned that the applicant wishes to treat as confidential. The same file name as in the Technical dossier should be used, but including the 'conf' suffix.

2) Language

In order to facilitate and speed the processing of the applications and make the scientific assessment more efficient, scientific and technical documentation should preferably be submitted in English. EFSA may ask the applicant to translate the parts of the dossier that would not be submitted in English.

3) Format of the CD/DVD-ROMs

Appropriate labels should be attached to the disk and on the CD/DVD case including the following information: Name of the additive, company, target species (if applicable), date of submission, and disk number (if more than one is submitted per dossier, *disk # of #*).

4) File format

All documentation should be submitted preferably using the portable document format (PDF) in a Windows® environment.

All PDF files should be created using a software that allows reading, printing, word searching and copying from the PDF file into a word processing document with version 7.0 or above of Adobe® Acrobat®.

Specific recommendations for the preparation of electronic files are detailed in Annex D.

Submission of parts or the complete dossier may be acceptable using common word processing formats if they fulfil the same criteria as requested for PDF files.

Submission of datasets (raw data) can be done using other appropriate common electronic formats which may allow their use by the reviewers. (e.g., MS Excel)

Individual animal data, historical control data and any other relevant data or information could be provided as images (e.g., TIFF, JPEG, GIF files).

5) Identification of studies/reports in Section II (identification), Section III (safety) and Section IV efficacy) of the additive

All the studies mentioned in the dossier for Section II (identification), Section III (safety) and Section IV (efficacy) should be identified using a unique ID.

Reference in the dossier to a specific study should be done using the unique ID number for the study and the exact page number.

A complete list of the references included in each section should be presented at the beginning of the corresponding section using the following standard format:

Ref	Date	Authors	Title	Test Facility	Report Number	GLP Compliant	Published (if so, add reference)	Page
III.2.1	2007	Smith et al.	Effect of additive X on the growth of …	Central Research Lab	RN1234	Yes	Smith et al. 2008. *Journal of additive research*, 42: 125-128	III.26

6) Trial protocol data sheet for tolerance and efficacy studies in target animals

For each one of the tolerance and efficacy studies in target animals included in the dossier, the applicant must compile the trial protocol data sheet and have it signed by the study director (see Annex C).

7) Tables and figures

Applicants are encouraged, where possible, to present information in tabular form.

Tables and figures should be inserted in their intended positions in the text where it is feasible to do so and should be numbered with a unique identification number across the dossier.

Portrait (vertical) rather than landscape (horizontal) lay-out for tables and figures should, if possible, be used. It is better not to construct a table covering several pages, as a series of separate single-page tables are easier to follow.

8) Standard units, terms and abbreviations

The International System of Units (SI)[10] should be used in reporting tests and studies. Other units, may be used between parentheses if considered relevant.

In order to avoid confusion, standard technical terms and abbreviations should be used. A concise explanation of each term or abbreviation should be provided in the text when it is used for the first time. In addition, a list of all additional terms and abbreviations should be provided at the beginning of each relevant section.

1.3. Completeness check list

The completeness check list is a document prepared by EFSA for the administrative verification of the completeness of the dossier (see Annex B). It does not substitute in any case for the requirements referred to in the Community regulatory texts in force concerning feed additives, i.e. Regulations (EC) No 1831/2003 and No 429/2008.

[10] Bureau International des Poids et Mesures

This check list should be used by applicants when preparing a dossier to verify that all the particulars and documents that must be submitted to EFSA are provided. It follows the structure of Annex II of Regulation (EC) No 429/2008. The level of detail of the information required varies according to the type of application and/or type of additive. The check list thus allows applicants to identify which information is provided, not provided (to be justified) and/or not relevant.

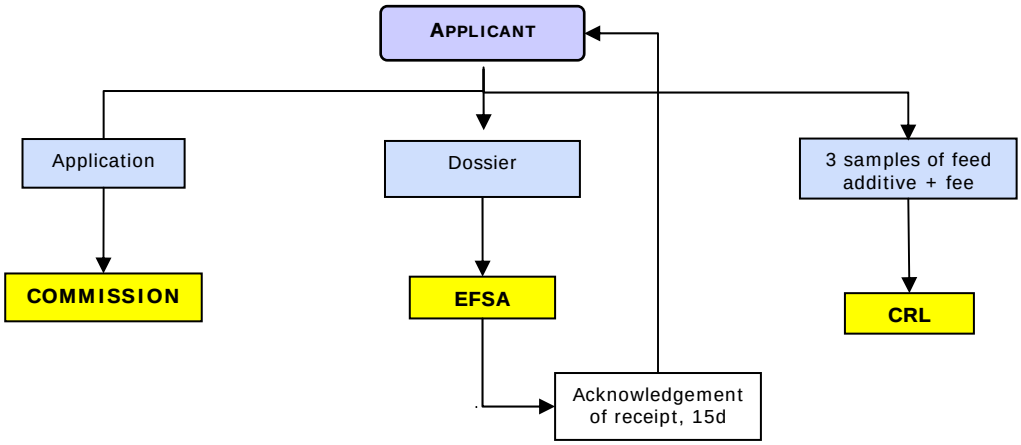
The completion of this check list by the applicant does not replace the administrative verification conducted by EFSA before the dossier is considered valid.

1.4. Procedural steps

1.4.1. Reception of the dossier

1.4.1.1. Reception of the dossier from the applicant

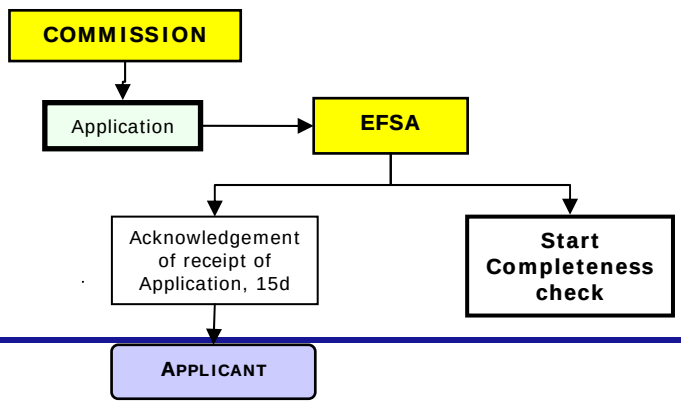
Within 15 days of the reception of the technical dossier and accompanying particulars, EFSA shall acknowledge to the applicant receipt of all the documents submitted to EFSA.



