



EUROPEAN COMMISSION
DIRECTORATE-GENERAL
JOINT RESEARCH CENTRE
Directorate F - Health, Consumers and Reference Materials
European Union Reference Laboratory for Feed Additives

EURL-FA Administrative Guidance for Applicants

Date: 28/06/2018
Version: 4.01

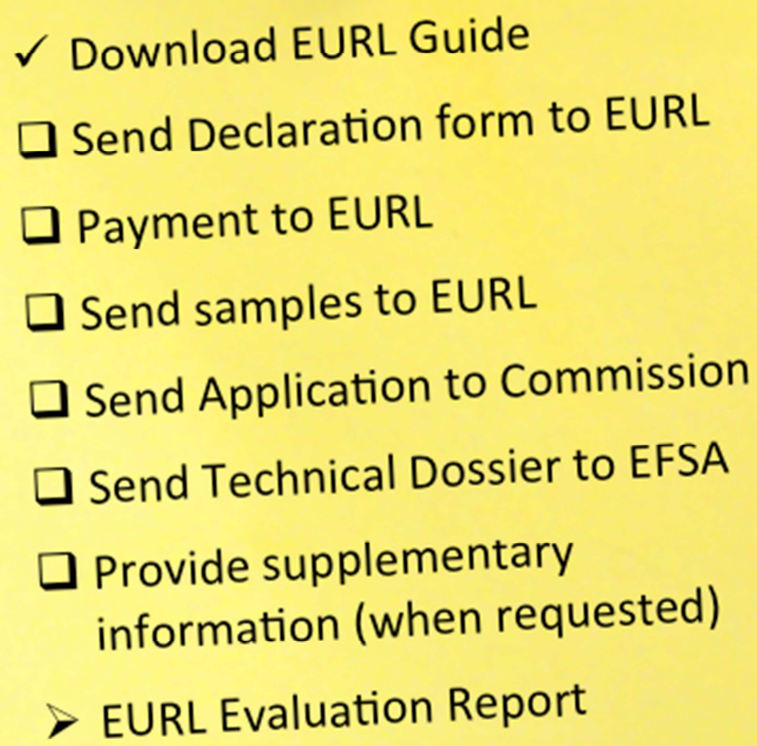
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Document History

Version	Date	Comment	Modified Pages
1.00	01/12/2009	Document created by Giuseppe Simone	
1.02	02/05/2010	Modified by Giuseppe Simone	
2.01	05/03/2014	Modified by Johanna Keltti Adapted to the new COM layout; Updated contact info; Annexes removed and replaced by relevant links	Throughout the document
2.01		Revised by Piotr Robouch	
2.01	17/7/2014	Approved by Christoph von Holst	
3.01	26/10/2015	Modified by Stefano Bellorini Adapted to the most recent legislation	Throughout the document
3.01		Revised by EURL team	
3.01	27/11/2015	Approved by Christoph von Holst	
4.01	24/04/2018	Modified by Aneta Stroh	
4.01	27/06/2018	Revised & modified by EURL team	
4.01	28/06/2018	Approved by Christoph von Holst	

EURL QUICK REFERENCE

- 
- ✓ Download EURL Guide
 - Send Declaration form to EURL
 - Payment to EURL
 - Send samples to EURL
 - Send Application to Commission
 - Send Technical Dossier to EFSA
 - Provide supplementary information (when requested)
 - EURL Evaluation Report



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1. INTRODUCTION AND PURPOSE

1.1. Introduction

Regulation (EC) No 1831/2003 on additives for use in animal nutrition defines the European Union procedure for authorisation of feed additives and establishes the Joint Research Centre (JRC) of the European Commission as the European Union Reference Laboratory for Feed Additives (EURL-FA, former CRL-FA).

The duties and tasks of EURL-FA are outlined in the above mentioned *Regulation (EC) No 1831/2003* and in *Commission Regulation (EC) No 378/2005*, as last amended by *Commission Implementing Regulation (EU) 2015/1761*.

The EURL-FA is assisted by a consortium of National Reference Laboratories (NRLs) (*Annex of Commission Implementing Regulation (EU) 2015/1761*).

