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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

amending Regulation (EC) No 378/2005 as regards reference samples, fees, evaluation reports and the national reference laboratories

(Text with EEA relevance)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 Article 7(4), first subparagraph and Article 21, third paragraph, thereof,

After consulting the European Food Safety Authority,

Whereas:

(1) Regulation (EC) No 1831/2003 establishes the procedure for authorising the placing on the market and use of 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.

(2) Article 21, first paragraph, of Regulation (EC) No 1831/2003 provides that the Community reference laboratory (the CRL) has the duties and tasks set out in Annex II to that Regulation. That Annex provides that the CRL referred to in Article 21 of Regulation (EC) No 1831/2003 is the Joint Research Centre of the Commission. The CRL may be assisted by a consortium of national references laboratories (the consortium) and is conferred responsibility for the overall coordination of the consortium.

(3) Commission Regulation (EC) No 378/2005[2] lays down detailed rules for the implementation of Regulation (EC) No 1831/2003 as regards the duties and tasks of the CRL, including specific requirements concerning the reference samples to be provided in applications for authorisation, the fee rates that the CRL is to charge applicants, and the development of guidance by the CRL for the national reference laboratories participating in the consortium. Annex I to Regulation (EC) No 378/2005 sets out the requirements for national reference laboratories to take part in the consortium assisting the CRL with its duties and tasks. Annex II to that Regulation lists those national reference laboratories, and Annex IV to that Regulation provides for the rates for fees that the CRL is to charge applicants.

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1 OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.

2 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 (OJ L 59, 5.3.2005, p. 8, ELI: http://data.europa.eu/eli/reg/2005/378/oj).

(4) Article 3(4) of Regulation (EC) No 378/2005 sets out exceptions to the requirement to supply reference samples for applications. These exceptions concern applications for a new use of a feed additive where reference samples had been previously sent to the CRL for another use for which the feed additive was authorised, or for changing the terms of an existing authorisation, where 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. In these cases, the reference samples submitted for previous applications are still in the form in which the feed additive is intended to be placed on the market. Experience has shown that the same situation exists for certain applications for renewal of an existing authorisation. The exceptions to the requirement to supply reference samples should therefore be extended to applications for renewal of an existing authorisation provided that the reference samples previously supplied still correspond to the form in which the feed additive, for which the renewal of authorisation is requested, is intended to be placed on the market.

(5) However, the exceptions to the requirement to supply reference samples should not affect the obligations of the applicant, laid down in Article 3(3) of Regulation (EC) No 378/2005, to supply new reference samples to replace those expired, or additional reference samples where requested by the CRL. Article 3(4) of Regulation (EC) No 378/2005 should therefore be amended accordingly.

(6) Article 4 of Regulation (EC) No 378/2005 provides that the CRL is to charge applicants fees in accordance with the rates set out in Annex IV to that Regulation. Such fees are determined in accordance with the type of application for authorisation of feed additives. To take into account the costs of possible additional tasks to be performed by the CRL during the authorisation procedure, the CRL should have the possibility of charging an additional fee, allowing the applicant to notify his disagreement thereto within a certain timeframe. Article 4 of Regulation (EC) No 378/2005 should therefore be amended accordingly.

(7) Should the applicant notify his disagreement on the communication by the CRL on an additional fee, the CRL should indicate in its evaluation report to the Authority in accordance with Article 5(1) of Regulation (EC) No 378/2005 which of its duties and tasks could not be carried out. Article 5(2) of Regulation (EC) No 378/2005 should therefore be amended accordingly.

(8) In accordance with Article 5(4) of Regulation (EC) No 378/2005, certain applications for a new use of a feed additive, for changing the terms of an existing authorisation or for the renewal of an existing authorisation are exempted from the requirement of an evaluation report by the CRL. Article 5(4), second subparagraph, of Regulation (EC) No 378/2005 provides however that a new evaluation of the methods of analysis may be considered necessary by the Commission, the CRL or the Authority on the basis of legitimate factors relevant to the application. For purposes of legal certainty, it should be clarified that such factors may include the need to adapt the methods of analysis to take account of scientific and technological developments and that any related impact on the calculation of the rates for fees is to be considered, where relevant. Article 5(4), second subparagraph, of Regulation (EC) No 378/2005 should therefore be amended accordingly.

