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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)

(OJ L 59, 5.3.2005, p. 8)

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(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.
- (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.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

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- (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

Article 1

Subject matter and scope

This Regulation lays down detailed rules for the implementation of Regulation (EC) No 1831/2003 as regards:

- (a) applications for authorisation of a feed additive or for a new use of a feed additive as provided for in Article 4(1) of that Regulation (the application); and
- (b) the duties and tasks of the Community Reference Laboratory (the CRL).

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

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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).

*Article 3***Reference samples**

1. Any person making an application shall send reference samples:
 - (a) in a form in which the feed additive is intended to be placed on the market by the applicant; or
 - (b) that are suitable to be converted easily in a form in which the feed additive is intended to be placed on the market by the applicant.
2. The three reference samples 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 supply feed and/or food test materials related to the samples if requested by the CRL.

*Article 4***Fees****▼M1**

1. The CRL shall charge the applicant a fee of EUR 6 000 for each application (the fee).

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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.

*Article 5***Evaluation reports by the CRL**

1. The CRL shall submit a full evaluation report to the European Food Safety Authority (the Authority) for each application 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 that the application is very complex, it may extend that period by an additional month. The CRL shall inform the Commission, the Authority and the applicant where the period is extended.
2. The evaluation report provided for in paragraph 1 shall include in particular:
 - (a) an evaluation indicating if the methods of analysis in the data submitted in the application are suitable to be used for official controls;

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- (b) an indication if testing of a method of analysis is considered necessary;
- (c) an indication if a validation of a method of analysis by an inter-comparison study is considered necessary.

CHAPTER II

NATIONAL REFERENCE LABORATORIES

*Article 6***National reference laboratories**

1. The CRL shall be assisted by a consortium of national reference laboratories (the consortium) for the duties and tasks set out in 2.2, 2.4 and 3 of Annex II to Regulation (EC) No 1831/2003.
2. The consortium is open to national reference laboratories which comply with the requirements set out in Annex I. The laboratories listed in Annex II are hereby appointed national reference laboratories to take part in the consortium.
3. The members of the consortium, including the CRL, shall enter into a contract to define the relations between them, particularly in financial matters. In particular, the contract may provide that the CRL is to distribute a share of the fees it receives to the other members of the consortium. Subject to this contract, the CRL may issue guidance to the members of the consortium as provided for in Article 12.
4. Any Member State may submit requests to the Commission for the designation of further national reference laboratories to take part in the consortium. If it considers that such laboratories comply with the requirements set out in Annex I, the Commission shall amend the list in Annex II in accordance with the procedure referred to in Article 22 (2) of Regulation (EC) No 1831/2003. The same procedure shall apply if a Member State wishes to withdraw one of its national reference laboratories from the consortium. The contractual arrangements between the members of the consortium shall be adjusted to reflect any changes to the consortium.

*Article 7***Rapporteur laboratories**

1. The CRL shall appoint one laboratory to act as rapporteur laboratory for each application (the rapporteur laboratory).
However, the CRL may also act as rapporteur laboratory for applications.
2. When appointing a rapporteur laboratory, the CRL shall take into account the expertise, experience and workload of the laboratory.
3. The laboratories shall send comments to the rapporteur laboratory within 20 days from the date of receipt of the initial evaluation report provided for in Article 8(a).

*Article 8***Duties and tasks of rapporteur laboratories**

The rapporteur laboratories shall be responsible for:

- (a) drafting an initial evaluation report concerning the data submitted in each application and submitting it for comments to the other laboratories;

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- (b) compiling the comments received from the other laboratories and preparing a revised evaluation report;
- (c) submitting the revised evaluation report to the CRL in sufficient time to allow the CRL to submit its full evaluation report to the Authority within the deadline referred to in Article 5(1).

*Article 9***Duties and tasks of the laboratories participating in the consortium**

1. The laboratories participating in the consortium shall be responsible for contributing to the initial evaluation report prepared by the rapporteur laboratory by sending comments to the rapporteur laboratory within 20 days of the reception of the initial report.
2. Each laboratory shall communicate to the CRL by 30 January each year an estimate of the number of applications for which the laboratory considers itself able to carry out the tasks of rapporteur laboratory for that year. The CRL shall make available annually to all the laboratories a compilation of the estimates provided.

CHAPTER III

TESTING AND VALIDATION OF METHODS OF ANALYSIS, REPORTING AND GUIDANCE*Article 10***Testing of methods of analysis and validation of methods of analysis**

1. The CRL shall indicate in its evaluation report to the Authority, as provided for in Article 5(2), and shall inform the applicant and the Commission, if it considers that the following are necessary:

- (a) testing of methods of analysis;
- (b) validation of methods of analysis.