Article 12 of Regulation (EC) No 378/2005 foresees the possibility that the EURL-FA establishes guidance for Applicants concerning:

- a) reference samples;
- b) testing of methods of analysis, including in particular criteria about when such testing may be required;
- c) validation of methods of analysis, including in particular criteria about when such validation may be required; together with
- d) requirements concerning methods of analysis submitted in accordance with paragraph 2.6 of *Annex II of Commission Regulation (EC) No 429/2008*.

1.2. Purpose of this Guidance document

This Guidance aims to help Applicants in the administrative process for the authorisation of feed additives as laid down in *Regulation (EC) No 429/2008*. In particular it defines the administrative procedure for:

- (i) **payment** of the fee foreseen by *Commission Regulation (EC) No 378/2005*, last amended by *Commission Implementing Regulation (EU) 2015/1761*, and
- (ii) submission of the **reference samples** to the EURL-FA.

The EURL-FA commits itself to regularly update the present document according to new legislation or new best practices identified. It cannot be guaranteed that all the information is completely current. The primary function of **the Guidance is for informative purposes only and nothing within should be construed as legal advice**. Applicants are always invited to consult the latest version of this document, available from:

<https://ec.europa.eu/jrc/en/eurl/feed-additives/guidance-for-applicants>

Additional information related to the submission of the “Application” and of the “Technical Dossier” can be found on the European Commission (DG SANTE) and the European Food Safety Authority (EFSA) websites:

https://ec.europa.eu/food/safety/animal-feed/feed-additives_en

<http://www.efsa.europa.eu/en/feedapguidance/feedapadminguidance.htm>

2. ADMINISTRATIVE PROCEDURE

The EURL-FA administrative procedure consists of four phases:



2.1. Declaration

- ❖ The Applicant shall send the **Declaration Form (DF)** to the EURL-FA at least **six weeks before** the intended date of submission of the corresponding Application to the European Commission. The DF shall be properly completed with the required information and can be downloaded from:

<https://ec.europa.eu/jrc/en/eurl/feed-additives/guidance-for-applicants>

- ❖ The DF shall be accompanied by a cover letter carrying the official heading or logo of the Applicant

Both documents should be sent electronically (no hardcopies are required) to the following e-mail address:

JRC-EURL-FEED-ADDITIVES-AUTHORISATION@ec.europa.eu

The information provided will be checked by the EURL-FA.

The fee to be paid will be determined based on the information provided and in accordance with the provisions laid down in *Commission Regulation (EC) No 378/2005, last amended by Commission Implementing Regulation (EU) 2015/1761*.

- If a fee is due, the EURL-FA will send to the Applicant a **Debit Note (DN)** for the appropriate fee rate. The Applicant shall pay the fee **within two weeks**. Upon reception of the payment, the EURL-FA will send the **Fee Acknowledgement of Receipt (FAR)** to the Applicant.
- If no fee is due, the EURL-FA will send the **No Fee Acknowledgement (NFA)** to the Applicant. In this case the samples validation procedure and the EURL-FA evaluation phase (described in this document) do not apply.

The EURL-FA will send electronic copies of the NFA or FAR to DG SANTE and EFSA.

2.2. Application

- ❖ The Applicant shall then complete the **Application Form (AF)** and send it - in original and signed - **to the European Commission (DG SANTE)**.
- ❖ The Applicant is advised to provide the same information in the corresponding fields of the DF and AF.
- ❖ Copy of the NFA or the FAR shall be enclosed to the AF.

The AF and any additional information related to the submission of the Application can be found on the European Commission (DG SANTE) website:

https://ec.europa.eu/food/safety/animal-feed/feed-additives_en

2.3. Sample Validation

The Applicant shall provide Reference Samples to the EURL-FA.

Samples will be considered valid when

- ✓ sufficient quantity is provided;
- ✓ properly packed;
- ✓ properly labelled (including expiry date);
- ✓ accompanied by the Sample Validity Checklist and the documentation listed therein.

The Sample Validity Checklist and the labels can be downloaded from:

<https://ec.europa.eu/jrc/en/eurl/feed-additives/guidance-for-applicants>

Relevant details are provided in section 4.2 of the present Guidance.

Once the samples are considered valid, the **Valid Samples Acknowledgement of Receipt (VSAR)** is sent to the Applicant. A copy is sent to DG SANTE and EFSA.