1.4.1.2. Reception of the application from the European Commission

Within 15 days of receipt of an application forwarded by the European Commission, EFSA shall acknowledge to the applicant receipt of the application. The date of receipt of the application by EFSA is the starting point of the completeness check of the dossier (internal administrative procedure).

At this point, the dossier receives a unique reference number in the format FAD-20YY-XXXX. Applicants are invited to use this number for all contacts with EFSA regarding the application of reference.

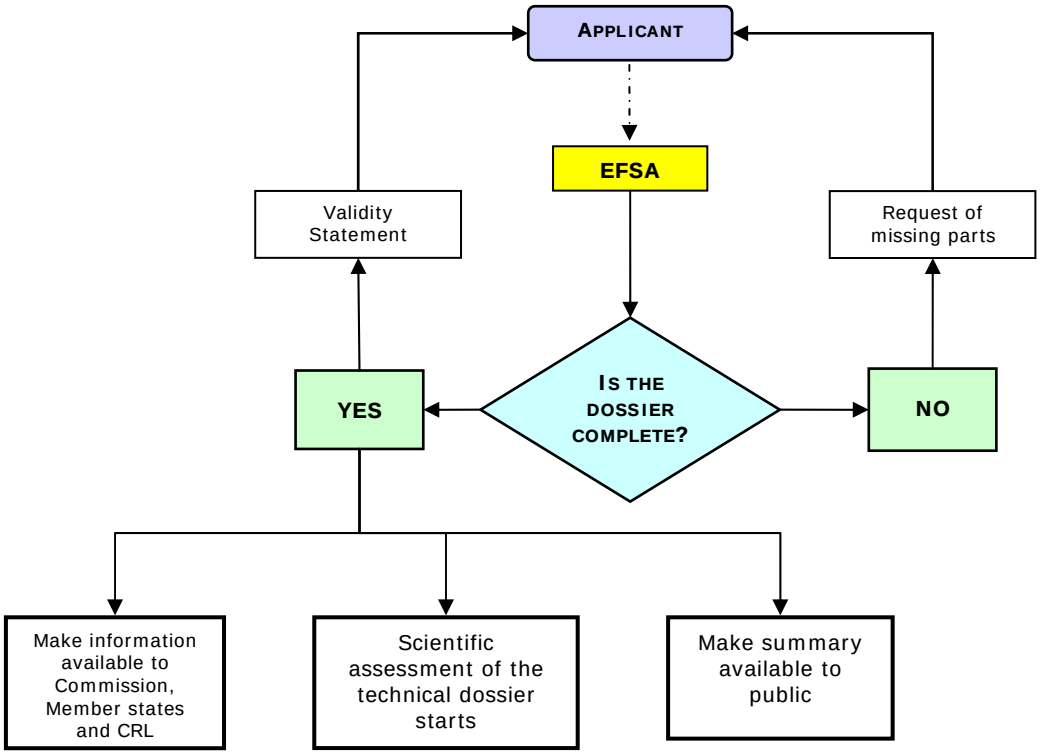


1.4.2. Completeness check / Validation

The completeness check of the dossier is performed maximum within 30 working days from the date of receipt of the application by EFSA.

In case a dossier is considered not complete, EFSA will contact and inform the applicant. EFSA may request the applicant to submit the necessary modifications to the application/dossier in order to fulfil the conditions of validity or may reject the dossier in the present form. The deadline for submitting the missing particulars is usually 30 days. However, this deadline can be extended upon request by the applicant. The missing information should be integrated into the corresponding sections of the dossier and resent to EFSA duly named and completed, first in electronic format by e-mail and then in the form of CD/DVD-ROMs and paper copy. The updated sections will replace the original submitted once the data is considered complete. If the information submitted contains data that should be treated as confidential, this should be clearly specified and a copy of the confidential information should also be submitted in a separate file. Regarding recommended file names for the confidential parts of the dossier please see *Part 2: "Technical dossier "*of this document.

A dossier is considered complete, and therefore the application considered valid by EFSA, when it fulfils the requirements laid down in Regulation (EC) No 1831/2003 and Regulation (EC) No 429/2008 and further detailed in this guidance document. Once the dossier is considered complete, a statement of validity is sent to the applicant. The date of validity is the starting point for the scientific assessment of the dossier. Also, EFSA will make all the information supplied by the applicant available to the European Commission, the CRL and the Member States through the EFSA extranet (ScienceNet).