In doing so, the CRL shall provide the applicant with a document describing the work to be carried out through the consortium including a time schedule and an estimate of a special fee to be paid by the applicant. The applicant shall inform the CRL about his agreement to the document within 15 days of receipt of the communication.

2. The CRL shall supplement the report to the Authority, as provided for in Article 5(1), with an addendum concerning the outcome of the application of the procedure foreseen in paragraph 1 within 30 days of the availability to the CRL of the results of the testing and validation work.

*Article 11***Reporting**

The CRL shall be responsible for preparing an annual report on each year's activities carried out for the implementation of this Regulation and shall submit it to the Commission. The consortium shall contribute to this annual report.

The CRL may also organise an annual meeting with the consortium, in view of the establishment of the annual report.

▼B*Article 12***Guidance**

1. The CRL may establish detailed guidance for applicants concerning:
 - (a) reference samples;
 - (b) the testing of methods of analysis, including in particular criteria about when such testing may be required;
 - (c) the validation of methods of analysis, including in particular criteria about when such validation may be required.
2. The CRL shall establish detailed guidance for laboratories, including criteria for appointing rapporteur laboratories.

CHAPTER IV

FINAL PROVISIONS*Article 13***Amendments to Regulation (EC) No 1831/2003**

Paragraphs 2 and 3 of Annex II to Regulation (EC) No 1831/2003 are replaced by the text in Annex III to this Regulation.

*Article 14***Entry into force**

This Regulation shall enter into force on the twentieth day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

*ANNEX I***Requirements for laboratories participating, as referred to in Article 8**

Laboratories participating in the consortium must satisfy the following minimum requirements:

- (a) have been proposed as a national reference laboratory by a Member State for the purpose of taking part in the consortium referred to in Annex II to Regulation (EC) No 1831/2003;
- (b) have suitable qualified staff that are adequately trained in analytical methods used for the feed additives on which they are involved;
- (c) possess the equipment needed to carry out the analysis of feed additives, in particular the ones on which they are carrying tasks under this Regulation;
- (d) have an adequate administrative infrastructure;
- (e) have sufficient data-processing capacity to produce technical reports and to enable rapid communication with the other laboratories participating in the consortium;
- (f) provide assurance that their staff respect the confidential aspects of issues, results or communications involved in the handling of applications for authorisation submitted in accordance with Regulation (EC) No 1831/2003 and in particular the information referred to in Article 18 of that Regulation;
- (g) have sufficient knowledge of international standards and practices in laboratory work;
- (h) must be accredited, or being in the process of accreditation according to international standards such as ISO 17025.

▼ **M1***ANNEX II***Community Reference Laboratory and consortium of National Reference Laboratories, as referred to in Article 6(2)**

COMMUNITY REFERENCE LABORATORY

Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements, Geel, Belgium.

NATIONAL REFERENCE LABORATORIES OF THE MEMBER STATES

Belgique/België

- Federaal Voedingslabo Tervuren (AFSCA-FAVV), Tervuren,
- Vlaamse Instelling voor Technologisch Onderzoek (VITO), Mol.

Česká republika

- Ústřední kontrolní a zkušební ústav zemědělský (ÚKZÚZ), Praha.

Danmark

- Plantedirektoratets Laboratorium, Lyngby.

Deutschland

- Schwerpunktlabor Futtermittel des Bayerischen Landesamtes für Gesundheit und Lebensmittelsicherheit (LGL), Oberschleißheim,
- Landwirtschaftliche Untersuchungs- und Forschungsanstalt (LUF) Speyer, Speyer,
- Sächsische Landesanstalt für Landwirtschaft, Fachbereich 8 — Landwirtschaftliches Untersuchungswesen, Leipzig,
- Thüringer Landesanstalt für Landwirtschaft (TLL), Abteilung Untersuchungswesen. Jena.

Eesti

- Põllumajandusuringute Keskus (PMK), Jäädik ja saasteainete labor, Saku, Harjumaa,
- Põllumajandusuringute Keskus (PMK), Taimse materjali analüüsi labor, Saku, Harjumaa.

Éire/Ireland

- The State Laboratory, Kildare.

España

- Laboratorio Arbitral Agroalimentario, Ministerio de Agricultura, Pesca y Alimentación, Madrid,
- Laboratori Agroalimentari, Departament d'Agricultura, Ramaderia i Pesca, Generalitat de Catalunya, Cabrils.

France

- Laboratoire de Rennes, Direction générale de la concurrence, de la consommation et de la répression des fraudes (DGCCRF), Rennes.

Italia

- Istituto Superiore di Sanità, Dipartimento di Sanità alimentare ed animale, Roma,
- Centro di referenza nazionale per la sorveglianza ed il controllo degli alimenti per gli animali (CReAA), Torino.