The Applicant is requested to keep the VSAR for future reference and to retain in particular the **EURL Sample Number** (required in case of future applications related to the same feed additive). The Applicant is reminded to take note of the **Expiry Date** of the sent Reference Samples in order to supply, whenever applicable, replacement samples on time. Important details regarding samples are given in chapter 4 of this document.

Exceptions

Reference Samples are not required when the application is submitted in accordance with:

- *Article 4 (1) of Regulation (EC) No 1831/2003* for a new use of an already authorised feed additive¹;
- *Article 13 (3) of Regulation (EC) No 1831/2003* for changing the terms of an existing authorisation

In both cases, these provisions are only applicable at the condition that the proposed modification of the terms of the authorisation is not related to the characteristics of the product or its composition.

Furthermore, Reference Samples are not required when the application is submitted in accordance with:

- *Article 14 of Regulation (EC) No 1831/2003* for renewal of an existing authorisation.

2.4. EURL-FA Evaluation phase

The EURL-FA evaluation of the technical dossier starts when EFSA sends copy of the **Statement of Validity for the Application** and makes all the information supplied by the Applicant available to the EURL-FA. EFSA's scientific assessment starts in parallel on the same date.

When insufficient information is provided in the technical dossier no conclusion can be drawn on the suitability of the methods of analysis for official control.

If only minor information is required, the EURL-FA may directly contact the Applicant for a fast clarification. When major experimental data is missing, the EURL-FA will ask EFSA to request from the Applicant

¹ See further details in chapter 4.1 of this guideline

Supplementary Information (SIN). EFSA, issuing the request of SIN, automatically stops the EURL-FA' evaluation period (*clock stop*). The applicants send the SIN to EFSA and in copy to the EURL-FA and the evaluation period will resume when the SIN is assessed as sufficient by the EURL-FA. An official communication is issued by EFSA and send to the Applicant.

The Rapporteur prepares an Initial Report that is made available to the NRLs for peer review. The Rapporteur will then implement the comments received and deliver the revised version to the EURL-FA. The EURL-FA Evaluation Report is then finalised and sent to EFSA, DG SANTE and the Applicant.

Exceptions

The EURL-FA evaluation report is not required when the application is submitted in accordance with:

- *Article 4 (1) of Regulation (EC) No 1831/2003* for a new use of an already authorised feed additive;
- *Article 13 (3) of Regulation (EC) No 1831/2003* for changing the terms of an existing authorisation;
and
- *Article 14 of Regulation (EC) No 1831/2003* for renewal of an existing authorisation.

However, these provisions are only applicable when:

- the methods of analysis for the concerned feed additive were submitted according to *Regulation (EC) No 429/2008* and were already evaluated by the EURL-FA;
- the proposed conditions for the new use or the proposed modification of the conditions fall within the scope of the methods already evaluated by the EURL-FA.

Nevertheless, if DG SANTE, EFSA or the EURL-FA considers that a new evaluation is necessary, a report will be drafted by the EURL-FA and the Applicant may be requested to pay the corresponding fee.

The EURL-FA evaluation report is also not required when the application is officially withdrawn.

2.5. Amendments to the EURL-FA Evaluation Report

Upon request by EFSA or DG SANTE, the EURL-FA shall amend an Evaluation Report already delivered mainly when:

- the conditions for placing the feed additive on the market resulting from EFSA's opinion are significantly different from those originally proposed by the Applicant; or
- SIN provided by the Applicant to EFSA affects the method of analysis.

2.6. Addendum to the EURL-FA Evaluation Report

When the EURL-FA Evaluation Report indicates that further testing and/or validation of the analytical method by the consortium of NRLs is considered necessary, the EURL-FA shall inform the Applicant EFSA and DG SANTE accordingly. At the same time the EURL-FA will provide to the Applicant a detailed work plan, including an estimate of the time schedule and of the fee to be paid. The Applicant shall inform the EURL-FA about his agreement within 15 days.

The EURL-FA will deliver the addendum to the Evaluation Report within 30 days after availability of the results provided by the Applicant.