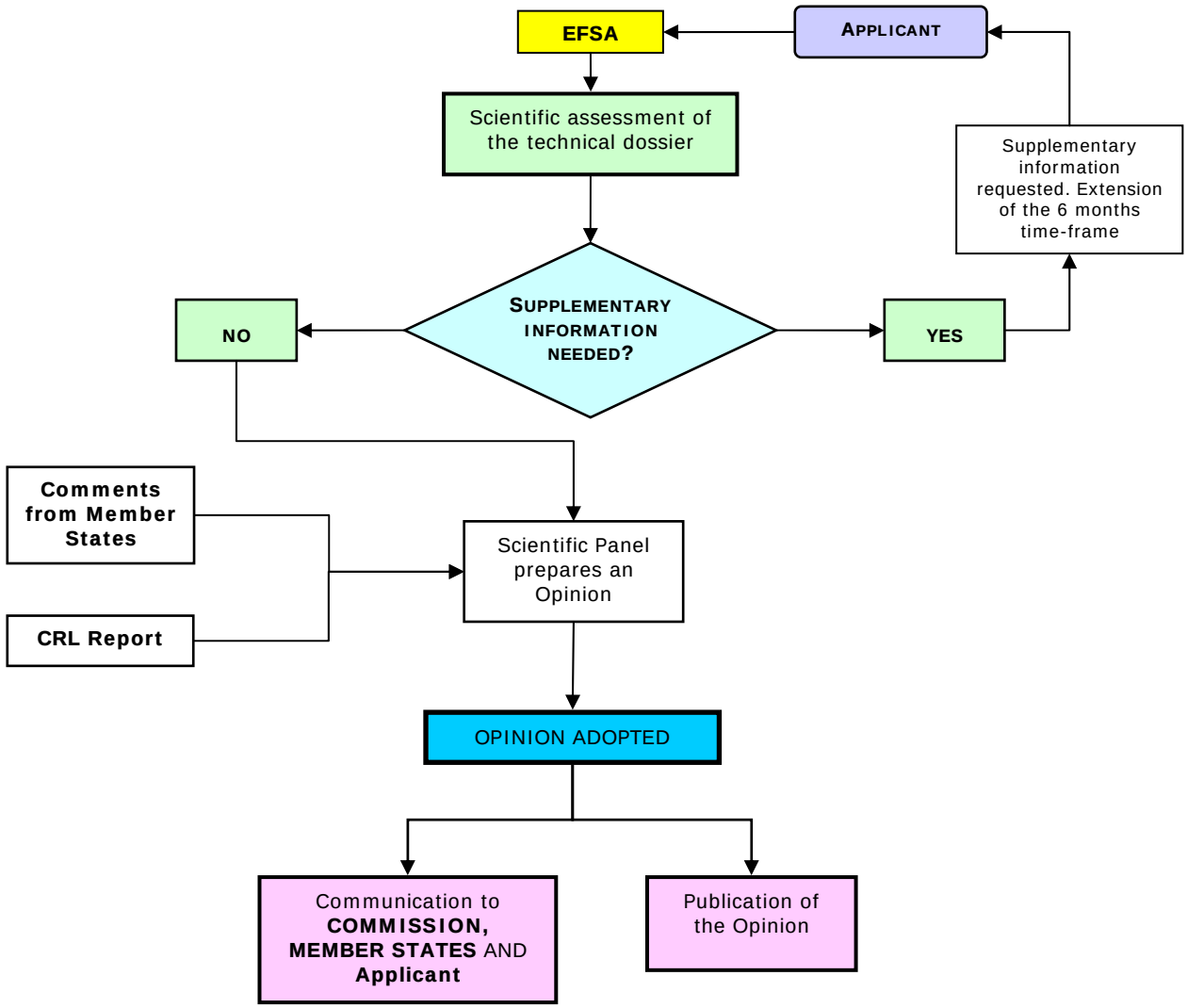
1.4.3. Scientific assessment

The scientific assessment should be completed within six months of the validation of the dossier. During the first three months of the scientific assessment, Member States can send comments to EFSA and the CRL elaborates and sends to EFSA a report on the methods of analysis included in the dossier.

During the scientific evaluation, EFSA may request the applicant to submit supplementary information. In that case, as provided by in Article 8 of Regulation (EC) No 1831/2003, the time limit of six months to deliver an opinion shall be extended. The length of the extension will be specified by EFSA after consultation with the applicant. The deadline for providing the supplementary information is normally 30 working days. However, this deadline may be extended when requested by the applicant and agreed by EFSA.

Documents submitted as a supplement to the original dossier in response to EFSA's request should follow the format requirements presented in this guidance document. If the supplementary information submitted contains data that should be treated as confidential, this should be clearly specified and a copy of the confidential information should also be submitted in a separate file. Regarding recommended file names for the confidential parts of the dossier, please see *Part 2: "Technical dossier "*of this document. One paper copy and two CD-ROMs should be submitted to EFSA, unless otherwise indicated. The applicant should keep additional paper and electronic copies of all information submitted to EFSA readily available in case EFSA would require them.

EFSA will inform, at all stages, the European Commission, the CRL and the Member States of the status of the applications received via the EFSA extranet (ScienceNet).



1.4.4. Adoption and publication of the opinion

After its adoption, the opinion is checked for editorial review and confidentiality following the agreement between the European Commission and the applicant. The summaries of the opinion are translated into French, German and Italian. The opinion and its summaries are commonly published within two weeks time from the date of adoption.

2. Modification of authorisation of a feed additive (Article 13(3) of Regulation (EC) No 1831/2003)

If the holder of an authorisation proposes changing the terms of the authorisation, as according to Article 13(3) of Regulation (EC) No 1831/2003, s/he should do so by submitting an application to the European Commission accompanied by the relevant data supporting the request for the changes, as specified in Annex III (9) of Regulation (EC) No 429/2008.

2.1. Documentation

The following documents and particulars should be provided to the corresponding institutions:

(a) European Commission

- Application form in accordance with Annex I of Regulation (EC) No 429/2008[11]
- Administrative data of the applicant(s)
- Public summary of the dossier
- Detailed summary of the dossier (scientific summary)
- List of the parts of the dossier requested to be treated as confidential (with accompanying justification) and a copy of the corresponding parts of the dossier
- Confirmation that the fee to the CRL has been paid (if applicable)

Those particulars must be sent to the following address:

European Commission
Health and Consumer Protection Directorate-General
Unit D2 Feed
Rue Froissart 101 00/30
B-1049 Brussels (Belgium)

(b) Community Reference Laboratory (CRL)

Applicants should note that Regulation (EC) No 885/2009[12] has specific provisions regarding the submission of samples and the payment of the fee to the CRL for applications for the modification of the terms of authorisation. Therefore, in case of doubt, the applicant is encouraged to consult the CRL website or contact directly the CRL for clarifications on the required documents and particulars that need to be sent. CRL contact: jrc-irmm-crl-feed-additives@ec.europa.eu

Where required, the particulars must be sent to the following address:

Community Reference Laboratory for Feed Additives
European Commission - Joint Research Centre
Institute for Reference Materials and Measurements
Retieseweg 111
B-2440 Geel (Belgium)

The applicant should inform EFSA of the particulars requested by the CRL.

(c) EFSA

The following information must be sent in the form of 1 paper copy and 2 CD/DVD-ROMs.

- Administrative documents (see Part 1)
- Cover letter accompanying the technical dossier
- Copy of the application form in accordance with Annex I of Regulation (EC) No 429/2008 sent to the European Commission

[11] Available at http://ec.europa.eu/food/food/animalnutrition/feedadditives/guidelines_en.htm

[12] Commission Regulation (EC) No 885/2009 of 25 September 2009 amending Regulation (EC) No 378/2005 as regards reference samples, fees and the laboratories listed in Annex II. OJ L 254, 26.9.2009, p. 58

- Contact details (Annex E)[13]
- Description and conditions of use of the additive (Annex A)
- Completeness check list (Annex B)
- Declaration of conformity between the electronic and paper copies of the dossier
- Technical dossier (see Part 2)
- Confidential parts of the dossier (see Part 3)

Those particulars must be sent to the following address:

European Food Safety Authority
Feed additives applications (FEEDAP)
Largo N. Palli 5/A
I-43121 Parma (Italy)

2.2. Preparation of the dossier

Please refer to Section 1.2 of this document.

Note that in the preparation of the technical dossier for the modification of an existing authorisation, the following sections are always required:

SECTION I: Summary of the dossier
SECTION II: Identity, characterisation and conditions of use; Methods of analysis

The applicant should evaluate which of the following sections need to be prepared in order to support the proposed change of terms of the authorisation:

SECTION III: Studies concerning the safety of the additive
SECTION IV: Studies concerning the efficacy of the additive
SECTION V: Post-market monitoring plan

2.3. Completeness check list

Please refer to Section 1.3 of this document.

2.4. Procedural steps

Please refer to Section 1.4 of this document.

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

The authorisation of a feed additive under Regulation (EC) No 1831/2003 is renewable for ten-year periods. An application for renewal shall be sent to the European Commission at the latest one year before the expiry date of the authorisation, as according to Article 14 of Regulation (EC) No 1831/2003.

The conditions required for this type of submissions are set up in Regulation (EC) No 429/2008. Please refer to point 10 of Annex III of the above-mentioned Regulation in order to

[13] The applicant must notify EFSA, the European Commission and the CRL of any change in the contact details of the applicant.

identify the documents and particulars that should be provided to the corresponding institutions.

4. Status of the dossier

Information concerning the status of the dossiers submitted to EFSA as well as the related documents are available through the Register of Questions on the EFSA website.

ANNEX A: DESCRIPTION AND CONDITIONS OF USE OF THE ADDITIVE

This form should be submitted using a common word processing format (e.g. MS Word).

Please note that this proposal is not binding to EFSA.

Additive				
Registration number/EC No/No (if appropriate)				
Category(ies) of additive				
Functional group(s) of additive				
Description				
Composition, description		Chemical formula	Purity criteria (if appropriate)	Method of analysis (if appropriate)
Trade name (if appropriate)				
Name of the holder of authorisation (if appropriate)				
Conditions of use				
Species or category of animal	Maximum Age	Minimum content	Maximum content	Withdrawal period (if appropriate)
		mg or Units of activity or CFU/kg of complete feedingstuffs (select what applicable)		
Other provisions and additional requirements for the labelling				
Specific conditions or restrictions for use (if appropriate)				
Specific conditions or restrictions for handling (if appropriate)				
Post-market monitoring (if appropriate)				
Specific conditions for use in complementary feedingstuffs (if appropriate)				
Maximum Residue Limit (MRL) (if appropriate)				
Marker residue		Species or category of animal	Target tissue(s) or food products	Maximum content in tissues

ANNEX B: COMPLETENESS CHECK LIST

The completeness check list is a document prepared by EFSA for the administrative verification of the completeness of the dossier. It can be used by applicants when building up dossiers in relation to the authorisation of feed additives according to Regulation (EC) No 1831/2003. It does not substitute in any case for the requirements concerning the preparation of a dossier referred to in Regulation (EC) No 1831/2003, Regulation (EC) No 429/2008 and in the EFSA administrative guidance document for applicants.

The completion of this check list by the applicant does not replace the administrative verification conducted by EFSA before the dossier is considered valid.

How to complete the completeness check list?

The first part of the check list concerns the administrative data and structure requirements related to the dossier. The second part concerns the technical dossier and confidential parts of the dossier; it follows the sections, headings and numbering detailed in Annex II of Regulation (EC) No 429/2008.

This check list allows applicants to identify which information has been provided, not provided (to be justified) and/or is not considered relevant, depending on the different parts/sections. Applicants must select the respective boxes. The definitions of the different options are detailed below:

> **Information provided**: The relevant section/subsection/paragraph is required by the relevant guidelines/guidance and the information is provided by the applicant in the relevant section/subsection/paragraph of the dossier.
>
> **Not provided (to be justified)**: The relevant section/subsection/paragraph is required by the guidelines but the information is not provided by the applicant in the relevant section/subsection/paragraph of the dossier. Appropriate justification for the omission of that data needs to be provided in the relevant section/subsection/paragraph of the dossier.
>
> **Not relevant**: The relevant section/subsection/paragraph is not relevant, either because it is not required in Annex III or due to the nature or use of the substance. No specific justification needs to be provided in the dossier.

Comments can be added at the end of each part/section in the apposite window.

The check list must be signed and dated, then sent to EFSA.

