Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (Text with EEA relevance)

COMMISSION REGULATION (EC) No 378/2005

of 4 March 2005

on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[(1)], and in particular the first subparagraph of Article 7(4) and the third subparagraph of Article 21 thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 lays down rules for the placing on the market and use of feed additives in animal nutrition. It provides that any person seeking an authorisation for a feed additive or a new use of a feed additive is to submit an application for authorisation to the Commission in accordance with that Regulation (the application).

(2) Regulation (EC) No 1831/2003 provides for a Community reference laboratory (the CRL) to carry out certain duties and tasks set out in Annex II to that Regulation. It also provides that the Joint Research Centre of the Commission is to be the CRL and that it may be assisted by a consortium of national reference laboratories to perform the duties and tasks set out in that Annex.

(3) In accordance with Regulation (EC) No 1831/2003, it is necessary to adopt detailed rules for implementing Annex II to that Regulation, including practical conditions for the duties and tasks of the CRL and to amend that Annex accordingly.

(4) In addition, the samples to be provided in the application, in accordance with Regulation (EC) No 1831/2003, should meet specific requirements in view of the duties and tasks of the CRL.

(5) It is necessary to establish a precise timing for the delivery of the evaluation report from the CRL to the European Food Safety Authority (the Authority) in order to ensure that the procedures provided for in Regulation (EC) No 1831/2003 can be met.

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EC) No 378/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(6) The CRL should be authorised to charge a fee to applicants towards the costs of supporting the duties and tasks of the CRL and the consortium of national reference laboratories.

(7) National reference laboratories should be part of the consortium of laboratories assisting the CRL only if they meet specific requirements in order to properly perform the duties and tasks laid down in Regulation (EC) No 1831/2003. Member States should be permitted to apply to the Commission for the designation of such laboratories.

(8) In order to ensure the effective functioning of the consortium, it is necessary to appoint a rapporteur laboratory to carry out an initial assessment of the method(s) of analysis of each individual application and to establish clearly the duties and tasks of the rapporteur laboratories and the other laboratories participating in the consortium.

(9) It is necessary to establish special procedures for the cases where the data in the application are insufficient concerning testing or validation of the method(s) of analysis.

(10) In the interests of stability and efficacy and also in order to make the consortium operational, it is necessary to appoint the national reference laboratories participating in the consortium.

(11) The relations between the members of the consortium should be defined by contract between them. In this context the CRL may develop guidance for applicants and for the laboratories participating in the consortium.

(12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

[F1 Article 1

Subject matter and scope

This Regulation lays down detailed rules for the implementation of Regulation (EC) No 1831/2003 as regards the duties and tasks of the Community Reference Laboratory (the CRL).**]**

Textual Amendments

F1 Substituted by 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 (Text with EEA relevance).

***Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EC) No 378/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(a) ‘reference sample’ means a representative sample of the feed additive, as referred to in Article 7(3)(f) of Regulation (EC) No 1831/2003, which is the object of an application;

(b) ‘method of analysis’ means the procedure for the determination of the active substance(s) of the feed additive in feedingstuffs, and where appropriate, of its residue(s) or metabolite(s) in food, as referred to in Article 7(3)(c) of the Regulation (EC) No 1831/2003;

(c) ‘evaluation of the method of analysis’ means the thorough assessment of the protocol of the method of analysis as described in the application, including, if appropriate, literature research but not necessarily any experimental work;

(d) ‘testing of a method of analysis’ means the application of the method of analysis in a laboratory and comparison of results with those described in the application;

(e) ‘validation of a method of analysis’ means the process of proving that a method of analysis is fit for the intended purpose, by an intercomparison study according to ISO 5725-1 to 6 or other internationally harmonised guidelines for validation of methods by intercomparison study;

(f) ‘feed test material’ means a feedingstuff sample or premixture sample with or without the inclusion of the feed additive which is the object of the application, to be used for experimental studies on the method of analysis for the determination of the feed additive in feedingstuffs and/or premixtures;

(g) ‘food test material’ means a food sample derived from an animal that has been fed with feedingstuffs with or without the inclusion of the feed additive which is the object of the application, to be used for experimental studies on the method of analysis for the determination of the feed additive in the residue(s) or metabolite(s)**[**[F1];**]**

(h) **[**[F2]‘multi-analyte methods’ are methods based on a defined principle applicable for the single or simultaneous determination of one or more substance(s)/agent(s) in the specific matrices defined in the scope of the method;

(i) ‘reference standard’ is a sample of a pure active agent used for calibration purposes.**]**

Textual Amendments

F1 Substituted by 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 (Text with EEA relevance).