▼ M1**Κύπρος**

— Εργαστήριο Ελέγχου Ζωοτροφών, Τμήμα Γεωργίας, Λευκωσία.

Latvija

— Valsts veterinārmedicīnas diagnostikas centrs (VVMDC), Rīga.

Lietuva

— Nacionalinė veterinarijos laboratorija, Vilnius,

— Klaipėdos apskrities VMVT laboratorija, Klaipėda.

Luxembourg

— Laboratoire de contrôle et d'essais — ASTA, Ettelbruck.

Magyarország

— Mezőgazdasági Szakigazgatási Hivatal (MgSzH) Élelmiszer- és Takarmánybiztonsági Igazgatóság, Központi Takarmányvizsgáló Laboratórium – Nemzeti Referencia Laboratórium, Budapest.

Nederland

— RIKILT-Instituut voor Voedselveiligheid, Wageningen,

— Rijksinstituut voor Volksgezondheid en Milieu (RIVM), Bilthoven.

Österreich

— Österreichische Agentur für Gesundheit und Ernährungssicherheit (AGES), Wien.

Polska

— Instytut Zootechniki w Krakowie, Krajowe Laboratorium Pasz, Lublin,

— Państwowy Instytut Weterynaryjny, Puławy.

Portugal

— Laboratório Nacional de Investigação Veterinária, Lisboa.

Slovenija

— Univerza v Ljubljani, Veterinarska fakulteta. Nacionalni veterinarski inštitut, Enota za patologijo prehrane in higieno okolja, Ljubljana,

— Kmetijski inštitut Slovenije, Ljubljana.

Slovensko

— Skúšobné laboratórium – Oddelenie analýzy krmív, Ústredný kontrolný a skúšobný ústav poľnohospodársky, Bratislava.

Suomi/Finland

— Elintarviketurvallisuusvirasto/Livsmedelssäkerhetsverket (Evira), Helsinki/Helsingfors.

Sverige

— Foderavdelningen, Statens Veterinärmedicinska Anstalt (SVA), Uppsala.

United Kingdom

— The Laboratory of the Government Chemist, Teddington.

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NATIONAL REFERENCE LABORATORIES OF EFTA COUNTRIES

Norway

— LabNett AS, Agricultural Chemistry Laboratory, Stjørdal.

*ANNEX III***Text replacing paragraphs 2 and 3 of Annex II to Regulation (EC) No 1831/2003**

2. For the duties and tasks set out in this Annex, the CRL may be assisted by a consortium of national reference laboratories.

The CRL shall be responsible for:

- 2.1. the reception, storage and maintenance of the samples of the feed additive sent by the applicant as provided for in Article 7(3)(f);
 - 2.2. evaluating the method of analysis of the feed additive, and of other relevant methods of analysis related to it, on the basis of the data provided in the application for authorisation of the feed additive as regards its suitability for official control in accordance with the requirements of the implementing rules referred to in Article 7(4) and (5) and the guidance of the Authority referred to in Article 7(6);
 - 2.3. submitting a full evaluation report to the Authority on the results of the duties and tasks referred to in this Annex;
 - 2.4. where necessary, the testing of the method(s) of analysis.
3. The CRL shall be responsible for coordination of the validation of the method(s) of analysis of the additive, in accordance with the procedure provided for in Article 10 of Regulation (EC) No 378/2005 (*). This task may involve the preparation of food or feed test material.
4. The CRL shall provide scientific and technical assistance to the Commission, especially in cases where Member States contest the results of analyses related to the duties and tasks referred to in this Annex, without prejudice to any role defined for it under Articles 11 and 32 of Regulation (EC) No 882/2004 of the European Parliament and of the Council (**).
5. On request by the Commission, the CRL may also be responsible for conducting special analytical or other related studies in a manner similar to the duties and tasks referred to in point 2. This may be the case, in particular, for existing products notified under Article 10 and included in the Register and for the period until an application for authorisation under Article 10(2) is submitted in accordance with Article 10(2).
6. The CRL shall be responsible for the overall coordination of the consortium of national reference laboratories. The CRL shall ensure that the relevant data concerning the applications are made available to the laboratories.
7. Without prejudice to the responsibilities of the Community reference laboratories laid down in Article 32 of Regulation (EC) No 882/2004, the CRL may create and maintain a database of methods of analysis available for control of feed additives and make it available to official control laboratories from Member States and other interested parties.'

(*) OJ L 59, 5.3.2005, p. 8.

(**) OJ L 165, 30.4.2004, p. 1. Corrigendum OJ L 191, 28.5.2004, p. 1.