All the fields in grey are reserved for EFSA's use and should thus not be filled in by the applicant.

FAD-

ADMINISTRATIVE DATA OF APPLICANT(S)

Name of the applicant or representative	

DESCRIPTION AND PROPOSED CLASSIFICATION OF THE ADDITIVE

Additive name	
Trade name	
Category(-ies)	
Functional group(s)	
Animal species/category(ies)	

TYPE OF APPLICATION

New additive/ New use (Article 4(1) of Regulation (EC) No 1831/2003)	☐
Authorisation of existing product (Article 10(2) or 10(7) of Regulation (EC) No 1831/2003)	☐
Modification of an authorisation (Article 13 (3) of Regulation (EC) No 1831/2003)	☐
Renewal of an authorisation (Article 14 of Regulation (EC) No 1831/2003)	☐

STRUCTURE AND FORMAT REQUIREMENTS

	Information provided	For EFSA use
Dossier structured in three parts		
Administrative documents	☐	☐
Technical dossier	☐	☐
Confidential parts	☐	☐
One file per section, report, etc	☐	☐
Files smaller than 20 MB	☐	☐
Word searchable	☐	☐
Not password protected	☐	☐
2 CD/DVD-ROMs	☐	☐
1 Paper copy	☐	☐

Comments [max 500 characters]
For EFSA use

ADMINISTRATIVE DOCUMENTS		
	Information provided	**For EFSA use**
Cover letter accompanying the dossier	☐	☐
Copy of the application form in accordance with Annex I of Regulation (EC) No 429/2008	☐	☐
Contact details (Annex E)	☐	☐
Description and conditions of use of the additive (pdf and doc format) (Annex A)	☐	☐
Declaration of conformity between the electronic and paper copies	☐	☐

Comments [max 500 characters]
For EFSA use

TECHNICAL DOSSIER

Section I. SUMMARY OF THE DOSSIER

	Information provided	Not relevant	For EFSA use
1.1 Public Summary			
(a) Name of the applicant(s)	☐	☐	☐
(b) Identification of the feed additive			
• Name of the additive	☐	☐	☐
• Proposed classification by category and functional group	☐	☐	☐
• Target species/animal categories and doses	☐	☐	☐
(c) Method of production and method of analysis			
• Manufacturing process	☐	☐	☐
• General procedures of the analytical methods for the official controls of the additive	☐	☐	☐
- in premixtures	☐	☐	☐
- in feedingstuffs	☐	☐	☐
- or its metabolites in food (if appropriate)	☐	☐	☐
(d) (Conclusions of the) Studies on safety and efficacy of the additive	☐	☐	☐
(e) Proposed conditions for use			
• Levels of use in water or feed	☐	☐	☐
• Detailed conditions of use in complementary feedingstuffs	☐	☐	☐
• Other methods of administration	☐	☐	☐
• Any specific condition for use (e.g. incompatibilities)	☐	☐	☐
• Labelling requirements	☐	☐	☐
• Animal species	☐	☐	☐
(f) A proposal for post-market monitoring	☐	☐	☐
The public summary does not contain any confidential information	☐	☐	☐
1.2 Scientific summary of the dossier	☐	☐	☐
1.3 List of documents and other particulars (Index)	☐	☐	☐
1.4 List of confidential volumes and pages of the dossier	☐	☐	☐

Comments [max 500 characters]
For EFSA use

Section II: IDENTITY, CHARACTERISATION AND CONDITIONS OF USE OF THE ADDITIVE; METHODS OF ANALYSIS				
	Information			For EFSA use
	Provided	Not provided	Not relevant	
2.1 Identity of the additive				
2.1.1 Name of the additive	☐	☐	☐	☐
2.1.2 Proposal for classification				
By category and functional group	☐	☐	☐	☐
Data from other uses	☐	☐	☐	☐
Other authorisations	☐	☐	☐	☐
2.1.3 Qualitative and quantitative composition of the additive				
Active substance(s)/agent(s) and all other components (% by weight)	☐	☐	☐	☐
Batch to batch variations of the active substance(s)/ agent(s)	☐	☐	☐	☐
In-house identifiers list and statement of identity with final product	☐	☐	☐	☐
2.1.4 Purity	☐	☐	☐	☐
2.1.5 Physical state of each form of the product				
For solid preparations				
- Particle size distribution	☐	☐	☐	☐
- Particle shape	☐	☐	☐	☐
- Density	☐	☐	☐	☐
- Bulk density	☐	☐	☐	☐
- Dusting potential	☐	☐	☐	☐
- Other characteristics	☐	☐	☐	☐
For liquid preparations				
- Viscosity	☐	☐	☐	☐
- Surface tension	☐	☐	☐	☐
Solubility/dispersion in water	☐	☐	☐	☐

Comments [max 500 characters]
For EFSA use

Section II: IDENTITY, CHARACTERISATION AND CONDITIONS OF USE OF THE ADDITIVE; METHODS OF ANALYSIS				
	Information			For EFSA use
	Provided	Not provided	Not relevant	
2.2 Characterisation of the active substance(s)/ agent(s)				
2.2.1 Description				
Qualitative description				
For chemically well defined substances:	☐	☐	☐	☐
Generic name/ chemical name/ IUPAC/ CAS number	☐	☐	☐	☐
Structural formula, molecular formula and weight	☐	☐	☐	☐
For flavourings chemically defined: FLAVIS N° and chemical group	☐	☐	☐	☐
For plant extracts: phytochemical markers	☐	☐	☐	☐
For mixtures: major constituents, marker compounds	☐	☐	☐	☐
For enzymes: Number and/or systematic name	☐	☐	☐	☐
For micro-organisms (as a product or production strain)	☐	☐	☐	☐
Name and taxonomic classification (ICN)	☐	☐	☐	☐
History of modifications	☐	☐	☐	☐
Certificate of deposition	☐	☐	☐	☐
Morphological, physiological and molecular characteristics for identification	☐	☐	☐	☐
Means to confirm genetic stability	☐	☐	☐	☐
For GMOs	☐	☐	☐	☐
Description of the genetic modifications	☐	☐	☐	☐
Unique identifier Reg. (EC) No 65/2004	☐	☐	☐	☐
Origin	☐	☐	☐	☐
Biological origin of each enzyme activity	☐	☐	☐	☐
Microbial origin of chemical substances produced by fermentation	☐	☐	☐	☐
Purity	☐	☐	☐	☐
Relevant characteristics	☐	☐	☐	☐
2.2.2 Relevant properties				
Chemical substances:				
Physical and chemical properties	☐	☐	☐	☐
For fermentation substances: Absence of antimicrobial activities	☐	☐	☐	☐
Micro-organisms				
Toxins and virulence factors	☐	☐	☐	☐
Antibiotic production and resistance	☐	☐	☐	☐

Comments [max 500 characters]
For EFSA use

Section II:	IDENTITY, CHARACTERISATION AND CONDITIONS OF USE OF THE ADDITIVE; METHODS OF ANALYSIS				
		Information			For EFSA use
		Provided	Not provided	Not relevant	
2.3	**Manufacturing process including any specific processing procedure**				
	Material Safety Data Sheet of the chemicals used to produce the additive	☐	☐	☐	☐
2.3.1	**Active substance(s)/agent(s)**				
	Production process	☐	☐	☐	☐
	Media used (fermentation and/or cultivation)	☐	☐	☐	☐
	Purification methods	☐	☐	☐	☐
2.3.2	**Additive**				
	Manufacturing process	☐	☐	☐	☐
2.4	**Physico-chemical and technological properties of the additive**				
2.4.1	**Stability**				
	of each formulation of the additive/shelf-life	☐	☐	☐	☐
	in premixtures	☐	☐	☐	☐
	in feedingstuffs	☐	☐	☐	☐
	in water	☐	☐	☐	☐
2.4.2	**Homogeneity**				
	in premixtures	☐	☐	☐	☐
	in feedingstuffs	☐	☐	☐	☐
	in water	☐	☐	☐	☐
2.4.3	**Other characteristics**	☐	☐	☐	☐
2.4.4	**Physico-chemical incompatibilities or interactions**	☐	☐	☐	☐

Comments [max 500 characters]
For EFSA use

Section II:	IDENTITY, CHARACTERISATION AND CONDITIONS OF USE OF THE ADDITIVE; METHODS OF ANALYSIS				
		Information			For EFSA use
		Provided	Not provided	Not relevant	
2.5	**Conditions of use of the additive**				
2.5.1	**Proposed mode of use in animal nutrition**				
	Animal species / categories/ age group/ production stage	☐	☐	☐	☐
	Proposed use (feed, water)	☐	☐	☐	☐
	Contraindications	☐	☐	☐	☐
	Proposed method of administration and level of inclusion	☐	☐	☐	☐
	Proposed dose in complete feed	☐	☐	☐	☐
	Duration of administration	☐	☐	☐	☐
	Proposed withdrawal period	☐	☐	☐	☐
	Use in the complementary feedingstuffs	☐	☐	☐	☐
2.5.2	**Information related to users/workers safety**				
	For chemical substances proposed MSDS	☐	☐	☐	☐
	For micro-organisms:				
	Classification according to Directive 2000/54/EC	☐	☐	☐	☐
	Protective measures for workers	☐	☐	☐	☐
2.5.3	**Labelling requirements**	☐	☐	☐	☐
	General requirements according to Article 16 of Regulation (EC) No 1831/2003	☐	☐	☐	☐
	Specific labelling requirements	☐	☐	☐	☐
	Specific conditions of use and handling	☐	☐	☐	☐
	Instructions for proper use	☐	☐	☐	☐

Comments [max 500 characters]
For EFSA use

Section II:	IDENTITY, CHARACTERISATION AND CONDITIONS OF USE OF THE ADDITIVE; METHODS OF ANALYSIS				
		Information			For EFSA use
		Provided	Not provided	Not relevant	
2.6	**Methods of analysis and reference samples**				
2.6.1	**Protocol of the methods of analysis for the active substance according to ISO 78:2 format**				
	In the additive	☐	☐	☐	☐
	In premixtures	☐	☐	☐	☐
	In feedingstuffs	☐	☐	☐	☐
	In water	☐	☐	☐	☐
	Validation reports (ring test, in house)				
	In the additive	☐	☐	☐	☐
	In premixtures	☐	☐	☐	☐
	In feedingstuffs	☐	☐	☐	☐
	In water	☐	☐	☐	☐
	Verification reports of in-house validated methods of the active substance				
	In the additive	☐	☐	☐	☐
	In premixtures	☐	☐	☐	☐
	In feedingstuffs	☐	☐	☐	☐
	In water	☐	☐	☐	☐
2.6.2	**Protocol of the methods of analysis for the determination of the residues of the additive or of its metabolites according to ISO 78:2 format**				
	Validation report	☐	☐	☐	☐
	Verification report of in-house validated method of analysis for the determination of the residues of the additive or of its metabolites	☐	☐	☐	☐
2.6.3	**Methods of analysis relating to the identity and characterization of the additive**				
	(2.1.3.) Qualitative & quantitative composition	☐	☐	☐	☐
	(2.1.4.) Purity (determ. active substance)	☐	☐	☐	☐
	(2.1.5.) Physical state of the additive	☐	☐	☐	☐
	(2.2.2.) Relevant properties	☐	☐	☐	☐
	(2.4.1.) Stability of the additive	☐	☐	☐	☐
	(2.4.2.) Homogeneity	☐	☐	☐	☐
	(2.4.3.) Other characteristics	☐	☐	☐	☐
	(2.3.4.) Physico-chemical Incompatibilities or Interactions	☐	☐	☐	☐
	Index of the section	☐	☐		☐
	Copy of all studies and raw data	☐	☐	☐	☐