3. APPLICABLE FEE

The fee is composed of two components, to support:

- The EURL-FA administrative costs and the costs related to the handling of the Reference Samples.
- The costs of the Rapporteur Laboratory for the scientific evaluation and the preparation of the evaluation report.

The applicability of these two components depends on the type of application submitted and determines the total fee to be paid.

Generally, the first component is applicable when Reference Samples are sent to the EURL-FA. The second component is related to the evaluation of the analytical methods.

The various cases are specified in in Annex IV of *Commission Regulation (EC) No 378/2005, last amended by Commission Implementing Regulation (EU) 2015/1761*.

4. SAMPLES

4.1. General

Applicants seeking authorisation for a feed additive shall send three **Reference Samples** to the EURL-FA. These samples must be representative of the feed additive intended to be placed on the market.

- ❖ In addition to the Reference Samples, the Applicant shall supply **Reference Standards** of the pure active agents (used for calibration) in the following cases:
 - Zootechnical additives (except micro-organisms);
 - Coccidiostats and histomonostats;
 - When the application falls within the scope of Community legislation relating to the marketing of products consisting of, containing or produced from genetically modified organisms (GMOs);
 - When the application concerns the setting of Maximum Residue Limits

In case of enzymes, a preparation with certified activity shall be submitted as reference standard.

- ❖ The applicant shall provide the EURL with samples to replace those expired (replacement samples). Once the feed additive is authorised, the legal validity of the samples covers the entire authorisation period. No replacement samples are then required. However, within the authorisation period, the EURL may request to the applicant additional reference samples.
- ❖ In addition, new replacement samples are required, when for an application submitted in accordance with article 4 (1) of Regulation (EC) No 1831/2003 (new use of a feed additive) the reference samples previously sent to the EURL are already expired and the feed additive is not yet authorised.

Furthermore, in case the Application concerns microorganisms, a letter of access to the culture collection shall be provided.

4.2. Requirements

4.2.1. Quantity

The quantity required for the three Reference Samples should be between 10 and 100 g considering (i) the concentration or the activity of the active agent in the product and (ii) the maximum dose proposed in the conditions of use. The quantity of the reference standards should be sufficient to allow for 100 analyses and should not be less than 1 gram.

In the case of coccidiostats, 100 mg/vial of reference standards are acceptable. In case of doubts, the Applicant should contact the EURL-FA.

4.2.2. Packaging

The container used (bottle, bag, etc.) should not influence the physical/chemical properties of the content. It shall be **sealed** using a tamper-proof closure that has to be broken in order to open the container, thus revealing whether the container has been opened.

The following containers may be used:

Plastic bottles	<p>High density polyethylene (HDPE) bottles with wide neck (for liquids, powders, granulates) or narrow neck (for liquids). For photosensitive substances, amber/brown HDPE bottles shall be used.</p> <p>Closures: screw polypropylene (PP) closures with <u>tamper evident</u> ring and conical seal, Teflon[®] cup seal, or Polytetrafluoroethylene (PTFE)-coated silicone seal (depending on the compatibility) shall be used.</p>
Glass bottles	<p>Whenever possible, glass containers should be avoided. Glass bottles can be used when the feed additive or its components are incompatible with plastic bottles.</p> <p>Glass bottle can be clear or amber coloured depending on the photosensitivity of the components of the feed additive.</p> <p>For hazardous substances (e.g. acids), glass bottles with external plastic coating shall be used in order to avoid leakage in case of damages to the bottle during the transport.</p> <p>Closures: in all cases standardised (DIN-thread GL) screw polypropylene (PP) closures with <u>tamper evident</u> ring and conical seal, Teflon[®] cup seal, or Polytetrafluoroethylene (PTFE)-coated silicone seal (depending on the compatibility) shall be used.</p>
Aluminium foil bags	<p>Aluminium foil bags thermally sealed can be used when the required sample quantity is so small that other types of containers are not appropriate</p>

❖ Whenever other containers are considered, the Applicant shall contact the EURL-FA for approval.

4.2.3. Storage conditions

❖ The intended storage conditions and corresponding shelf-life shall be clearly stated on the label.

❖ Storage temperature different from room temperature (~ 20° C) should be considered by the Applicant, especially if this would extend significantly the shelf life of the product, thus resulting in a less frequent replacement of the samples (see paragraph 4.1).