(9) Article 6(4) of Regulation (EC) No 378/2005 provides that amendments to the list of national reference laboratories laid down in Annex II to that Regulation are to be adopted by the Commission in accordance with the procedure referred to in Article 22(2) of Regulation (EC) No 1831/2003. However, it appears that this procedure lacks

the flexibility required to adapt the list to the changes requested by the Member States in a timely manner. In addition, considering its responsibility for the overall coordination of the consortium, the CRL would be best placed to publish and update the list of those laboratories. In view of this situation, laboratory designations by the Member States should be submitted not only to the Commission but also directly to the CRL, for the purpose of the publication and update of the list of national reference laboratories by the CRL. Therefore, the list of national reference laboratories should no longer be included in Regulation (EC) No 378/2005 and Annex II to that Regulation should be deleted. As a result, the reference in Annex II to Regulation (EC) No 378/2005 to the Joint Research Centre of the Commission acting as CRL should be included in Article 1 of that Regulation. Additionally, Article 6 of Regulation (EC) No 378/2005 and the title and point (a) of Annex I to that Regulation should be amended accordingly.

(10) Furthermore, it is appropriate to clarify in Article 6 of Regulation (EC) No 378/2005 that the relations between the members of the consortium and the CRL are the subject of arrangements rather than a contract in the strict sense.

(11) Article 9(2) of Regulation (EC) No 378/2005 requires an annual communication by each national reference laboratory to the CRL regarding the estimated number of applications for which the national reference laboratory considers itself able to act as rapporteur laboratory for the year concerned. In accordance with the same provision, the CRL is required to make available annually to all the national reference laboratories a compilation of the estimates provided. However, it appears that it would be more efficient if the appointment of rapporteur laboratories in accordance with Article 7 of Regulation (EC) No 378/2005 was effected directly by the CRL through its ongoing consultations with the consortium without formal annual communications from each national reference laboratory regarding its administrative capacities. Consequently, to reduce unnecessary administrative burden both on the CRL and on the national reference laboratories, Article 9(2) of Regulation (EC) No 378/2005 should be deleted.

(12) Article 12(2) of Regulation (EC) No 378/2005 requires the CRL to establish detailed guidance for laboratories participating in the consortium assisting it with its duties and tasks, including criteria for appointing rapporteur laboratories. However, experience has shown that the development of such guidance is not needed for the good functioning of the relations between the CRL and the national reference laboratories as in practice regular consultations with the consortium and other initiatives organised by the CRL ensure the smooth functioning of that consortium, including the appointment of rapporteur laboratories. The establishment of detailed guidance by the CRL for national reference laboratories should therefore not be mandatory and Article 12(2) of Regulation (EC) No 378/2005 should be amended accordingly.

(13) The exception to the requirement to supply reference samples for applications for the renewal of authorisations, as provided for in Article 3(4) of Regulation (EC) No 378/2005, should be reflected in the calculation of the fees in accordance with the type of application. Point 5 of Annex IV to Regulation (EC) No 378/2005, under the heading concerning the rates according to the type of application for authorisations of feed additives in accordance with Regulation (EC) No 1831/2003, should therefore be amended accordingly.

(14) For the purposes of completeness, the rates for fees should include the cases where an application for changing the terms of an existing authorisation or an application for

renewal of an authorisation does not fall within the scope of the exceptions to the requirement to supply reference samples, as provided for in Article 3(4) of Regulation (EC) No 378/2005. Points 4 and point 5 of Annex IV to that Regulation, under the heading concerning the rates according to the type of application for authorisations of feed additives in accordance with Regulation (EC) No 1831/2003, should therefore be amended accordingly.

(15) The first publication of the list of national reference laboratories by the CRL should be with effect from the date of entry into force of this Regulation to ensure a smooth transition to the new procedure for the designation of those national reference laboratories.