Comments [max 500 characters]
For EFSA use

Section III: STUDIES CONCERNING THE SAFETY OF THE ADDITIVE				
	Information			For EFSA use
	Provided	Not provided	Not relevant	
3.1 Studies concerning the safety of use of the additive for the target animals				
3.1.1 Tolerance studies for the target species	☐	☐	☐	☐
Trial Protocol Data Sheet	☐	☐	☐	☐
3.1.2 Microbial studies	☐	☐	☐	☐
Copy of all studies and raw data	☐	☐	☐	☐

Comments [max 500 characters]:
For EFSA use

	Information			For EFSA use
	Provided	Not provided	Not relevant	
3.2 Studies concerning the safety of use of the additive for consumers				
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	☐	☐	☐	☐
3.2.2.5 Reproduction toxicity studies	☐	☐	☐	☐
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 Acceptable Daily Intake (ADI)	☐	☐	☐	☐
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	☐	☐	☐	☐
Copy of all studies and raw data	☐	☐	☐	☐
Original reports signed by study director	☐	☐	☐	☐

Comments [max 500 characters]:
For EFSA use

Section III: STUDIES CONCERNING THE SAFETY OF THE ADDITIVE				
	Information			For EFSA use
	Provided	Not provided	Not relevant	
3.3 Studies concerning the safety of use of the additive for users/workers				
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	☐	☐	☐	☐
Copy of all studies and raw data	☐	☐	☐	☐
Original reports signed by study director	☐	☐	☐	☐

Comments [max 500 characters]:
For EFSA use

	Information			For EFSA use
	Provided	Not provided	Not relevant	
3.4 Studies concerning the safety of use of the additive for the environment				
3.4.1 Phase I assessment	☐	☐	☐	☐
3.4.2 Phase II assessment	☐	☐	☐	☐
Copy of all studies and raw data	☐	☐	☐	☐
Original reports signed by study director	☐	☐	☐	☐

Comments [max 500 characters]:
For EFSA use

Index of the section	☐	☐		☐

Section IV: STUDIES CONCERNING THE EFFICACY OF THE ADDITIVE	Information			For EFSA use
	Provided	Not provided	Not relevant	
Efficacy studies	☐	☐	☐	☐
Trial Protocol Data Sheet	☐	☐	☐	☐
Biological or chemical interactions	☐	☐	☐	☐
4.6 Studies on quality of animal products	☐	☐	☐	☐
Copy of all studies and raw data	☐	☐	☐	☐
Original reports signed by study director	☐	☐	☐	☐
Index of the section	☐	☐		☐

Comments [max 500 characters]:
For EFSA use

Section V: POST-MARKET MONITORING	Information			For EFSA use
	Provided	Not provided	Not relevant	
Proposal for post-market monitoring	☐	☐	☐	☐

Comments [max 500 characters]:
For EFSA use

CONFIDENTIAL PARTS OF THE DOSSIER	Information		For EFSA use
	Provided	Not relevant	
Copy of the parts of the dossier to be treated as confidential	☐	☐	☐

Comments [max 500 characters]:
For EFSA use

Date	Signature of applicant or representative

ANNEX C: TRIAL PROTOCOL DATA SHEET

This trial protocol data sheet should be added to each trial report concerning tolerance or efficacy of the additive for the target animal. It should be filled in by the applicant and signed by the study director.

For terrestrial animals

Identification of the additive:	Batch number:
Trial ID:	Location:
Start date and exact duration of the study:	
Number of treatment groups (+ control(s)):	Replicates per group:
Total number of animals:	Animals per replicate:
Dose(s) of the additive/active substance(s)/agent(s) (mg or Units of activity or CFU/kg complete feed or L water) Intended: Analysed: † Substances used for comparative purposes: Intended dose: Analysed:	
Animal species/category: Breed: Identification procedure: Sex: Age at start: Body weight at start: Physiological stage: General health:	
Additional information for field trials:	
Location and size of herd or flock: Feeding and rearing conditions: Method of feeding:	
Diets (type(s)): Presentation of the diet: Mash ☐ Pellet ☐ Extruded ☐ Other Composition (main feedingstuffs): Nutrient content (relevant nutrients and energy content) Intended values: Analysed values:	
Date and nature of the examinations performed: Method(s) of statistical evaluation used: Therapeutic/preventive treatments (reason, timing, kind, duration): Timing and prevalence of any undesirable consequences of treatment:	
Date	Signature Study Director or Signature of applicant or representative

† In case the concentration of the additive in complete feed/water may reflect insufficient accuracy, the dose of the additive can be given per animal/day or mg/kg body weight or as concentration in complementary feed.

For aquatic animals

Identification of the additive:	Batch number:
Trial ID:	Location:
Start date and exact duration of the study:	
Number of treatment groups (+ control(s)):	Replicates per group:
Total number of animals:	Animals per replicate:
Dose(s) of the additive/active substance(s)/agent(s) (mg, Units of activity, CFU/kg complete feed or L water) Intended: Analysed: † Substances used for comparative purposes: Intended dose: Analysed:	
Route of administration:	
Animal species/category: Colloquial name: Latin binomial: Breed: Identification procedure: Sex*: Age at start: Body weight at start: Physiological stage: General health**: Fork length at start: Lighting conditions: Water quality including temperature, salinity, O_2 and CO_2:	
Additional information for field trials:	
Location, size and number of tanks or pens at the farm, production volume: Feeding and rearing conditions: Method of feeding:	
Diets (type(s)): Presentation of the diet: Mash ☐ Pellet ☐ Extruded ☐ Live feed ☐ Other Composition (main feedingstuffs): Nutrient content (relevant nutrients and energy content of the feed) Intended values: Analysed values:	
Date and nature of the examinations performed: Response measures for efficacy and tolerance: Method(s) of statistical evaluation used: Therapeutic/preventive treatments (reason, timing, kind, duration): Timing and prevalence of any undesirable consequences of treatment:	
Date	Signature Study Director or Signature of applicant or representative

† In case the concentration of the additive in complete feed/water may reflect insufficient accuracy, the dose of the additive can be given per animal/day or mg/kg body weight or as concentration in complementary feed.

