TECHNICAL REPORT

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Administrative guidance on the preparation of applications for authorisation of additives for use in animal nutrition

European Food Safety Authority

Abstract

This document provides guidance to applicants submitting applications for authorisation of additives for use in animal nutrition within the scope of Regulation (EC) No 1831/2003 and Commission Regulation (EC) No 429/2008, which are to be evaluated by EFSA. It describes the administrative requirements for the preparation and submission of the dossier to support an application for a new authorisation, for the modification or the renewal of an existing authorisation of a feed additive.

The procedure and the associated timelines for handling applications for authorisation, from their submission to the adoption and publication of the EFSA scientific opinion are also described.

The document ultimately presents the different possibilities to interact with EFSA staff and the support initiatives available during the different stages of the application life-cycle.

Key words: Application, submission, feed additives, animal nutrition, Regulation (EC) No 1831/2003, Commission Regulation (EC) No 429/2008.

Requestor: European Food Safety Authority

Question number: EFSA-Q-2009-00981

Correspondence: apdesk.applications@efsa.europa.eu

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Summary

This document provides guidance to applicants submitting applications for the authorisation of additives for use in animal nutrition (hereinafter referred to as "feed additive") in the European Union within the scope of Regulation (EC) No 1831/2003[1] and Commission Regulation (EC) No 429/2008[2].

The present guidance document consists of three main chapters, three appendixes and one annex:

- Chapter 1. *Introduction* provides the Background and Terms of Reference for the publication of this guidance document
- Chapter 2. *Guidance* describes the procedure, the associated timelines and the documentation to be provided for an application submitted for the authorisation of a feed additive, and for the modification or the renewal of an existing authorisation of a feed additive
- Chapter 3. *Interaction with EFSA staff* provides information on the different possibilities to interact with EFSA staff during the life-cycle of the application, from the reception of the application to the adoption and publication of the EFSA scientific opinion
- Appendices A to C provide forms to be used by applicants for presenting part of the information required for the application.

  Appendix A includes the forms for the reporting of safety and efficacy studies on target animals.

  Appendix B corresponds to the completeness checklist. It supports applicants in the preparation of the dossier and helps them to verify that all information required for the application is included in the dossier, or its omission is justified.

  Appendix C should be used to provide administrative data of the applicant and the contact details of the person responsible for the application.
- Annex A contains the list of modifications to this guidance documents since its first publication.

This administrative guidance will be updated, if needed, in accordance with relevant changes of the sectoral legislation and/or guidance documents.

[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. 29–43

[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 the presentation of applications and the assessment and the authorisation of feed additives, OJ L 133, 22.5.2008, p. 1–65

Table of contents

1. Introduction

1.1. Background and Terms of Reference as provided by EFSA

Regulation (EC) No 1831/2003 describes the procedure for applications on additives for use in animal nutrition in the European Union (EU). The rules for implementation of that Regulation and the detailed procedures to be followed for the preparation and the presentation of applications and technical dossiers for authorisation have been established by Commission Regulation (EC) No 429/2008.

In accordance with Article 7(6) of Regulation (EC) No 1831/2003 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.

1.2. Interpretation of the Terms of Reference

Since 2013, EFSA has been implementing a project to develop a customer-oriented approach for regulated products[3] aiming at supporting applicants and other stakeholders during the whole life-cycle of applications for regulated products. In this context, EFSA updated the administrative guidance on the preparation and presentation of applications for authorisation of additives for use in animal nutrition, in order to provide applicants with updated and detailed information as regards the procedure for submitting an application, the format of the dossier and the handling of the application by EFSA. It aims at improving the understanding of the requirements for applications and the services in place in EFSA during the life-cycle of the applications, from submission to adoption and publication of the EFSA scientific opinion.

This guidance document follows the scope of Regulation (EC) No 1831/2003 and Commission Regulation (EC) No 429/2008 regarding applications for authorisation of a feed additive or a new use of a feed additive (Article 4), 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)[4].

This document is to be read in conjunction with the above-mentioned Regulations. In case of discrepancy between the content of this document and a provision of an applicable legal act, the latter prevails.

For the purpose of this guidance document, an "applicant" means any legal or natural person (e.g. individuals, business operators, industry associations, consultancy companies), based within the EU or having a representative in the EU, who has submitted an application.

EFSA will update this document, if needed, in line with relevant changes of the legislation and/or guidance documents and according to the experience gained in the handling and assessment of applications on feed additives. Therefore, applicants are advised to always consult the latest published version of this document available on the EFSA website[5].

[3] EFSA REPRO Customer oriented approach mandate: http://registerofquestions.efsa.europa.eu/roqFrontend/mandateLoader?mandate=M-2014-0106

[4] The terms for submitting application for the re-evaluation of an authorised additive pursuant to Article 10 of Regulation (EC) No 1831/2003 are expired, therefore the present version of this guidance document does not contain any longer information on submission of applications under Article 10.

[5] http://www.efsa.europa.eu/en/applications/feedadditives/regulationsandguidance

2. Guidance

Procedure for handling applications on additives for use in animal nutrition

The various steps and estimated timelines of the procedure for handling applications for authorisation of additives for use in animal nutrition are presented in Figure 1. The workflow starts from the submission of an application to the European Commission, followed by its reception and assessment by EFSA, until the adoption by the EFSA Panel on additives and products or substances used in animal feed (FEEDAP), and the publication of the scientific opinion.

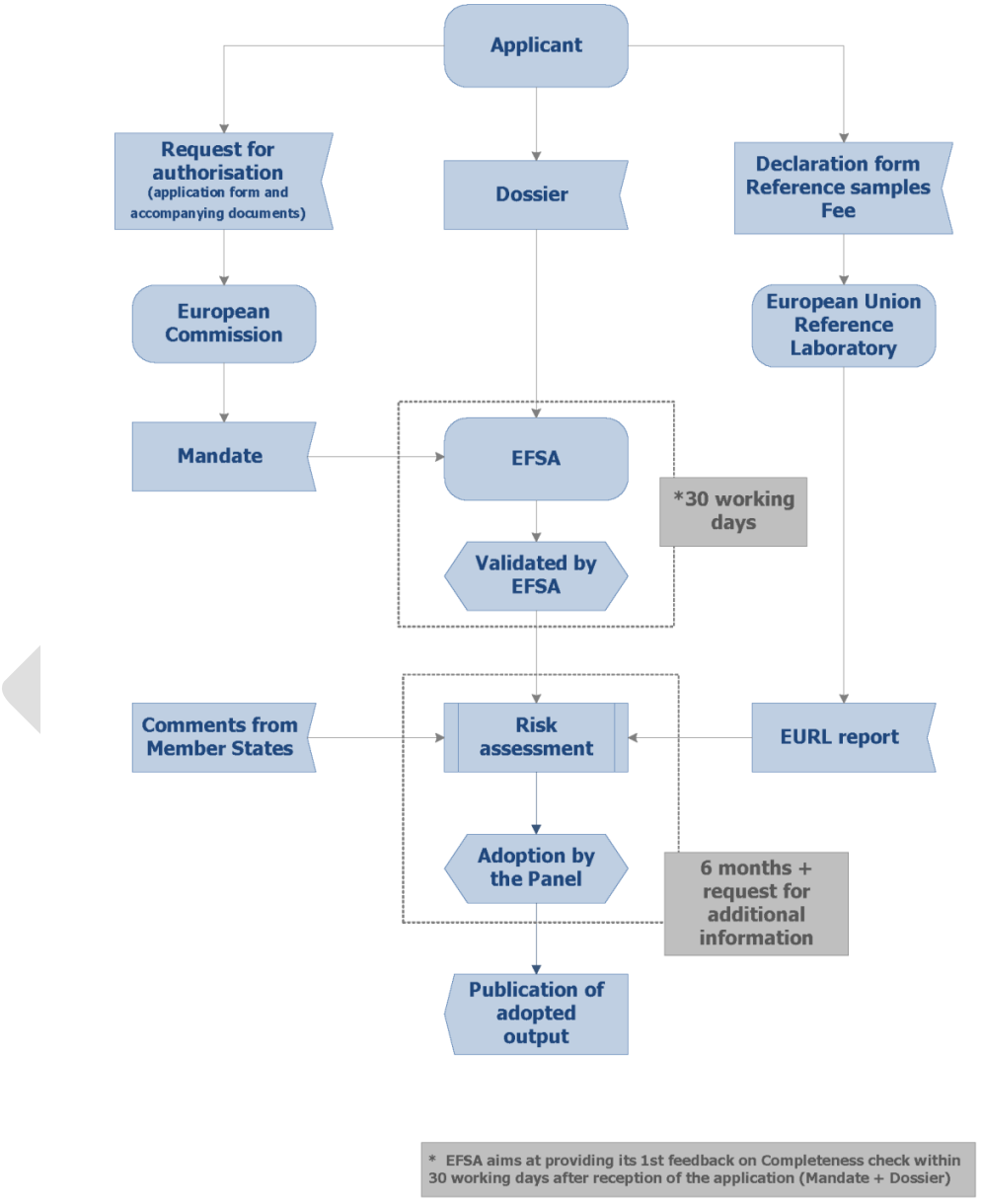

Figure 1: Applications procedure for additives for use in animal nutrition submitted under Regulation (EC) No 1831/2003

Overview of the main preliminary actions related to the preparation of an application for authorisation of a feed additive

Before starting to prepare an application for the authorisation of a feed additive, applicants are strongly advised to check the list below concerning the preliminary actions to be considered in order to correctly submit an application.

- ✓ Consult the animal feed section on the European Commission (EC) website for information on the regulatory framework and the authorisation process for feed additives: https://ec.europa.eu/food/safety/animal-feed_en

- ✓ In case of questions on the authorisation process and for any doubt on the need to submit an application for authorisation, seek confirmation from the EC: sante-consult-e5@ec.europa.eu; SANTE-ANIMAL-NUTRITION@ec.europa.eu

- ✓ If an application on a feed additive has actually to be submitted, consult the EFSA administrative and scientific guidance documents on feed additives for information on how to prepare the dossier supporting the application: http://www.efsa.europa.eu/en/applications/feedadditives/regulationsandguidance

- ✓ In case of doubt on the requirements described in the EFSA guidance documents, ask for clarification to EFSA using the Applications helpdesk webform: https://www.efsa.europa.eu/en/applicationshelpdesk/askaquestion

- ✓ Prepare and submit the application

- ✓ Consult the 'EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products' for an overview of the support initiatives provided by EFSA to applicants: http://www.efsa.europa.eu/en/supporting/pub/1025e

Specific indications on how to prepare and submit the application are provided in the following sections of the guidance document (see in particular Sections 2.1-2.4).