(16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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), which is the Joint Research Centre of the Commission located in Geel, Belgium.';

(2) Article 3(4) is amended as follows:

(a) the introductory phrase is replaced by the following:

'Unless the applicant is required to supply reference samples in accordance with paragraph 3, reference samples shall not be required for:';(b) the following point (c) is added:

'(c) an application for renewal of an existing authorisation submitted in accordance with Article 14 of Regulation (EC) No 1831/2003, provided the reference samples held by the CRL in relation to the existing authorisation of the feed additive are in the form in which the feed additive is intended to be placed on the market.';

(3) in Article 4, the following paragraph 4 is added:

'4. Where the CRL considers that, due to developments following the submission of the application, additional duties and tasks are to be performed and the final fee rates relevant to the type of application concerned are to be higher than those calculated at the time of the submission of the application, it shall communicate those considerations and the corresponding additional fee to the applicant. The applicant shall notify the CRL about any disagreement on the additional fee within 15 days of receipt of the communication.';

(4) in Article 5(2), the following point (aa) is added:

‘(aa) an indication of which of the duties and tasks set out in Annex II to Regulation (EC) No 1831/2003 could not be carried out as a result of the disagreement notified by the applicant on additional fees as referred to in Article 4(4);’

(5) in Article 5(4), the second subparagraph is replaced by the following:

‘Notwithstanding paragraph 4, the Commission, the CRL or the Authority may, on the basis of legitimate factors relevant to the application, in particular the need to adapt the methods of analysis in the light of scientific and technological developments, consider that a new evaluation of the methods of analysis is necessary. In such cases the applicant shall be informed by the CRL and Article 4(4) shall apply.’;

(6) Article 6 is replaced by the following:

‘*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 points 2.2, 2.4 and 3 of Annex II to Regulation (EC) No 1831/2003.

2. The Member States may designate national reference laboratories for the purpose of inclusion in the list of national reference laboratories participating in the consortium, provided that the designated national reference laboratories comply with the requirements set out in Annex I. The Member States shall communicate those designations to the CRL and the Commission. The CRL shall be responsible for the publication on its website of the list of the national reference laboratories designated by the Member States, including the name and address of each of them, and for the update of that list, whenever necessary, upon reception of the relevant information. The same procedure shall apply if a Member State wishes to withdraw from the consortium a national reference laboratory that it designated.

3. The first publication by the CRL of the list of national reference laboratories designated by the Member States to take part in the consortium shall be with effect from [*date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*].

4. The members of the consortium and the CRL shall make arrangements for defining the relations between them, particularly in financial matters. In particular, the arrangements may provide that the CRL is to distribute a share of the fees it receives to the members of the consortium. The arrangements between the members of the consortium and the CRL shall be adapted to reflect any changes to the consortium. Without prejudice to the provisions of those arrangements, the CRL may issue guidance to the members of the consortium as provided for in Article 12(2). ’;

(7) Article 9(2) is deleted;

(8) Article 12(2) is replaced by the following:

‘2. The CRL may establish detailed guidance for national reference laboratories, including criteria for appointing rapporteur laboratories.’;

(9) Annex I is amended as follows:

(a) the title is replaced by the following:

‘**Requirements for laboratories participating in the consortium of national reference laboratories, as referred to in Article 6(2)**’;

(b) point (a) of Annex I is replaced by the following:

‘(a) have been designated as a national reference laboratory by a Member State for the purpose of taking part in the consortium referred to in Article 21 and Annex II to Regulation (EC) No 1831/2003;’;

(10) Annex II is deleted;

(11) Annex IV, under the heading ‘Rates according to the type of application for authorisations of feed additives in accordance with Regulation (EC) No 1831/2003’, is amended as follows:

(a) point 4 is replaced by the following:

‘4. Applications for changing the terms of an existing authorisation (Article 13(3) of Regulation (EC) No 1831/2003):

— when Article 3(4), point (b) and Article 5(4), point (b) apply:

Fee = EUR 0

— when only Article 3(4), point (b) applies, only Component 2 is applicable:

Fee = EUR 4 000

— when neither Article 3(4), point (b) nor Article 5(4), point (b) applies:

Fee = Component 1 + Component 2 = EUR 6 000’;

(b) point 5 is replaced by the following:

‘5. Applications for renewal of an authorisation of a feed additive (Article 14 of Regulation (EC) No 1831/2003):

— when Article 3(4), point (c) and Article 5(4), point (c) apply:

Fee = EUR 0

— when only Article 3(4), point (c) applies, only Component 2 is applicable:

Fee = EUR 4 000

— when neither Article 3(4), point (c) nor Article 5(4), point (c) applies:

Fee = Component 1 + Component 2 = EUR 6 000.’.

Article 2

This Regulation shall enter into force on the twentieth day following that of 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.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN