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)

COMMISSION REGULATION (EC) No 885/2009

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amending Regulation (EC) No 378/2005 as regards reference samples, fees and the laboratories listed in Annex II

(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 paragraph of Article 21 thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 of the European Parliament and of the Council establishes a Community procedure for authorising the placing on the market and use of feed additives in animal nutrition. It provides that any person seeking authorisation for a feed additive or a new use of a feed additive is to submit an application for authorisation in accordance with that Regulation.

(2) Commission Regulation (EC) No 378/2005[(2)] lays down detailed rules for the implementation of Regulation (EC) No 1831/2003 as regards applications for authorisation of a feed additive or for a new use of a feed additive and the duties and tasks of the Community Reference Laboratory (CRL).

(3) It provides that any person making an application is to send reference samples in a form in which the feed additive is intended to be placed on the market by the applicant or 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.

(4) Regulation (EC) No 378/2005 also provides that the CRL is to charge applicants a fee of EUR 6 000 for each application. In addition, Annex II to that Regulation sets out a list of the consortium of national reference laboratories assisting the CRL in its duties and tasks.

(5) The experience gained during the operation of Regulation (EC) No 378/2005 shows that it is desirable to clarify certain details of the existing requirements for the reference samples to be submitted by applicants in some cases and to simplify them in the cases of a) applications for new uses of already authorised additives and b) applications for changing the terms of authorisations 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.

(6) Experience has shown that different rates should be established for the fee depending on the different types of applications, in particular taking into account the need for new reference samples and new evaluations of the method of analysis for feed additives already authorised.

(7) In addition, there are multi-analyte 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. Experience has shown that it is possible to carry out the evaluations of the methods of analysis for similar feed additives in groups when the methods of analysis are similar and particularly in the case of these multi-analyte methods.

(8) A number of already authorised feed additives subject to the re-evaluation process provided for in Article 10(2) of Regulation (EC) No 1831/2003 may be subject to applications submitted simultaneously in homogeneous groups when they belong to the same category of feed additives, functional group and sub classification, if applicable, and when the methods of analysis used for them are of the type multi-analyte methods.

(9) The substances classified in the group 'chemically defined flavourings' appearing in the Community Register of Feed Additives, belonging to the category sensory additives and allocated within the functional group flavouring compounds, are a group of feed additives representing nearly two thirds of the entries of the Community Register of Feed Additives at present. Those chemically defined flavourings are subject to the re-evaluation process provided for in Article 10(2) of Regulation (EC) No 1831/2003 and therefore may represent a significant workload in the process. These chemically defined flavourings also represent an homogeneous group of feed additives in terms of their conditions of authorisation and their safety assessment to be carried out following the specific requirements for them laid down in 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[(3)]. The methods of analysis used for many of these chemically defined flavourings may be of the type of multi-analyte methods.

(10) It is therefore appropriate to establish a system of reduced fees for groups of applications for authorisations concerning already authorised feed additives such as the chemically defined flavourings when the applications are submitted simultaneously and contain similar methods of analysis, particularly of the type multi-analyte methods.

(11) For the purpose of the calculation of the different fees, the fee is considered to be composed of two components. The first component is intended to support the CRL administrative costs and the costs related to the handling of the reference samples. The second component is intended to support the costs of the Rapporteur Laboratory for the scientific evaluation and preparation of the evaluation report.

(12) It is also appropriate to adapt the scope of the guidance to applicants prepared by the CRL following the adoption of Regulation (EC) No 429/2008 and also to introduce other minor amendments to Regulation (EC) No 378/2005, taking into account the experience gained.

(13) Belgium has submitted a request to the Commission for the designation of Centre wallon de recherches agronomiques (CRA-W) in Gembloux, as a new national reference laboratory to take part in the consortium. Since that laboratory complies with the requirements set out in Annex I to Regulation (EC) No 378/2005 it should be inserted in the list of laboratories set out in Annex II to that Regulation. Lithuania has informed the Commission that it wishes to withdraw Klaipėdos apskrities VMVT laboratorija, in Klaipėda, from the consortium of national reference laboratories. That laboratory should therefore be deleted from that list of laboratories. In addition several Member States have informed the Commission that certain details of their national reference laboratories taking part in the consortium have changed. The list in Annex II to Regulation (EC) No 378/2005 should be amended accordingly. In the interests of clarity of Community legislation, it should be replaced in its entirety by the list in the Annex I to this Regulation.

(14) Regulation (EC) No 378/2005 should therefore be amended accordingly.

(15) 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:

Article 1

Regulation (EC) No 378/2005 is amended as follows:

1. Article 1 is replaced by the following:

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).

2. In Article 2, the following points (h) and (i) are added:

(h) "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.

3. Article 3 is replaced by the following:

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[(4)] 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[(5)], 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;

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.

4. In Article 4, paragraph 1 is replaced by the following:

1. The CRL shall charge the applicant a fee in accordance with the rates set out in Annex IV ("the fee").

5. Article 5 is amended as follows:

(a) Paragraph 1 is replaced by the following:

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.

However, the time limit for the CRL to submit the evaluation report to the Authority shall not exceed the time limit for Authority to provide its opinion, as provided for in Article 8(1) of Regulation (EC) No 1831/2003.

(b) The following paragraphs 3 and 4 are added:

3. The evaluation report provided for in paragraph 1 may be amended by the CRL at the request of the Commission or the Authority where:

a the conditions for placing the feed additive on the market resulting from the Authority's opinion in accordance with Article 8(3)(a) of Regulation (EC) No 1831/2003 differ from those originally proposed by the applicant;

b supplementary information relevant to the method of analysis have been provided by the applicant to the Authority.

4 An evaluation report shall not be required for:

a applications for a new use of a feed additive submitted in accordance with Article 4(1) of Regulation (EC) No 1831/2003, when the proposed conditions for placing the feed additive on the market for the new use fall within the scope of the method of analysis previously submitted in accordance with paragraph 2.6 of Annex II to Regulation (EC) No 429/2008 and already evaluated by the CRL;

b applications 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 or the new conditions for