2.1. Submission of an application for authorisation of a feed additive or a new use of a feed additive (Article 4(1) of Regulation (EC) No 1831/2003)

Any person seeking an authorisation for a feed additive or for a new use of a feed additive, according to Article 4(1) 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.

Documentation

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

1. European Commission[6]
   - **Application form** in accordance with Annex I of Commission Regulation (EC) No 429/2008
   - **Public summary** of the dossier according to Article 7(3)(h) of Regulation (EC) No 1831/2003
   - **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

   Those particulars must be sent to the following address:

   European Commission

   Directorate-General Health and Consumers (DG-SANTE)

   Unit E5 Animal Nutrition, veterinary medicines

   Rue Froissart 101 00/30

   B-1049 Brussels (Belgium)

2. European Union Reference Laboratory for feed additives (EURL-FA)[7]

   Commission Regulation (EC) No 885/2009[8] has specific provisions regarding the submission of **samples/reference standards** and the payment of a **fee** to the EURL for applications for authorisation of feed additives.

   The list of documents and particulars to be submitted to the EURL-FA is available in the EURL's administrative guidance to applicants[9].

   For any clarifications on the required documents and particulars that need to be sent, applicants can contact the EURL[10].

   The particulars required must be sent to the following address:

   Directorate General Joint Research Centre

   Directorate F - Health, Consumers and Reference Materials

   European Union reference Laboratory for Feed Additives

   Retieseweg 111

   B-2440 Geel (Belgium)

[6] https://ec.europa.eu/food/safety/animal-feed/feed-additives/authorisation-types-withdrawal_en
[7] https://ec.europa.eu/jrc/en/eurl/feed-additives
[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. 58–65
[9] https://ec.europa.eu/jrc/en/eurl/feed-additives/guidance-for-applicants
[10] EURL contact: JRC-EURL-FEED-ADDITIVES-AUTHORISATION@ec.europa.eu

3. EFSA

- **Dossier** (administrative documents, technical dossier, confidential parts, structured as described below)

The dossier should be submitted electronically only, using a standard physical medium (e.g. one CD-ROM, one DVD, or one USB key). It should be accompanied by the original of a signed cover letter listing the annexes of the application.

Those particulars must be sent to the following address:

European Food Safety Authority

Applications Desk Unit

Feed additive applications

Via Carlo Magno 1A

43126 Parma (Italy)

Structure of the dossier

The dossier should contain three distinct parts (administrative documents, technical dossier, confidential parts of the dossier). For each part, a corresponding folder should be created:

ADMINISTRATIVE DOCUMENTS
TECHNICAL DOSSIER
CONFIDENTIAL PARTS

The dossier should follow the structure and the naming convention detailed below.

For technical details on the preparation of the dossier, please refer to Section 2.4.

Part 1: Administrative documents

Part 1 of the dossier should contain all the administrative documents related to the application. The list of documents and the corresponding recommended file names and types can be found below.

ADMINISTRATIVE DOCUMENTS

File name and type	Content
EFSA_letter	Cover letter
Annex_I	Copy of the application form in accordance to Annex I of Commission Regulation (EC) No 429/2008 sent to EC
CClist	Completeness check list (**Appendix B**)
Contact	Contact details (**Appendix C**)

Part 2: Technical dossier

The technical dossier included in an application for the authorisation of a feed additive within the framework of Regulation (EC) No 1831/2003 should be compiled according to the legislative requirements, the relevant EFSA scientific guidance documents[11] and according to the format proposed in this guidance document. It has to consist of the elements specified in Article 7 of Regulation (EC) No 1831/2003 and detailed in Annex II and Annex III of Commission Regulation (EC) No 429/2008. The technical dossier should follow the sections and numbering presented in Annex II of Commission Regulation (EC) No 429/2008.

The dossier consists of five distinct sections, each of which addresses different issues. It 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 individual 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.

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

Note that the technical dossier (Part 2) should contain all the information (not confidential and confidential). The information considered confidential should be evidenced (e.g. using a different font colour) throughout the technical dossier (Part 2) and must not be removed.

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

[11] The list of scientific guidance documents to be considered in the preparation of an application is available at: http://www.efsa.europa.eu/en/applications/feedadditives/regulationsandguidance

TECHNICAL DOSSIER

Folder structure and content	Description of content in accordance with Annex II of Commission Regulation (EC) No 429/2008
SECTION I	
PubSum	Section I. Point 1.1. Public summary
ScSum	Section I. Point 1.2. Scientific summary
ListDoc	Section I. Point 1.3. List of documents and other particulars
ConfInfo	Section I. Point 1.4. List of parts requested to be treated as confidential
SECTION II	
Sect_II_Identity	Section II. Identity, Characterisation and conditions of use of the additive, methods of analysis
Annexes_Sect. II	
Annex_II_1_xxx	Any study report, individual data, etc., related to Section II
Annex_II_2_xxx	
…	
SECTION III	
Sect_III_Safety	Section III. Safety of the additive
Annexes_Sect. III	
Annex_III_1_xxx	Any study report, individual data, etc., related to Section III
Annex_III_2_xxx	
Annex_III_3_xxx	
…	
…	
SECTION IV	
Sect_IV_Efficacy	Section IV. Efficacy of the additive
Annexes_Sect. IV	
Annex_IV_1_xxx	Any study report, individual data, etc., related to Section IV
Annex_IV_2_xxx	
Annex_IV_3_xxx	
…	
…	
SECTION V	
Sect_V_Post_Mark	Section V. Post-market monitoring

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Part 3: Confidential parts of the dossier

Part 3 of the dossier should include:

- a copy of the list of the parts of the dossier requested to be treated as confidential, identical to the ConfInfo file provided under Section I, Part 2 of the dossier. The list shall make reference to the relevant volumes and pages of the dossier considered as confidential
- a copy of the concerned parts of the dossier mentioned in the list
- a copy of each annex containing (in whole or in part) confidential information

The recommended file names for this part of the dossier are shown below.

CONFIDENTIAL PARTS

File name and type	Content
ConfInfo	Copy of the List of parts requested to be treated as confidential (Section I. Point 1.4)
Sect_II_Identity_Conf	Confidential information from Section II
Sect_III_Safety_Conf	Confidential information from Section III
Sect_IV_Efficacy_Conf	Confidential information from Section IV
Sect_V_Post_Mark_Conf	Confidential information from Section V
Annex_XX_1_xxx_Conf	Confidential information from any study report, individual data, etc., related to a section mentioned that the applicant wishes to treat as confidential. The same file name as in technical dossier should be used, but including the 'Conf' suffix
Annex_XX_2_xxx_Conf	

Applicants should also send a copy of Part 3 of the dossier to the European Commission (see Article 2(2) of Commission Regulation (EC) No 429/2008).

Each time a request for treating a piece of information as confidential is claimed by the applicant during the life-cycle of the application (i.e. first submission of a dossier and each subsequent submission of information), this should be specified and a copy of the confidential information should be submitted separately to EFSA and to the EC.

2.2. Submission of an application for modification of the terms of the authorisation of a feed additive (Article 13(3) of Regulation (EC) No 1831/2003)

A modification of the terms of the authorisation of a feed additive according to Article 13(3) of Regulation (EC) No 1831/2003 can be requested by the holder of the authorisation by submitting an application to the European Commission. The request needs to be accompanied by the relevant data supporting the request for the changes, as specified in Annex III(9) of Commission Regulation (EC) No 429/2008.

Documentation

When submitting an application for modification of the authorisation of a feed additive, the following documents and particulars should be provided to the corresponding entities:

1. European Commission[12]
   - **Application form** in accordance with Annex I of Commission Regulation (EC) No 429/2008
   - **Public summary** of the dossier according to Article 7(3)(h) of Regulation (EC) No 1831/2003
   - **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

   Those particulars must be sent to the following address:

   European Commission

   Directorate-General Health and Consumers (DG-SANTE)

   Unit E5 Animal Nutrition, veterinary medicines

   Rue Froissart 101 00/30

   B-1049 Brussels (Belgium)

2. European Union Reference Laboratory for feed additives (EURL-FA)[13]

Commission Regulation (EC) No 885/2009[14] has specific provisions regarding the submission of **samples/reference standards** and the payment of a **fee** to the EURL for applications for the modification of the terms of authorisation.

The list of documents and particulars to be submitted to the EURL-FA is available in the EURL's administrative guidance to applicants[15].

For any clarifications on the required documents and particulars that need to be sent, applicants can contact the EURL[16].

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

Directorate General Joint Research Centre

Directorate F - Health, Consumers and Reference Materials

European Union reference Laboratory for Feed Additives

[12] https://ec.europa.eu/food/safety/animal-feed/feed-additives_en
[13] https://ec.europa.eu/jrc/en/eurl/feed-additives
[14] 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. 58–65
[15] https://ec.europa.eu/jrc/en/eurl/feed-additives/guidance-for-applicants
[16] EURL contact: JRC-EURL-FEED-ADDITIVES-AUTHORISATION@ec.europa.eu

Retieseweg 111

B-2440 Geel (Belgium)

3. EFSA

- **Dossier** (administrative documents, technical dossier, confidential parts, structured as described below)

The dossier should be submitted electronically only, using a standard physical medium (e.g. one CD-ROM, one DVD or one USB key). It should be accompanied by the original of a signed cover letter listing the annexes of the application.

Those particulars must be sent to the following address:

European Food Safety Authority

Applications Desk Unit

Feed additive applications

Via Carlo Magno 1A

43126 Parma (Italy)

Structure of the dossier

The dossier should contain three distinct parts (administrative documents, technical dossier, confidential parts of the dossier). For each part, a corresponding folder should be created:

ADMINISTRATIVE DOCUMENTS
TECHNICAL DOSSIER
CONFIDENTIAL PARTS

Each part should correspond to a folder in the electronic version of the dossier. The dossier should follow the structure and the naming convention detailed below.

For technical details on the preparation of the dossier, please refer to Section 2.4.

Part 1: Administrative documents

Part 1 of the dossier should contain all the administrative documents related to the application. The list of documents and the corresponding recommended file names and types can be found below.