* Where possible

** Certified by a veterinary

ANNEX D: PREPARATION OF ELECTRONIC FILES

This document is intended to assist applicants in preparing PDF files for the compilation of technical dossiers. The following recommendations are meant to help applicants in creating files that are compatible with EFSA's current information technology capabilities and to ensure the confidentiality, integrity, security and authenticity of the data submitted to EFSA for evaluation of feed additives dossiers.

Documents submitted in electronic format should:

- enable the user to easily view a clear and legible copy of the information;
- allow the user to search for specific words or phrases within the document submitted;
- enable the user to print each document page by page, as if it had been provided on paper, maintaining fonts, special orientations, table formats, and page numbers;
- include a well-structured table of contents and allow the user to navigate easily through the submission;
- allow the user to copy text, images and data electronically into other common software formats.

Therefore, the recommended format for electronic files is portable document format (PDF). PDF is an open, published format created by Adobe Systems Inc. It is not necessary to use a product from Adobe or from any specific company to produce PDF documents (free PDF creators are available). PDF has been accepted as a standard for providing documents in electronic format by the International Conference on Harmonisation (ICH).

The following recommendations will help the applicant create PDF files that facilitate the review process by EFSA, its scientific experts, anyone commissioned for the evaluation of the documentation and those involved in the authorisation process, including the European Commission.

Version

EFSA should be able to read all PDF files with Acrobat Reader® version 7.0 and above with the search plug in. No additional software should be required to read and navigate the PDF files.

To ensure that PDF files can be accessed efficiently, PDF files should be no larger than 20 Mb. PDF files should be optimized for fast web view.

Fonts

All fonts used in the document should be embedded in the PDF files to ensure that those fonts will always be available to the reviewer. When embedding fonts, all the characters for the font should be embedded, not just a subset of the fonts being used in the document. Embedding fonts requires additional computer storage space. To help and limit the storage space taken by embedding fonts, applicants are encouraged to limit the number of fonts used in each document: use only True Type or Adobe Type 1 fonts and avoid customized fonts.

Recommended font point sizes are 11-12 for normal text, 9-10 for tables and 10 for footnotes. The recommended font colour is black. Blue font can be used for hypertext links.

Page format and numbering

The print area for pages should fit on DIN A4 sheet of paper with sufficient margins. Pages should be properly oriented to reduce the effort of rotating pages. The page orientation of landscape pages should be set to landscape prior to saving the PDF document in final form.

All pages in the dossier should be numbered using a unique page ID. In order to create this unique page ID, numeration should re-start at the beginning of each section, and should include the section number (using roman numerals) and the page number.

Page headings detailing the section number, additive name, target species and date of submission are encouraged.

Source of electronic document

Whenever it is possible, PDF documents should be created from an electronic source document in order to guarantee the quality of the document. PDF documents produced by scanning paper documents are usually of lower quality, making it difficult to read. Moreover, it typically does not allow word search or copy and paste text for editing in other documents. They should be avoided if at all possible. If optical character recognition (OCR) software is used, the resulting converted text should be verified to be an accurate conversion of the original. We recommend saving the PDF file as image + text.

Documents that are available only in paper should be scanned at resolutions that will ensure the pages are legible both on the computer screen and when printed. Normally 600 dpi gives good results without compromising file size. After scanning, re-sampling to a lower resolution should be avoided.

Paper documents and photographs containing handwritten notes should be scanned at 600 dpi. If black and white photos are submitted, consider 8-bit grey scale images. If colour photos are submitted, consider 24-bit RGB images. A captured image should not be subjected to non-uniform scaling (i.e., sizing). High-pressure liquid chromatography or similar images should be scanned at 300 dpi.

Applicants should validate the quality of the renditions

Index, hypertext linking and bookmarks

There should be a general index for the dossier, included in Section I, detailing the different sections and subsections, indicating the file name and page number. Additionally, each section should have an index, identifying clearly the different subsections. Every report in sections III and IV should have an index entry.

To improve navigation through PDF documents, the use of bookmarks and hypertext links should be used. Hypertext links can be designated by rectangles using thin lines or by blue text. In general, bookmarks and hypertext links should be provided for each item listed in the index including all tables, figures, publications, other references and appendices. These bookmarks and hypertext links are essential for the efficient navigation through the documents.

Security

The electronic files should not be password-protected or include any security settings that may interfere with the process of assessment by the reviewers. For instance, printing, selecting and copying text and graphics and saving should be possible for all files.

ANNEX E: CONTACT DETAILS

Administrative data of applicant(s) for submitting an application for authorisation of a feed additive under Regulation (EC) No 1831/2003[14]

1- **Applicant company or person[15]**
   a. **Name of the applicant or company:**
   b. **Address**
      i. **street, number:**
      ii. **post code:**
      iii. **city/town:**
      iv. **country:**
   c. **Telephone:**
   d. **Fax:**
   e. **E-mail:**

2- **Contact person[16] (for all correspondence with Commission, Authority and CRL)**
   a. **Name of contact person:**
   b. **Company** (if different than that of the applicant)**:**
   c. **Position:**
   d. **Address**
      i. **street, number:**
      ii. **post code:**
      iii. **city/town:**
      iv. **country:**
   e. **Telephone:**
   f. **Fax:**
   g. **E-mail:**

[14] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p.29

[15] According to Article 4(3) of Regulation (EC) No 1831/2003

[16] The applicant must notify EFSA, the European Commission and the CRL of any change in the contact details during the evaluation process.