F2 Inserted by 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 (Text with EEA relevance).

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EC) No 378/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

I[F1] Article 3

Reference samples

1 Any person submitting an application for an authorisation for a feed additive or for a new use of a feed additive, as provided for in Article 4(1) of Regulation (EC) No 1831/2003, shall send three reference samples in a form in which the feed additive is intended to be placed on the market by the applicant.

In addition, the applicant shall provide to the CRL:

a reference standards of the pure active agents in the case of feed additives:
- — belonging to the category zootechnical additives referred to in Article 6(1)(d) of Regulation (EC) No 1831/2003, except feed additives consisting of or containing micro-organisms;
- — belonging to the category coccidiostats and histomonostats referred to in Article 6(1)(e) of Regulation (EC) No 1831/2003;
- — falling within the scope of Community legislation relating to the marketing of products consisting of, containing or produced from genetically modified organisms (GMOs);
- — for which Maximum Residue Limits have been established in Annex I or III of Council Regulation (EEC) No 2377/90[(2)] or following Regulation (EC) No 1831/2003.

b where the application concerns a feed additive consisting of or containing micro-organisms, an authorisation to the CRL to access the microbial strain deposited at the internationally recognised culture collection mentioned in point 2.2.1.2. of Annex II of Commission Regulation (EC) No 429/2008[(3)], if requested by the CRL.

Where the application concerns a feed additive belonging to the category sensory additives and allocated within the functional group flavouring compounds referred to at point 2(b) of Annex I to Regulation (EC) No 1831/2003, subject to Article 10(2) of that Regulation, which forms part of a group of applications, the reference samples must be representative of all the compounds/substances in the group.

2 The three reference samples of the feed additive shall be accompanied by a written statement by the applicant that the fee provided for in Article 4(1) has been paid.

3 The applicant shall maintain the reference samples valid for the entire period of the authorisation of the feed additive by supplying new reference samples to the CRL to replace those expired.

The applicant shall supply additional reference samples, reference standards, feed and/or food test materials, as defined in Article 2, if requested by the CRL. Upon justified request of the national reference laboratories of the consortium and without prejudice of Articles 11, 32 and 33 of Regulation (EC) No 882/2004, the CRL may request to the applicant additional reference samples, reference standards, feed and/or food test materials.

4 Reference samples shall not be required for:

a an application for a new use of a feed additive, already authorised for another use, submitted in accordance with Article 4(1) of Regulation (EC) No 1831/2003, when reference samples have been previously sent to the CRL for that other use;

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b an application for changing the terms of an existing authorisation submitted in accordance with Article 13(3) of Regulation (EC) No 1831/2003, when the proposed change is not related to the characteristics of the feed additive previously sent to the CRL as reference sample of the feed additive concerned.**]**

Textual Amendments

F1 Substituted by 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 (Text with EEA relevance).

Article 4

Fees

[[F1]1 The CRL shall charge the applicant a fee in accordance with the rates set out in Annex IV (‘the fee’).**]**

2 The CRL shall use the fees towards supporting the costs of the duties and tasks as set out in Annex II to Regulation (EC) No 1831/2003, and in particular those referred to in 2.1, 2.2 and 2.3 of that Annex.

3 The amount of the fee mentioned in paragraph 1 may be adapted once a year in accordance with the procedure referred to in Article 22(2) of Regulation (EC) No 1831/2003. The adaptation shall take into account the experience gained during the operation of this Regulation and in particular the possibility of fixing different fees for different types of applications.

Textual Amendments

F1 Substituted by 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 (Text with EEA relevance).

Article 5

Evaluation reports by the CRL

[[F1]1 The CRL shall submit a full evaluation report to the European Food Safety Authority (the Authority) for each application, or for each group of applications, within three months from the date of receipt of a valid application as referred to in Article 8(1) of Regulation (EC) No 1831/2003 and the payment of the fee.

However, if the CRL considers the application to be very complex, it may extend that period by an additional month. The CRL shall inform the Commission, the Authority, and the applicant when the period is extended.

The time limits provided for in this paragraph may be further extended with the agreement of the Authority, whenever the CRL requests supplementary information which cannot be provided by the applicant and/or cannot be evaluated by the CRL within those time limits.