ADMINISTRATIVE DOCUMENTS

File name and type	Content
EFSA_letter	Cover letter
Annex_I	Copy of the application form in accordance to Annex I of Commission Regulation (EC) No 429/2008 sent to EC
CClist	Completeness check list (**Appendix B**)
Contact	Contact details (**Appendix C**)

Part 2: Technical dossier

The technical dossier included in an application for modification of an existing authorisation of a feed additive within the framework of Regulation (EC) No 1831/2003 should be compiled according to the legislative requirements, the relevant EFSA scientific guidance documents[17] and according to the format proposed in this guidance document. It has to consist of the elements specified in Article 7 of Regulation (EC) No 1831/2003 and detailed in Annex II and Annex III(9) of Commission Regulation (EC) No 429/2008. The technical dossier should follow the sections and numbering presented in Commission Regulation (EC) No 429/2008.

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 individual 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.

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

Note that the technical dossier (Part 2) should contain all the information (not confidential and confidential). The information considered confidential should be evidenced (e.g. using a different font colour) throughout the technical dossier (Part 2) and must not be removed.

[17] The list of scientific guidance documents to be considered in the preparation of an application is available at: http://www.efsa.europa.eu/en/applications/feedadditives/regulationsandguidance

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

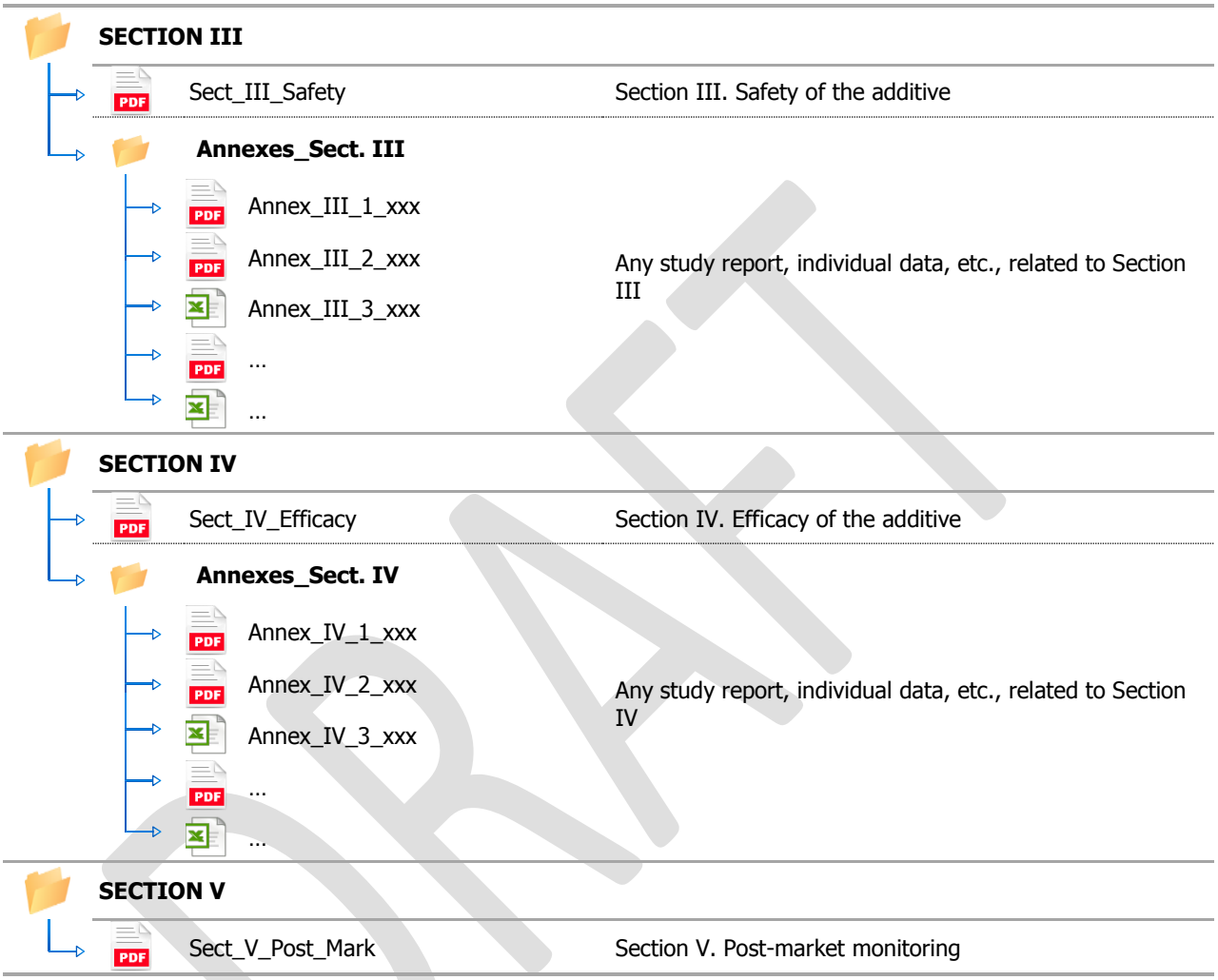
Note that in the preparation of the technical dossier for the modification of an existing authorisation, the following sections are always required:

TECHNICAL DOSSIER

Folder structure and content	Description of content in accordance with Annex II of Commission Regulation (EC) No 429/2008
SECTION I	
PubSum	Section I. Point 1.1. Public summary
ScSum	Section I. Point 1.2. Scientific summary
ListDoc	Section I. Point 1.3. List of documents and other particulars
ConfInfo	Section I. Point 1.4. List of parts requested to be treated as confidential
SECTION II	
Sect_II_Identity	Section II. Identity, Characterisation and conditions of use of the additive, methods of analysis
Annexes_Sect. II	
Annex_II_1_xxx	Any study report, individual data, etc., related to Section II
Annex_II_2_xxx	
…	

As regards Sections III, IV and V, the applicant should evaluate which sections need to be prepared in order to support the proposed change of terms of the authorisation.

The folder structure of Sections III, IV and V is shown below. If one or more of these sections are not relevant, they can be omitted.



Part 3: Confidential parts of the dossier

Part 3 of the dossier should include:

- a copy of the list of the parts of the dossier requested to be treated as confidential, identical to the ConfInfo file provided under Section I, Part 2 of the dossier. The list shall make reference to the relevant volumes and pages of the dossier considered as confidential
- a copy of the concerned parts of the dossier mentioned in the list
- a copy of each annex containing (in whole or in part) confidential information

The recommended file names for this part of the dossier are shown below.

CONFIDENTIAL PARTS

File name and type	Content
ConfInfo	Copy of the List of parts requested to be treated as confidential (Section I. Point 1.4)
Sect_II_Identity_Conf	Confidential information from Section II
Sect_III_Safety_Conf	Confidential information from Section III
Sect_IV_Efficacy_Conf	Confidential information from Section IV
Sect_V_Post_Mark_Conf	Confidential information from Section V
Annex_XX_1_xxx_Conf	Confidential information from any study report, individual data, etc., related to a section mentioned that the applicant wishes to treat as confidential. The same file name as in technical dossier should be used, but including the 'Conf' suffix
Annex_XX_2_xxx_Conf	

Applicants should also send a copy of Part 3 of the dossier to the EC (see Article 2(2) of Commission Regulation (EC) No 429/2008).

Each time a request for treating a piece of information as confidential is claimed by the applicant during the life-cycle of the application (i.e. first submission of a dossier and each subsequent submission of information), this should be specified and a copy of the confidential information should be submitted separately to EFSA and to the EC.

2.3. Submission of an application for 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, in accordance to Article 14 of Regulation (EC) No 1831/2003. The conditions required for this type of submissions are set up in Commission Regulation (EC) No 429/2008 (see Annex III(10)).

Documentation

When submitting an application for the renewal of the authorisation of a feed additive, the following documents and particulars should be provided to the corresponding entities:

1. European Commission[18]

   - **Application form** in accordance with Annex I of Commission Regulation (EC) No 429/2008
   - **Public summary** of the dossier according to Article 7(3)(h) of Regulation (EC) No 1831/2003
   - **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

   Those particulars must be sent to the following address:

   European Commission

   Directorate-General Health and Consumers (DG-SANTE)

   Unit E5 Animal Nutrition, veterinary medicines

   Rue Froissart 101 00/30

   B-1049 Brussels (Belgium)

2. European Union Reference Laboratory for feed additives (EURL-FA)[19]

   The list of documents and particulars to be submitted to the EURL-FA is available in the EURL's administrative guidance to applicants[20].

   Commission Regulation (EC) No 885/2009[21] has specific provisions regarding the submission of **samples/reference standards** and the payment of a **fee** to the EURL for applications for renewal of authorisation. Therefore applicants are advised to consult the EURL's administrative guidance and contact directly the EURL for clarifications on the required documents and particulars that need to be sent[22].

   The particulars required must be sent to the following address:

   Directorate General Joint Research Centre

   Directorate F - Health, Consumers and Reference Materials

   European Union reference Laboratory for Feed Additives

   Retieseweg 111

   B-2440 Geel (Belgium)

[18] https://ec.europa.eu/food/safety/animal-feed/feed-additives_en
[19] https://ec.europa.eu/jrc/en/eurl/feed-additives
[20] https://ec.europa.eu/jrc/en/eurl/feed-additives/guidance-for-applicants
[21] 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. 58–65
[22] EURL contact: JRC-EURL-FEED-ADDITIVES-AUTHORISATION@ec.europa.eu

3. EFSA

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Applications Desk Unit

Feed additive applications

Via Carlo Magno 1A

43126 Parma (Italy)

Structure of the dossier

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ADMINISTRATIVE DOCUMENTS
TECHNICAL DOSSIER
CONFIDENTIAL PARTS

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For technical details on the preparation of the dossier, please refer to Section 2.4.

Part 1: Administrative documents

Part 1 of the dossier should contain all the administrative documents related to the application. The list of documents and the corresponding recommended file names and types can be found below.

ADMINISTRATIVE DOCUMENTS

File name and type	Content
EFSA_letter	Cover letter
Annex_I	Copy of the application form in accordance to Annex I of Commission Regulation (EC) No 429/2008 sent to EC
CClist	Completeness check list (**Appendix B**)
Contact	Contact details (**Appendix C**)

Part 2: Technical dossier

The technical dossier included in an application for the renewal of an authorisation of a feed additive within the framework of Regulation (EC) No 1831/2003 should be compiled according to the legislative requirements, the relevant EFSA scientific guidance documents[23] and according to the format proposed in this guidance document. It has to consist of the elements specified in Article 7 of Regulation (EC) No 1831/2003 and detailed in Annex II and Annex III(10) of Commission Regulation (EC) No 429/2008. The technical dossier should follow the sections, numbering and headings presented in Commission Regulation (EC) No 429/2008.

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 individual 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.

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

Note that the technical dossier (Part 2) should contain all the information (not confidential and confidential). The information considered confidential should be evidenced (e.g. using a different font colour) throughout the technical dossier (Part 2) and must not be removed.

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

[23] The list of scientific guidance documents to be considered in the preparation of an application is available at: http://www.efsa.europa.eu/en/applications/feedadditives/regulationsandguidance

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

535

TECHNICAL DOSSIER

Folder structure and content	Description of content in accordance with Annex II and III of Commission Regulation (EC) No 429/2008
SECTION I	
PubSum	Section I. Point 1.1. Public summary
ScSum	Section I. Point 1.2. Scientific summary
ListDoc	Section I. Point 1.3. List of documents and other particulars
ConfInfo	Section I. Point 1.4. List of parts requested to be treated as confidential
PrevAuth	Section I. Chapter 10.1 of Annex III[24]
SECTION II	
Sect_II_Identity	Section II. Identity, Characterisation and conditions of use of the additive, methods of analysis
Annexes_Sect. II	
Annex_II_1_xxx	Any study report, individual data, etc., related to Section II
Annex_II_2_xxx	
…	
SECTION III	
Sect_III_Safety	Section III. Safety of the additive
Annexes_Sect. III	
Annex_III_1_xxx	Any study report, individual data, etc., related to Section III
Annex_III_2_xxx	
Annex_III_3_xxx	
…	
…	

536

537

[24] A copy of the original Community authorisation for placing the feed additive on the market, or the last renewal of authorisation, shall be provided (cf. Commission Regulation (EC) No 429/2008, Annex III, 10.1. Section I: Summary of the dossier).

As detailed in Commission Regulation (EC) No 429/2008 and in the EFSA Guidance for renewal of authorisations of feed additives[25], only in specific cases Sections IV applies. When relevant, it should be included as follows:

SECTION IV	
Sect_IV_Efficacy	Section IV. Efficacy of the additive
Annexes_Sect. IV	
Annex_IV_1_xxx	Any study report, individual data, etc., related to Section IV
Annex_IV_2_xxx	
Annex_IV_3_xxx	
…	
…	

Section V is generally not required. If the applicant includes a proposal for amending or supplementing the conditions of the original authorisation regarding the conditions concerning future monitoring, Section V has to be included, as detailed below:

SECTION V	
Sect_V_Post_Mark	Section V. Post-market monitoring

[25] http://www.efsa.europa.eu/en/efsajournal/pub/3431

548 Part 3: Confidential parts of the dossier

549 Part 3 of the dossier should include:

550 - a copy of the list of the parts of the dossier requested to be treated as confidential, identical
551 to the ConfInfo file provided under Section I, Part 2 of the dossier. The list shall make
552 reference to the relevant volumes and pages of the dossier considered as confidential

553 - a copy of the concerned parts of the dossier mentioned in the list

554 - a copy of each annex containing (in whole or in part) confidential information

555 The recommended file names for this part of the dossier are shown below.

556

CONFIDENTIAL PARTS

File name and type	Content
ConfInfo	Copy of the List of parts requested to be treated as confidential (Section I. Point 1.4)
Sect_II_Identity_Conf	Confidential information from Section II
Sect_III_Safety_Conf	Confidential information from Section III
Sect_IV_Efficacy_Conf	Confidential information from Section IV
Sect_V_Post_Mark_Conf	Confidential information from Section V
Annex_XX_1_xxx_Conf	Confidential information from any study report, individual data, etc., related to a section mentioned that the applicant wishes to treat as confidential. The same file name as in technical dossier should be used, but including the 'Conf' suffix
Annex_XX_2_xxx_Conf	

557

558 Applicants should also send a copy of Part 3 of the dossier to the EC (see Article 2(2) of Commission
559 Regulation (EC) No 429/2008).

560 Each time a request for treating a piece of information as confidential is claimed by the applicant
561 during the life-cycle of the application (i.e. first submission of a dossier and each subsequent
562 submission of information), this should be specified and a copy of the confidential information should
563 be submitted separately to EFSA and to the EC.

564

2.4. Preparation of the dossier

2.4.1. Submission format

The documentation submitted to EFSA during all phases of the application life-cycle (i.e. first submission of a dossier, consolidated version of a dossier, supplementary information, complementary information) is to be provided electronically using standard physical mediums (e.g. CD-ROMs, DVDs, USB keys). Only one copy is required. It should be accompanied by the original of a signed cover letter specifying the content of the submission.

Appropriate labels should be attached on the CD-ROM/DVD/USB key including the following information: name of the additive, name of the company, target species, date of submission, disk number (disk # of #).

2.4.2. Language

In order to facilitate the evaluation of the applications, scientific and technical documentation should be submitted in English. EFSA may ask the applicant to translate the parts of the dossier that would not be submitted in English.

2.4.3. File format, size and name

Documents submitted should:

- enable the user to easily view a clear and legible copy of the information
- include a well-structured table of contents to allow the user to navigate easily through the submission
- allow the user to search for specific words or phrases within the documents submitted
- allow the user to copy text, images and data into other common software.

The recommended format for the majority of the electronic files is portable document format (PDF).

Each PDF document should be accessible to allow reading, printing, word searching and copying of text from the file using Adobe Acrobat® Standard (version 7.0 or later) software. Text and figures of all parts of the application should be fully legible. Whenever it is possible, PDF documents should be created from an electronic source document.

Submission of datasets (e.g. individual data) can be done using other appropriate common electronic formats (preferably MS Excel).

When an extensive literature search is performed, the list of references included should be provided in .RIS format.

The size of single documents should be limited to 30 MB. If for technical reasons more than one file needs to be prepared (i.e. if the final file size is over 30 MB), the resulting files should be named using consecutive numbers (e.g. Annex II.3_Title_part1, Annex II.3_Title_part2).

The electronic files should not 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.

File and folder names should not include special characters, such as: \ / : * ? \" < > | #.

2.4.4. Page format and numbering

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 (e.g. II-3).

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

2.4.5. Index, hypertext linking and bookmarks

The use of bookmarks and hypertext links is encouraged. 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.

2.4.6. List of documents

As detailed previously (see Structure of the dossier), Section I should contain a list of all the documents (ListDoc) submitted in support of the application. The list should be presented using the following template **in MS Excel format**:

Ref	Date	Authors	Title	Test facility	Report number/ Publication reference	Quality assurance scheme[26]
Section III	2018		Safety of the additive			
III.2.1	2007	Smith et al.	Effect of additive X on the growth of carp	Central Research Lab	RN1234	GLP/ISO/…[27]
III.2.2.	yyyy	Surname followed by initial(s), Surname followed by Initial(s) etc..	Title		Name of Journal, Volume(Issue), pp-pp	

All published and unpublished studies, scientific papers and other documents should be identified using a unique number (e.g. Annex III.2.1). The corresponding file name should contain the number and a short description of the content (e.g. Annex III.2.1_Effect on growth of carp.pdf).

Reference in the dossier to a specific study should be done using this unique number.

The List of documents should be submitted with all the different datasets (i.e. first submission of a dossier, consolidated version of a dossier, supplementary information, complementary information).

[26] According to Regulation (EC) No 429/2008, *studies, including those that have been conducted and published previously or coming from peer review, shall be performed and documented according to appropriate quality standards (e.g. Good Laboratory Practice (GLP)) in accordance with Directive 2004/10/EC [..], regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances or International Organisation for Standardisation (ISO).*

[27] The quality assurance scheme under which each study is performed should be indicated.

2.4.7. Identification of bibliographic references in Sections II, III and IV of the technical dossier

When a list of bibliographic references is included at the end of a section, the following standard format is recommended:

Authors [add names in the format: Surname followed by Initial(s), Surname followed by Initial(s) and Surname followed by Initial(s)], Year of publication. Title. Periodical Title, Volume(Issue), pp-pp.

See for example:

Alderman G and Stranks MH, 1967. The iodine content of bulk herd milk in summer in relation to estimated dietary iodine intake of cows. Journal of the Science of Food and Agriculture, 18(4), 151–153.

2.4.8. 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 feasible and should be numbered with a unique identification number across the dossier. Portrait (vertical) rather than landscape (horizontal) layout for tables and figures should preferably 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.

2.4.9. Standard Units, terms and abbreviations

The International System of Units (SI)[28] must 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. Explanation for acronyms and abbreviations should be provided in the text when they are 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.

2.4.10. 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 Appendix A[29]). Depending on the target animals (i.e. terrestrial animals or aquatic animals), the appropriate section of the form needs to be filled in.

[28] http://www.bipm.org/utils/common/pdf/si_brochure_8_en.pdf

[29] The Appendix A corresponds to the Appendix A to the EFSA Guidance on the safety for the target species and to the EFSA Guidance on the efficacy of feed additives. It is downloadable in word format from the administrative guidance at: http://www.efsa.europa.eu/en/applications/feedadditives/regulationsandguidance

2.5. Reception of the application

Within 15 working days of the reception of the dossier, EFSA acknowledges to the applicant receipt of all the documents submitted to EFSA. At this point the dossier receives a unique reference number in the format FAD-20YY-XXXX. Applicants are invited to use this reference for all contacts with EFSA regarding the application of reference.

Within 15 working days of receipt of an application forwarded by the European Commission, EFSA issues an acknowledgement of receipt letter to the EC, with the applicant in copy of the correspondence. At that moment, the application is registered in the EFSA Register of Questions and receives a unique identification number (e.g. EFSA-Q-YYYY-XXXX referred to as "EFSA Question number").

The status of the application is regularly updated in the Register of Questions database and can be monitored by the applicant. The date of receipt of the application by EFSA is the starting point of the completeness check of the dossier. At this stage, the status of the application is 'under consideration'.

2.6. Completeness check of data for risk assessment and validation of the application

After reception of the application, the Applications Desk Unit (APDESK) checks the completeness of the application (Figure 1) and validates it when it fulfils the legal requirements and the ones detailed in the EFSA guidance documents on feed additives.

EFSA endeavours to communicate to the applicant the outcome of the completeness check within 30 working days after the reception date of the application.

In case the dossier is considered complete, the applicant is notified of its validity, the status of the application is updated in the EFSA Register of Questions from 'under consideration' to 'in progress', and the public summary of the dossier is made available to the public[30] in accordance with Article 7(2)(c) of Regulation (EC) No 1831/2003.

The completeness check process might require further exchange of information between the applicant and EFSA. In such case, EFSA informs the applicant, in writing, that certain parts of the dossier need modification or completion, in order to proceed to validation.

After receiving a request for missing information, the applicant should submit the response within 30 days. When this is not possible, the applicant should indicate to EFSA the date by which the response is expected, including an appropriate justification. EFSA will notify the acceptance of the new submission date via e-mail.