4.2.4. Shipment

- ❖ The Applicant is responsible for ensuring appropriate transport conditions (i.e. temperature, humidity) in accordance with the specific requirements for the stability of the product, in particular using special transport services.
 - ✓ Shipping boxes shall be sealed with tamper evident closures.
 - ✓ The box shall carry the indication “Laboratory samples – no commercial value”.
 - ✓ The box shall carry an external label stating the CRL/number for identification purposes
 - ✓ Hazardous materials shall be packed and labelled as required by transport regulations.
 - ✓ Care should be taken to prevent and minimise risk of breakage of fragile samples containers during transport.
- ❖ It is recommended to contact the EURL-FA well in advance in order to notify arrival date/time of refrigerated or frozen samples, specifying the required storage conditions.
- ❖ Applicants should take into account (i) the opening hours and (ii) the closure periods of the JRC-Geel reception (09:00 – 15:00) ².
- ❖ The final temperature for storage should be clearly indicated on the outer side of the box.

4.2.5. Samples documentation

Before the shipment of samples, the Applicant shall provide the documentation listed in the table below by e-mail to the following e-mail address:

JRC-EURL-FEED-ADDITIVES-AUTHORISATION@ec.europa.eu

Scope	X	X	X
Type of the document	New sample	Replacement Sample	Reference standard
This feed additive is authorised in the frame of Regulation (EC) 1831/2003		X	
Certificate of Analysis	X	X	X
Material Safety Data Sheet (MSDS)	X	X	X
Samples Validity checklist (F-0347)*	X	X	
Properly filled labels	X	X	X
Letter of access to culture collection (for microorganisms)	X		

(*) <https://ec.europa.eu/jrc/en/eurl/feed-additives/guidance-for-applicants>

² 1-2 January, Maundy Thursday-Easter Monday, Ascension Day and following Friday, 9 May, Whit Monday, 21 July, 15 August, 1-2 November, 24-31 December.

4.2.6. Labelling requirements

The label shall mention the information listed in the table below:

Labelling	Reference samples	Reference standards
Name of the additive (a)/active agent (b)	X (a)	X (b)
Name of the applicant (c)/producer (d)	X (c)	X (d)
Address of the applicant (e)/producer (f)	X (e)	X (f)
Specific name of active components	X	
Physical state	X	
Net weight-volume/container	X	X
Safety recommendations, if any	X	X
Specific requirements/Storage conditions	X	X
Identification number, if any	X	
Batch reference number	X	X
Manufacturing date	X	X
Expiry date	X	X
Concentration or activity (enzyme) or CFU (micro-organism)	X	X
Units	X	X
I.U.B. identification number (enzyme)	X	
Specific name of the enzyme	X	
Strain identification number (micro-org.)	X	

- ❖ The Applicant is requested to use the forms “Labels for Reference Samples” (F-0348) and “Labels for Reference Standards” (F-0349) and send the filled forms together with samples. Labels are available from the EURL-FA website:

<https://ec.europa.eu/jrc/en/eurl/feed-additives/guidance-for-applicants>

- ❖ When the sample containers are too small, the Applicant should provide the full sized label (on A4 paper), instead of reducing it.
- ❖ If the labels cannot be placed directly on the sample containers due to their small size (e.g. vials), it is recommended to seal the samples in transparent plastic bags or in larger plastic containers and stick the labels on the bag/container.

5. CONTACTS

- ❖ All documentation duly completed and signed whenever required shall be submitted electronically only to the following e-mail address:

JRC-EURL-FEED-ADDITIVES-AUTHORISATION@ec.europa.eu

- ❖ Samples shall be sent at the following postal address:

Attn: Ms. Aneta N. STROH

EURL Feed Additives

Joint Research Centre Geel

Retieseweg, 111

2440 Geel, Belgium

Tel: +32 14 57 18 89 or +32 14 57 12 73

- ❖ Samples are sent at ambient temperature, regardless of their storage conditions at the EURL
- ❖ If the applicant considers that special shipment conditions (i.e. refrigerated/frozen samples) are required, the EURL-FA needs to be contacted in advance to inform about the delivery date & time.
- ❖ Do not hesitate to contact the EURL-FA for further information.