When responding to EFSA questions, the applicant should submit an updated version of the entire dossier on an electronic medium (e.g. CD-ROM, DVD, USB key). EFSA advises to accompany the submission of the consolidated version of the dossier with a cover letter wherein the applicant precisely describes how each EFSA question was addressed and a statement confirming the absence of further changes. Missing information should be incorporated in all relevant parts of the application.

The consolidated version of the entire dossier will replace the original or previous submission. Should the consolidated version of the dossier include pieces of information that are requested to be considered as confidential, Part 3 (i.e. Confidential parts of the dossier) should be updated accordingly.

When the consolidated version of the dossier is received by EFSA, the applicant is notified via e-mail. The APDESK staff then checks the content of the submission and endeavours to inform the applicant

[30] The public summary of a dossier is made available at the validation in the EFSA Register of Questions, under the tab 'Question documents'.

within 15 working days on whether the consolidated dossier is complete and can be validated or if further revision is required.

The validity date is the starting point for the scientific assessment of the dossier. At that stage, EFSA will make all the information supplied by the applicant available to the EC, the EURL and the Member States.

In order to help applicants in preparing their applications, a completeness checklist is prepared by EFSA for the administrative verification of the completeness of the dossier (see Appendix B). It must be filled in by the applicant and submitted in Part 1 of the dossier.

The completeness checklist should be used by applicants when preparing a dossier to verify that all the information that must be submitted to EFSA is provided. The checklist follows the structure of Annex II of Commission Regulation (EC) No 429/2008. It does not substitute in any case for the requirements referred to in the European Union regulatory texts in force concerning feed additives.

The level of detail of the information required varies according to the type of application and/or type of additive. The checklist thus allows applicants to identify which information is provided, not provided (to be justified) and/or not relevant.

2.7. Risk assessment, adoption and publication of the EFSA scientific opinion

The FEEDAP Panel is supported by the Working Groups (WG) on feed additives to assess the application submitted to EFSA. Each valid application is tabled for discussion at the meeting of the assigned working group and the outcomes of such discussions are summarised in the WG meeting minutes, published on the EFSA website (see direct link included below in the 'Useful links' section). During this phase, the Feed Unit is responsible for the handling of the applications.

According to Article 8(1) of Regulation (EC) No 1831/2003, the timeline to finalise the assessment of an application for a feed additive by EFSA is six months. During the risk assessment phase by the WGs and the FEEDAP Panel, EFSA may request the applicant to submit supplementary information in line with Article 8(2) of Regulation (EC) No 1831/2003. In that case, the limit to deliver an opinion by EFSA is extended ("stop-the-clock procedure").

The deadline for providing the supplementary information is specified in the letter sent by EFSA to the applicant and is in line with the scientific report 'Indicative timelines for submitting additional or supplementary information to EFSA during the risk assessment process of regulated products' (EFSA, 2014). This deadline may be extended when requested by the applicant. In that case, the applicant must provide a justification of the time needed to provide the information, including a detailed calendar, which must be in any case, proportional to the amount and type of information requested. EFSA will decide on the acceptability of the extension request based on the justification given by the applicant and the nature of data requested.

When responding to EFSA questions, the applicant should submit the supplementary information in the form of 1 electronic copy (using a standard physical medium, e.g. CD-ROM, DVD, USB key) as one package answering all questions, together with a hard copy of the signed cover letter.

Should the supplementary information include data that are requested to be considered as confidential, an updated list of all the parts of the dossier to be treated as confidential should be provided.

After its adoption by the FEEDAP Panel at a plenary meeting, the scientific opinion is checked for editorial review and is published in the EFSA Journal[31], taking into consideration the decision of the

[31] EFSA Journal: http://www.efsa.europa.eu/en/publications

European Commission on the confidentiality, in line with Article 18(2) of Regulation (EC) No 1831/2003.

2.8. Spontaneous submission of information during the life-cycle of an application[32]

The applicant is expected to submit a complete application, including all relevant information available at the time of submission of an application for authorisation. The spontaneous submission of information by an applicant without a formal request by EFSA is possible, but limited to newly produced data and/or information which was not available at the time of the preparation of the original dossier and which has not been subject to EFSA's previous requests.

The applicant is expected to submit spontaneous information as early as possible during the risk assessment process and explain how it may influence the risk assessment.

The information should be sent to EFSA using a standard physical medium (e.g. CD-ROM, DVD, USB key). It should be accompanied by the original of a signed cover letter describing the content of the submission and by a List of documents prepared in accordance with the indications provided in Section 2.4.6.

Those particulars must be sent to the following address:

European Food Safety Authority

Feed Additives Unit

Via Carlo Magno 1A

43126 Parma (Italy)

Should the information include data that are requested to be considered as confidential, an updated list of all the parts of the dossier to be treated as confidential should be provided. A copy of the confidential information should be submitted separately to EFSA and to the EC.

2.9. Submission of complementary information following an inconclusive EFSA scientific opinion

Upon request from the European Commission, an applicant may be given the possibility to submit complementary information in order to complete the assessment and to allow a revision of a published EFSA scientific opinion in relation to specific aspects the FEEDAP Panel could not conclude on.

The complementary information, meaning a main document and its annexes (including all relevant study reports, individual data, bibliographic references) should be submitted to the European Commission, following its instructions. In addition, a copy of the documentation should be sent to EFSA using a standard physical medium (e.g. CD-ROM, DVD, USB key).

It should be accompanied by the original of a signed cover letter listing the content of the submission and by an updated Appendix C (contact details).

Those particulars must be sent to the following address:

[32] The approach described in this paragraph is stated in the 'Administrative guidance for the processing of applications for regulated products' (EFSA, 2018)

796 European Food Safety Authority
797 Applications Desk Unit
798 Feed additive applications
799 Via Carlo Magno 1A
800 43126 Parma (Italy)
801

802 A List of documents prepared in accordance with the indications provided in Section 2.4.6 should be
803 included.

804 Should the complementary information include data that are requested to be considered as
805 confidential, a list of all the parts to be treated as confidential should be provided. The information
806 considered confidential in the main document should be evidenced in the text (e.g. using a different
807 font colour).

808 A copy of the confidential information should be submitted separately to EFSA and to the EC.

809
810

811 2.10. Withdrawal of an application

812 Should an applicant wish to withdraw its application at any point in time, he/she should inform in
813 writing the European Commission, notifying also EFSA (email addresses:
814 apdesk.applications@efsa.europa.eu and feedadditives@efsa.europa.eu) and the EURL (email
815 address: JRC-EURL-FEED-ADDITIVES-AUTHORISATION@ec.europa.eu).

816 Once EFSA receives the official withdrawal letter from the European Commission, the evaluation stops.
817 The withdrawal letter is made publicly available on the EFSA Register of Questions[33].

818 The withdrawal of an application after the adoption of a scientific opinion has no effect on the
819 adopted output, which will be in any case published on the EFSA Journal.

820 Further information on withdrawal of applications is available in the dedicated section of the 'REPRO
821 administrative guidance for the processing of applications for regulated products'[34].

822

[33] EFSA Register of questions database: http://registerofquestions.efsa.europa.eu/roqFrontend/ListOfQuestionsNoLogin?1&panel=ALL
[34] Administrative guidance for the processing of applications for regulated products: http://www.efsa.europa.eu/en/supporting/pub/en-1362

3. Interaction with EFSA staff during preparation, submission, completeness check, risk assessment and adoption phases

EFSA has implemented several initiatives to support applicants in understanding the evaluation process of applications for regulated products and to engage with them during the life-cycle of applications.

Figure 2 below shows the different services that applicants can take advantage of in the different phases of the life-cycle of an application. The complete list of support initiatives in place and a full description of each service currently implemented can be found in the 'EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products' (EFSA, 2016)[35].

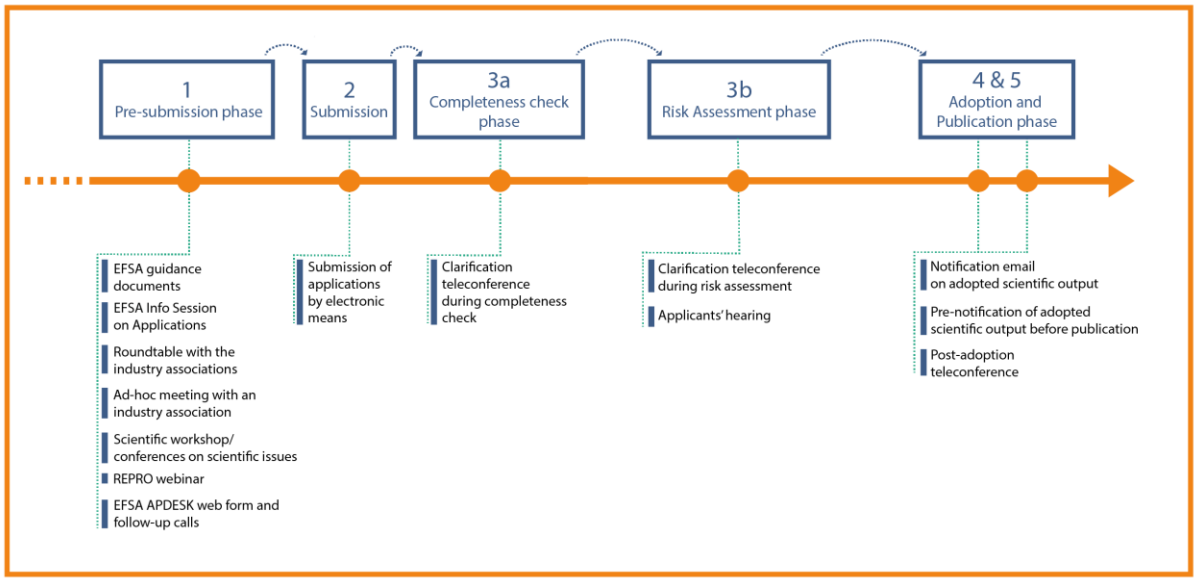

Figure 2 – Overview of EFSA support initiatives available during the life-cycle of an application for a feed additive

If an applicant is seeking information **during the preparation of an application** for the authorisation of a feed additive on aspects related to data for risk assessment, EFSA encourages the use of the APDESK web form[36] to submit any queries to EFSA. EFSA endeavours to reply within 15 working days of reception of the query.

If an applicant is seeking information on the **status of an application** already submitted to EFSA, the applicant may check this information in the EFSA Register of questions database[37].

During the completeness check, applicants have the possibility to contact the staff in the APDESK Unit. In each correspondence related to an application, the contact details of the EFSA staff following the specific application within the APDESK Unit are clearly mentioned to allow direct interaction between EFSA staff and the applicant. Applicants can contact EFSA staff to request further clarifications following a request for missing information letter or to clarify any outstanding issues during the completeness check phase. A telephone conference may be organised to further clarify the outcome of the completeness check.

During the risk assessment phase, applicants have the possibility to contact the staff of the Feed Unit. In each correspondence related to an application, the contact details of the EFSA staff to contact

[35] EFSA's catalogue of support initiatives: http://www.efsa.europa.eu/en/applications/about/services
[36] EFSA Applications Helpdesk webform: http://www.efsa.europa.eu/en/applicationshelpdesk/askaquestion.htm
[37] EFSA Register of Questions database: http://registerofquestions.efsa.europa.eu/roqFrontend/ListOfQuestionsNoLogin?1&panel=ALL

within the Feed Unit are mentioned. EFSA staff can be contacted to request further clarifications following a letter requesting supplementary information. A telephone conference may take place to further clarify the questions of the working groups and the FEEDAP Panel.

In addition, upon request from EFSA, applicants might be invited to attend a specific agenda item of a working group or Panel meeting – either in person or via teleconference – to answer questions about the submitted data and to clarify any outstanding issues on the application. EFSA will decide if this is necessary after examining the written response from the applicant to the EFSA's initial request for information or in case the experts of the working group and/or Panel need to clarify any outstanding issues on the application.

Following the publication of an EFSA scientific opinion, applicants have the possibility to request a post-adoption teleconference. The EFSA staff may organise the teleconference to explain the scientific rationale of the final opinion from the Panel.

For further details on each service, please consult the EFSA's catalogue of support initiatives on the EFSA website.

References

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EFSA FEEDAP Panel (EFSA Panel on additives and products or substances used in animal feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, López-Alonso M, López Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Anguita M, Galobart J, Innocenti ML and Martino L, 2017. Guidance on the assessment of the safety of feed additives for the target species. EFSA Journal 2017;15(10):5021, 19 pp. https://doi.org/10.2903/j.efsa.2017.5021

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EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, López-Alonso M, López Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Glandorf B, Herman L, Kärenlampi S, Aguilera J, Anguita M, Brozzi R and Galobart J, 2018. Guidance on the characterisation of microorganisms used as feed additives or as production organisms. EFSA Journal 2018;16(3):5206, 24 pp. https://doi.org/10.2903/j.efsa.2018.5206

EFSA FEEDAP Panel (EFSA Panel on additives and products or substances used in animal feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, López-Alonso M, López Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Anguita M, Galobart J, Innocenti ML and Martino L, 2018. Guidance on the assessment of the efficacy of feed additives. EFSA Journal 2018;16(5):5274, 25 pp. https://doi.org/10.2903/j.efsa.2018.5274

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP); Guidance on studies concerning the safety of use of the additive for users/workers. EFSA Journal 2012;10 (1):2539. [5 pp.] https://doi.org/10.2903/j.efsa.2012.2539.

European Union Reference Laboratory for feed additives, 2015. EURL-FA Administrative guidance to applicants

Useful links

- EFSA journal:
  http://www.efsa.europa.eu/en/publications
- Minutes of EFSA Animal feed Working groups and composition of the Working groups:
  https://www.efsa.europa.eu/en/animal-feed/working-groups
- Minutes of EFSA FEEDAP Panel plenary meetings and composition of the FEEDAP Panel:
  https://www.efsa.europa.eu/en/panels/feedap
- APDESK section on feed additives:
  http://www.efsa.europa.eu/en/applications/feedadditives
- Overview of regulations and guidance documents for feed additive applications:
  https://www.efsa.europa.eu/en/applications/feedadditives/regulationsandguidance
- Frequently Asked Questions on feed additives:
  https://www.efsa.europa.eu/en/applications/feedadditives/faq
- Animal feed topic:
  http://www.efsa.europa.eu/en/topics/topic/feed
- European Commission's website on feed additives:
  https://ec.europa.eu/food/safety/animal-feed/feed-additives_en
- Applicants can access the status of their application in the EFSA Register of Questions database:
  http://registerofquestions.efsa.europa.eu/roqFrontend/ListOfQuestionsNoLogin?1&panel=ALL

937 # Abbreviations

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APDESK	Applications Desk
CD-ROM	Compact Disk – Read Only Memory
DVD	Digital versatile disc or digital video disc
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
EURL	European Union Reference Laboratory
EURL-FA	European Union Reference Laboratory for feed additives
FEEDAP	Panel on additives and products or substances used in animal feed
GLP	Good Laboratory Practice
ISO	International Organisation for Standardisation
JRC	Joint Research Centre
PDF	Portable Document Format
RIS	Research Information Systems
SI	International System of Units
USB	Universal Serial Bus
WG	Working Group

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Appendix A – Trial protocol data sheet

941 **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:
Concentration(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 concentration:	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

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

944 **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:
Concentration(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 concentration:	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

945 * In case the concentration of the additive in complete feed/water may reflect insufficient accuracy, the dose of
946 the additive can be given per animal/day or mg/kg body weight or as concentration in complementary feed
947 ** where possible

Appendix B – Completeness checklist[38]

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, Commission Regulation (EC) No 429/2008 and in the EFSA guidance documents for applicants.

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

The completion of this checklist by the applicant does not replace the completeness check of the applications conducted by EFSA before they are considered valid.

How to fill in the completeness checklist?

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 Commission Regulation (EC) No 429/2008.

This checklist 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 designated box.

All the fields in blue are reserved for EFSA's use.

[38] **Disclaimer:** This checklist is provided by the European Food Safety Authority as help in the authorisation process. However, users are reminded that the texts of Regulations (EC) No 1831/2003 and 429/2008 are the only authentic legal references and that the information in this checklist does not constitute legal advice. The European Food Safety Authority does not accept any liability with regard to the content of this checklist.

FAD-	
ADMINISTRATIVE DATA OF APPLICANT(S)	
Name of the applicant(s) 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)	☐
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 30 MB	☐	☐
Files word-searchable	☐	☐

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Comments	
For EFSA use	

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ADMINISTRATIVE DOCUMENTS		
	INFORMATION PROVIDED	FOR EFSA USE
Cover letter accompanying the dossier	☐	☐
Copy of the application form in accordance with Annex I of Commission Regulation (EC) No 429/2008	☐	☐
Completeness check list in word format (Appendix B)	☐	☐
Contact details (Appendix C)	☐	☐

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Comments	
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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	☐	☐	☐
For applications under art.14: **1.5 Information on the previous authorisation and use of the additive**	☐	☐	☐

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SECTION II: Identity, characterisation and conditions of use of the additive; methods of analysis

2.1 Identity of the additive

Ref: EFSA Guidance on the identity, characterisation and conditions of use of feed additives[39]

	PROVIDED	NOT PROVIDED AND OMISSION JUSTIFIED	NOT RELEVANT	FOR EFSA USE
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	☐	☐	☐	☐
▪ Specification of the product	☐	☐	☐	☐
▪ Active substance(s)/agent(s) and all other components (% by weight)	☐	☐	☐	☐
▪ Batch to batch variations of the active substance(s)/ agent(s)	☐	☐	☐	☐
For applications under art. 4 or 13: ▪ Certificates of analysis of at least 5 batches demonstrating batch to batch variations of the active substance(s)/ agent(s) for each formulation/manufacturing method/origin/source	☐	☐	☐	☐
For applications under art. 14[40]: ▪ Certificates of analysis of at least 5 batches demonstrating batch to batch variations of the active substance(s)/ agent(s) not older than 1 year	☐	☐	☐	☐
▪ List of in-house identifiers (other names given to the additive) and statement of identity with final product	☐	☐	☐	☐
2.1.4 Purity	☐	☐	☐	☐
For applications under art. 4 or 13: ▪ Certificates of analysis of at least 3 batches, covering all relevant impurities for each manufacturing method/origin/source	☐	☐	☐	☐
For applications under art. 14[40]: ▪ Certificates of analysis of at least 3 batches, covering all relevant impurities not older than 1 year	☐	☐	☐	☐
2.1.5 Physical state of each form of the product	☐	☐	☐	☐
▪ For solid additives	☐	☐	☐	☐

[39] https://www.efsa.europa.eu/it/efsajournal/pub/5023
[40] Ref: EFSA Guidance on the renewal of the authorisation of feed additives: http://www.efsa.europa.eu/en/efsajournal/pub/3431

- Particle size distribution	☐	☐	☐	☐
- Density	☐	☐	☐	☐
- Bulk density	☐	☐	☐	☐
- Dusting potential (at least three batches)	☐	☐	☐	☐
- Other characteristics	☐	☐	☐	☐
▪ For liquid additives	☐	☐	☐	☐
- Viscosity	☐	☐	☐	☐
- Specific weight	☐	☐	☐	☐
- Vapour pressure	☐	☐	☐	☐
- Solubility/dispersibility in water	☐	☐	☐	☐

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Comments	
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2.2 Characterisation of the active substance(s)/agent(s)

Ref: EFSA Guidance on the identity, characterisation and conditions of use of feed additives[41]

	PROVIDED	NOT PROVIDED AND OMISSION JUSTIFIED	NOT RELEVANT	FOR EFSA USE
2.2.1 Description				
▪ Qualitative description	☐	☐	☐	☐
▪ For chemically defined substances:	☐	☐	☐	☐
- Generic name/ Chemical name (IUPAC)/ other names/ CAS number/ EINECS number/EC number/EEC number	☐	☐	☐	☐
- Structural formula, molecular formula, openSMILES notation and molecular weight	☐	☐	☐	☐
▪ For flavourings chemically defined:	☐	☐	☐	☐
- FLAVIS number and chemical group	☐	☐	☐	☐
▪ For additives of plant origin:	☐	☐	☐	☐
- scientific name of the plant and its botanical classification	☐	☐	☐	☐
- part of the plants used	☐	☐	☐	☐
- phytochemical markers	☐	☐	☐	☐
▪ For mixtures:	☐	☐	☐	☐
- major constituents	☐	☐	☐	☐
- marker compounds	☐	☐	☐	☐
▪ For natural product of non-plant origin: marker compounds	☐	☐	☐	☐
▪ For clays: elemental and mineralogical composition, structure	☐	☐	☐	☐
▪ For enzymes: Number and systematic name (IUB)	☐	☐	☐	☐
▪ For micro-organisms (as a product or production strain)[42]:	☐	☐	☐	☐
- Genus, species, strain name or code	☐	☐	☐	☐
- Certificate of deposition	☐	☐	☐	☐
- History of modifications	☐	☐	☐	☐
- Origin	☐	☐	☐	☐
- Morphological, physiological and molecular characteristics for identification	☐	☐	☐	☐
- Whole genome sequence analysis (WGS)	☐	☐	☐	☐
▪ For GMMs[43]:	☐	☐	☐	☐
- Characterisation of the genetic modifications	☐	☐	☐	☐
- Unique identifier Reg. (EC) No 65/2004	☐	☐	☐	☐
▪ For chemical substances produced by fermentation:	☐	☐	☐	☐

[41] https://www.efsa.europa.eu/it/efsajournal/pub/5023
[42] Ref: EFSA Guidance on the characterisation of microorganisms used as feed additives or as production organisms http://www.efsa.europa.eu/en/efsajournal/pub/5206
[43] See section 2.5 of the EFSA Guidance on the characterisation of microorganisms used as feed additives or as production organisms

microbial origin				
▪ Purity	☐	☐	☐	☐
▪ Relevant characteristics	☐	☐	☐	☐
2.2.2 Relevant properties				
▪ Chemical substances:	☐	☐	☐	☐
- Physical and chemical properties	☐	☐	☐	☐
- For fermentation products[44]:	☐	☐	☐	☐
○ Absence of antimicrobial activity	☐	☐	☐	☐
○ Absence of the production strain	☐	☐	☐	☐
○ Presence of DNA from the production strain	☐	☐	☐	☐
▪ Microorganisms[45]:	☐	☐	☐	☐
- Antimicrobial susceptibility				
- Antimicrobial production	☐	☐	☐	☐
- Toxigenicity and pathogenicity	☐	☐	☐	☐
- Compatibility with other additives showing antimicrobial activity	☐	☐	☐	☐

Comments	
For EFSA use	

[44] See section 3 of the EFSA Guidance on the characterisation of microorganisms used as feed additives or as production organisms

[45] See sections 2.5, 2.2, 2.3, 2.4 and 4.2 of the EFSA Guidance on the characterisation of microorganisms used as feed additives or as production organisms

2.3 Manufacturing process including any specific processing procedure

Ref: EFSA Guidance on the identity, characterisation and conditions of use of feed additives[46]

	PROVIDED	NOT PROVIDED AND OMISSION JUSTIFIED	NOT RELEVANT	FOR EFSA USE
2.3.1 Description				
▪ Production process (detailed description and flowchart) (For applications under art.14, the description of the production process needs to be reported and modification in the process, if any, needs to be clearly stated and described[47])	☐	☐	☐	☐
▪ Media used (fermentation and/or cultivation)	☐	☐	☐	☐
▪ Use of antimicrobial substances	☐	☐	☐	☐
▪ Purification methods	☐	☐	☐	☐
2.3.2 Additive				
▪ Manufacturing process (detailed description and flowchart) (For applications under art.14, the description of the production process needs to be reported and modification in the manufacturing process, if any, needs to be clearly stated and described[42])	☐	☐	☐	☐

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Comments	
For EFSA use	

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[46] https://www.efsa.europa.eu/it/efsajournal/pub/5023

[47] Ref: EFSA Guidance on the renewal of the authorisation of feed additives: http://www.efsa.europa.eu/en/efsajournal/pub/3431

2.4 Physico-chemical and technological properties of the additive

Ref: EFSA Guidance on the identity, characterisation and conditions of use of feed additives[48]

	PROVIDED	NOT PROVIDED AND OMISSION JUSTIFIED	NOT RELEVANT	FOR EFSA USE
2.4.1 Stability				
▪ of each formulation of the additive/shelf-life (data from at least 3 batches)	☐	☐	☐	☐
▪ 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	☐	☐	☐	☐

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Comments	
For EFSA use	

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[48] https://www.efsa.europa.eu/it/efsajournal/pub/5023

2.5 Conditions of use of the additive

Ref: EFSA Guidance on the identity, characterisation and conditions of use of feed additives[49]

	PROVIDED	NOT PROVIDED AND OMISSION JUSTIFIED	NOT RELEVANT	FOR EFSA USE
2.5.1 Proposed mode of use in animal nutrition (For applications under art.14, the mode of use needs to be reported and modification in the conditions of use, if any, needs to be clearly stated[50])	☐	☐	☐	☐
▪ Animal species / categories/ age group/ production stage	☐	☐	☐	☐
▪ Proposed use and level of inclusion (feed materials, feedingstuffs, water)	☐	☐	☐	☐
▪ Proposed method of administration	☐	☐	☐	☐
▪ Proposed dose in complementary feed or feed material	☐	☐	☐	☐
▪ Duration of administration	☐	☐	☐	☐
▪ Proposed withdrawal period	☐	☐	☐	☐
▪ Contraindications or restrictions in the handling or use	☐	☐	☐	☐
2.5.2 Information related to users/workers safety				
▪ For chemical substances: proposed SDS	☐	☐	☐	☐
▪ 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	
For EFSA use	

[49] https://www.efsa.europa.eu/it/efsajournal/pub/5023
[50] Ref: EFSA Guidance on the renewal of the authorisation of feed additives: http://www.efsa.europa.eu/en/efsajournal/pub/3431

2.6 Methods of analysis and reference samples

Ref: EFSA Guidance on the identity, characterisation and conditions of use of feed additives[51]

	PROVIDED	NOT PROVIDED AND OMISSION JUSTIFIED	NOT RELEVANT	FOR EFSA USE
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				
▪ Qualitative and quantitative composition (2.1.3)	☐	☐	☐	☐
▪ Purity (2.1.4)	☐	☐	☐	☐
▪ Physical state of the additive (2.1.5)	☐	☐	☐	☐
▪ Relevant properties (2.2.2)	☐	☐	☐	☐
▪ Stability of the additive (2.4.1)	☐	☐	☐	☐
▪ Homogeneity (2.4.2)	☐	☐	☐	☐
▪ Other characteristics (2.4.3)	☐	☐	☐	☐
▪ Physico-chemical incompatibilities or interactions (2.4.4)	☐	☐	☐	☐

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[51] https://www.efsa.europa.eu/it/efsajournal/pub/5023

Comments	
For EFSA use	

	INFORMATION PROVIDED	NOT RELEVANT	FOR EFSA USE
▪ Copy of all study reports	☐	☐	☐
▪ Individual data for each study	☐	☐	☐
▪ Certificates of analysis for each study	☐	☐	☐
▪ List of bibliographic references	☐	☐	☐
▪ Copy of bibliographic references (each reference is submitted as a separate PDF document)	☐	☐	☐
▪ Index of the section			

Comments	
For EFSA use	

SECTION III: Studies concerning the safety of the additive

For applications under art. 4 (and 13 when relevant):

3.1 Studies concerning the safety of use of the additive for the target animals

Ref: EFSA Guidance on the assessment of the safety of feed additives for the target species[52]

	PROVIDED	NOT PROVIDED AND OMISSION JUSTIFIED	NOT RELEVANT	FOR EFSA USE
▪ For extensive literature search:	☐	☐	☐	☐
- details on search methodology	☐	☐	☐	☐
- copy of all papers	☐	☐	☐	☐
- copyright licences agreement	☐	☐	☐	☐
- references list in .RIS format	☐	☐	☐	☐
▪ For toxicity data from repeated dose studies in laboratory animals: original study reports	☐	☐	☐	☐
▪ For each tolerance study for the target species:	☐	☐	☐	☐
- study report	☐	☐	☐	☐
- original study protocol	☐	☐	☐	☐
- individual data, results and outputs of the statistical analysis	☐	☐	☐	☐
- Certificates of analysis of the test item and for the different analysis performed	☐	☐	☐	☐
- Evidence of compliance with appropriate quality assurance scheme (e.g. GLP, ISO..)	☐	☐	☐	☐
▪ Microbial studies[53]	☐	☐	☐	☐

Comments	
For EFSA use	

[52] https://www.efsa.europa.eu/en/efsajournal/pub/5021

[53] See also section 4.1 of the EFSA Guidance on the characterisation of microorganisms used as feed additives or as production organisms

3.2 Studies concerning the safety of use of the additive for consumers

Ref: EFSA Guidance on the assessment of the safety of feed additives for consumers[54]

	PROVIDED	NOT PROVIDED AND OMISSION JUSTIFIED	NOT RELEVANT	FOR EFSA USE
3.2.1 Absorption, distribution, metabolism and excretion (ADME) and residue studies				
▪ ADME studies	☐	☐	☐	☐
- ADME studies in target animals	☐	☐	☐	☐
- ADME studies in laboratory animals	☐	☐	☐	☐
- *In vitro* studies	☐	☐	☐	☐
▪ Residues studies	☐	☐	☐	☐
- Total residues study	☐	☐	☐	☐
- Marker residue study	☐	☐	☐	☐
3.2.2 Toxicological studies				
▪ Genotoxicity studies	☐	☐	☐	☐
▪ Subchronic oral toxicity studies	☐	☐	☐	☐
▪ Chronic oral toxicity studies	☐	☐	☐	☐
▪ Carcinogenicity studies	☐	☐	☐	☐
▪ Reproduction toxicity studies	☐	☐	☐	☐
- Reproduction toxicity study	☐	☐	☐	☐
- Prenatal developmental toxicity studies	☐	☐	☐	☐
▪ Other studies	☐	☐	☐	☐
3.2.3 Assessment of consumer safety				
▪ Determination of a safe dose	☐	☐	☐	☐
▪ Highest safe intake	☐	☐	☐	☐
▪ Consumer exposure	☐	☐	☐	☐
▪ MRLs and withdrawal period	☐	☐	☐	☐

Comments	
For EFSA use	

[54] https://www.efsa.europa.eu/it/efsajournal/pub/5022

3.3 Studies concerning the safety of use of the additive for users/workers

Ref: EFSA Guidance on studies concerning the safety of use of the additive for users/workers[55]

	PROVIDED	NOT PROVIDED AND OMISSION JUSTIFIED	NOT RELEVANT	FOR EFSA USE
3.3.1 Toxicological risk assessment for user/worker safety				
▪ Effects on the respiratory system	☐	☐	☐	☐
▪ Effects on the eyes and skin	☐	☐	☐	☐
▪ Systemic toxicity	☐	☐	☐	☐
▪ Exposure assessment	☐	☐	☐	☐

Comments	
For EFSA use	

3.4 Studies concerning the safety of use of the additive for the environment

Ref: EFSA Guidance on the assessment of the safety of feed additives for the environment[56]

	PROVIDED	NOT PROVIDED AND OMISSION JUSTIFIED	NOT RELEVANT	FOR EFSA USE
▪ Phase I assessment	☐	☐	☐	☐
▪ Phase II assessment	☐	☐	☐	☐

Comments	
For EFSA use	

[55] http://www.efsa.europa.eu/en/efsajournal/pub/2539

[56] Link will be added once the guidance, which is currently undergoing a public consultation, is finalised

	INFORMATION PROVIDED	NOT RELEVANT	FOR EFSA USE
▪ Copy of all study reports	☐	☐	☐
▪ Individual data for each study	☐	☐	☐
▪ Certificates of analysis for each study	☐	☐	☐
▪ Evidence of compliance with appropriate quality assurance scheme (e.g. GLP, ISO..) for each study	☐	☐	☐
▪ List of bibliographic references	☐	☐	☐
▪ Copy of bibliographic references (each reference is submitted as a separate PDF document)	☐	☐	☐
▪ Index of the section	☐	☐	☐

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Comments	
For EFSA use	

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For applications under art. 14:

Studies concerning the safety of use of the additive for the target animals, consumers, users/workers, environment

Ref: EFSA Guidance on the renewal of the authorisation of feed additives[57]

	PROVIDED	NOT PROVIDED AND OMISSION JUSTIFIED	NOT RELEVANT	FOR EFSA USE
▪ Confirmation/evidence that the additive remains safe for target species, consumers, users/workers, environment under the approved conditions	☐	☐	☐	☐
- reports on adverse effects including accidents for target species, consumers, users/workers, environment	☐	☐	☐	☐
- reports on new interactions and incompatibilities identified	☐	☐	☐	☐
- data from residue monitoring, where appropriate	☐	☐	☐	☐
- data from epidemiologic and/or toxicological studies, where available	☐	☐	☐	☐
- any other information concerning the safety of the additive	☐	☐	☐	☐
▪ For structured database searches:	☐	☐	☐	☐
- name of the database and the service provider used	☐	☐	☐	☐
- date of the search and date range searched	☐	☐	☐	☐
- full search strategy	☐	☐	☐	☐
- copy of all relevant papers	☐	☐	☐	☐
▪ Report of the results of the post-market monitoring, when applicable	☐	☐	☐	☐

Comments	
For EFSA use	

	INFORMATION PROVIDED	NOT RELEVANT	FOR EFSA USE
▪ List of bibliographic references	☐	☐	☐
▪ Copy of bibliographic references (each reference is submitted as a separate PDF document)	☐	☐	☐
▪ Index of the section	☐	☐	☐

Comments	
For EFSA use	

[57] http://www.efsa.europa.eu/en/efsajournal/pub/3431

SECTION IV: Studies concerning the efficacy of the additive

4.1 Studies concerning the efficacy of the additive for the target animals

Ref: Guidance on the assessment of the efficacy of feed additives[58]

For applications under art. 4 (and 13 or 14 only when relevant):

	PROVIDED	NOT PROVIDED AND OMISSION JUSTIFIED	NOT RELEVANT	FOR EFSA USE
▪ For each efficacy study:	☐	☐	☐	☐
- study report	☐	☐	☐	☐
- original study protocol	☐	☐	☐	☐
- individual data, results and outputs of the statistical analysis	☐	☐	☐	☐
- Certificates of analysis of the test item and for the different analysis performed	☐	☐	☐	☐
- Evidence of compliance with appropriate quality assurance scheme (e.g. GLP, ISO..)	☐	☐	☐	☐
- For *in vivo* studies: Trial protocol data sheet (Appendix A to the EFSA Administrative guidance[59])	☐	☐	☐	☐
▪ Biological or chemical interactions	☐	☐	☐	☐
▪ Studies on quality of animal products when this is not the effect claimed	☐	☐	☐	☐

Comments	
For EFSA use	

	INFORMATION PROVIDED	NOT RELEVANT	FOR EFSA USE
▪ List of bibliographic references	☐	☐	☐
▪ Copy of bibliographic references (each reference is submitted as a separate PDF document)	☐	☐	☐
▪ Index of the section	☐	☐	☐

Comments	
For EFSA use	

[58] http://www.efsa.europa.eu/sites/default/files/engage/171204.pdf
[59] link

SECTION V Post-market monitoring				
	PROVIDED	NOT PROVIDED AND OMISSION JUSTIFIED	NOT RELEVANT	FOR EFSA USE
Proposal for post-market monitoring	☐	☐	☐	☐

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Comments	
For EFSA use	

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CONFIDENTIAL PARTS OF THE DOSSIER		
	INFORMATION PROVIDED	FOR EFSA USE
Confidential information is not removed from the technical dossier	☐	☐
The confidential parts in the technical dossier are evidenced (e.g. using a different font colour)	☐	☐
A copy of the confidential information is provided as a separate part of the dossier	☐	☐
A copy of the List of parts requested to be treated as confidential is included in the confidential parts of the dossier (see Section I, Point 1.4)	☐	☐

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Comments	
For EFSA use	

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Appendix C – Contact details

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ADMINISTRATIVE DATA OF APPLICANT(S) SUBMITTING AN APPLICATION FOR AUTHORISATION OF A FEED ADDITIVE UNDER REGULATION (EC) No 1831/2003
Applicant[60] (Company name):
Telephone:
E-mail:
Address (street, number):
Post code:
City/Town:
Country:
Name of the contact person responsible for the application[61]:
Company:
Telephone:
E-mail:
Address (street, number):
Post code:
City/Town:
Country:

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[60] In case of more than one company submitting an application, their names and addresses should be provided.
[61] To facilitate communication, only one contact person per application should be indicated.

Annex A – List of modifications to the guidance document since its first publication

Note that minor editorial changes are not specified.

Revision of xx 2018

- The structure and the format of the guidance document have been revised
- The following information has been added:
  - Workflow describing the procedure for handling applications; overview of preliminary actions related to the preparation of an application (in Chapter 2)
  - Spontaneous submission of information in relation to an application (Section 2.8)
  - Submission of complementary information following an inconclusive opinion (Section 2.9)
  - How to withdraw an application (Section 2.10)
  - Interaction with EFSA staff during the different phases of the application life-cycle (Chapter 3)
- The following information has been updated:
  - Submission of applications under Articles 4, 13(3) and 14 (Sections 2.1, 2.2 and 2.3)
  - Preparation of the dossier and submission format (Section 2.4)
  - Description of the different phases of the application life-cycle (Sections 2.5, 2.6 and 2.7)
- The former annexes have been changed as follows:
  - Annex A: Description and conditions of use of the additive has been deleted and replaced by a new Annex A: List of modifications to the guidance document
  - Annex B: Completeness checklist now corresponds to Appendix B. Its content has been revised.
  - Annex C: Trial protocol data sheet now corresponds to Appendix A. Signature by study director is required.
  - Annex D: Preparation of electronic files has been deleted. The relevant information is included under Section 2.4
  - Annex E: Contact details now corresponds to Appendix C

Revision of January 2014

- Section 1.4 – Section 1.4.2 has been updated to describe the modified procedure followed by EFSA for the completeness check of applications submitted in accordance with Articles 4, 13 and 14 of Regulation (EC) No 1831/2003
- Section 1.2 – A hyperlink to the Guidance on the renewal of the authorisation of feed additives was added
- Confidential Parts – Part 3: A copy of the List of parts requested to be treated as confidential should be included in this part of the dossier
- Annex B (completeness checklist): The introductory section was updated to request the applicant to provide a signed electronic copy of the completeness checklist and to include a

copy of the List of parts requested to be treated as confidential in the confidential parts of the dossier

Revision of February 2013

- Section 1.2 – hyperlinks to the documents listed below were updated:
  - Guidance on technological additives
  - Guidance on nutritional additives
  - Guidance on zootechnical additives
  - Guidance on user safety

Revision of October 2012

- Foreword: link to FAQ on feed additive applications has been added
- Sections 1.1(a) and 2.1(a) – The name of DG Health and Consumers Unit G1 Animal Nutrition has been updated. The postal address remains unchanged
- Sections 1.1(c) and 2.1(c) – Following the creation of EFSA's Applications Helpdesk, the documentation for EFSA must be sent to Applications Desk Unit instead of the Feed Unit
- Section 1.2 – The file format of the Completeness check list has been specified. The list and the hyperlinks of the guidance documents have been updated
- Section 1.4.3 – Scientific assessment. Information on requests for extension of the deadline has been updated
- Annex B: The file format of the Completeness check list has been specified. A definition of in-house identifiers has been added. The format requirements for the submission of the confidential parts have been detailed

Revision of January 2012

- Following the reorganisation of EFSA's structure, the name of the FEEDAP Unit has been changed to FEED Unit. This guidance has been updated accordingly
- Following the move of EFSA to the new seat, the address for postal mail has been updated. The name of the Community Reference Laboratory (CRL) has been changed to European Union Reference Laboratory (EURL). This guidance has been updated accordingly
- Hyperlinks to several guidance documents have been updated

Revision of July 2010

- Sections 1.1(b) and 2.1(b) – Documentation for the Community Reference Laboratory has been updated
- Sections 1.1(c) and 2.1(c) – Documentation for EFSA has been updated
- Section 1.2 – Structure of the dossier. EFSA's approach in case of discrepancies between the electronic and paper copies of the dossier
- Section 1.2.1 – Structure of the dossier. Part 3. Information on confidential parts of the dossier has been updated. A list of the parts of the dossier requested to be treated as confidential is needed under Section I of the technical dossier
- Section 1.4.2 – Completeness check / Validation. Information on submission of missing parts has been updated

Revision of December 2009

- Sections 1.1(c) and 2.1(c) – Documentation for EFSA. The number of CDs requested has been reduced from 6 to 2. DVDs are also accepted
- Sections 1.1(b) and 2.1(b) – Documentation for the Community Reference Laboratory
- Introduction of Regulation (EC) No 885/2009 on new provisions for samples and fees to CRL
- Section 1.2.1 – Structure of the dossier. Special characters not allowed in file names are exemplified
- Section 1.2.1 – Structure of the dossier. Part 3. Information on how to identify confidential information has been introduced
- Annex B: A more detailed explanation on the different terms 'information provided' and 'not provided' is available on page 18
- Annex C: The possibility that the study protocol data sheet could be signed by the applicant or its representative in case the Study director is not anymore available is on pages 30–31
- The name of SANCO Unit D2 (Feed) on page 4 has been updated
- Hyperlinks to several guidance documents have been updated