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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 and correcting that Regulation as regards Annex I thereto

(Text with EEA relevance)

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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 and correcting Annex I of that Regulation

(Text with EEA relevance)

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 nutrition¹, 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 378/2005² lays down detailed rules for the implementation of Regulation (EC) No 1831/2003 as regards the duties and tasks of

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>).

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.

- (4) Article 3(4) of Regulation (EC) No 378/2005 sets out exceptions to the requirement to supply reference samples for 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, and where therefore reference samples are still in the form in which the feed additive is intended to be placed on the market. Experience has shown that the reason for the above-mentioned exceptions to the requirement concerning the supply of reference samples is also valid for certain applications for renewal of an existing authorisation. It should therefore be clarified that the exceptions to that requirement include 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) The exception to the requirement to supply reference samples for applications for the renewal of authorisations 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.
- (7) 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. Point 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.
- (8) 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 according to the type of application for authorisation of feed additives. However, experience has shown that the rates for fees calculated at the time of the submission of the application may turn out to be different at a later stage of the authorisation procedure, due to new information received in the course of the procedure concerning that application, which may require additional tasks to be

performed by of the CRL. In order to take into account the costs of those additional tasks, the CRL should have the possibility to charge an additional fee. Article 4 of Regulation (EC) No 378/2005 should therefore be amended accordingly.

- (9) 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 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 fee rates is to be considered where relevant. Article 5(4), second subparagraph, of Regulation (EC) No 378/2005 should therefore be amended accordingly.
- (10) 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 in order to adapt the list to the changes requested by the Member States in a timely manner. In addition, considering in particular its responsibility for the overall coordination of the consortium, the CRL would be best placed to update and publish the list of those laboratories. In view of this situation, while requests for laboratory designations by the Member States would continue to be submitted to the Commission, the publication and regular update of the list of national reference laboratories should be carried out 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 point (a) of Annex I to that Regulation should be amended accordingly.
- (11) Furthermore, it is appropriate to clarify in 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 *stricto sensu*.
- (12) 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 in practice, the designation of rapporteur laboratories in accordance with Article 7 of Regulation (EC) No 378/2005 is conducted directly by the CRL through its ongoing consultations with the consortium without the need for 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.

- (13) Article 12(2) requires the CRL to establish detailed guidance for national reference laboratories participating in the consortium assisting it for its duties and tasks, including criteria for appointing rapporteur laboratories. However, experience has shown that the development of such guidance was not considered as needed until now for the good functioning of the relations between the CRL and the national reference laboratories, as in practice regular consultations with the consortium and initiatives organised by the CRL ensure the smooth functioning of that consortium, including regarding the appointment of rapporteur laboratories. The establishment of detailed guidance by the CRL for laboratories should therefore not be made mandatory and Article 12(2) should be amended accordingly.
- (14) By mistake, the title of Annex I to Regulation (EC) No 378/2005 refers to Article 8, instead of Article 6, of that Regulation and should therefore be corrected accordingly.
- (15) *[Transitional measures concerning the list of NRLs – to be completed]*
- (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
Amendments to Regulation (EC) No 378/2005

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 higher than those calculated at the time of the submission of the application, it shall communicate those considerations to the applicant and request an additional fee accordingly. Should the applicant notify

any disagreement on the additional fee within 15 days of receipt of the communication, the CRL shall indicate in the report referred to in Article 5(1) of this Regulation which of the duties and tasks set out in Annex II to Regulation (EC) No 1831/2003 could not be carried out.’;

- (4) 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, consider that a new evaluation of the methods of analysis is necessary. In particular, the Commission, the CRL or the Authority may consider that the methods of analysis need to be adapted in the light of scientific and technological developments. In such cases the applicant shall be informed by the CRL and Article 4(4) shall apply.’;

- (5) 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 consortium is open to national reference laboratories that comply with the requirements set out in Annex I.
 3. [With effect from *[date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]*, the CRL shall publish and update the list of national reference laboratories designated to take part in the consortium. *– To be further considered*]
 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. Subject to those arrangements, the CRL may issue guidance to the members of the consortium as provided for in Article 12.
 5. The Member States may designate any national reference laboratories that they consider as complying with the requirements set out in Annex I as national reference laboratories for the purpose of inclusion in the list of national reference laboratories designated to take part in the consortium. The Member States shall submit those designation requests to the Commission for onward transmission to the CRL. 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 from the Commission of the relevant information. The same procedure shall apply if a Member State wishes to withdraw one of its national reference laboratories from the consortium. The arrangements with the members of the consortium referred to in paragraph 4 shall be adjusted to reflect any changes to the consortium.’;
- (6) Article 9(2) is deleted;
- (7) Article 12(2) is replaced by the following:

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

(8) In Annex I, point (a) 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 Annex II to Regulation (EC) No 1831/2003;’

(9) Annex II is deleted;

(10) Annex IV, under the heading ‘Rates according to the type of application for authorisation 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)(b) and Article 5(4)(b) apply:

Fee = EUR 0

– when only Article 3(4)(b) applies, only Component 2 applies:

Fee = EUR 4000

– when neither Article 3(4)(b) nor Article 5(4)(b) applies:

Fee = Component 1 + Component 2 = EUR 6000’

(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)(c) and Article 5(4)(c) apply:

Fee = EUR 0

– when only Article 3(4)(c) applies, only Component 2 applies:

Fee = EUR 4 000

– when neither Article 3(4)(c) nor Article 5(4)(c) applies:

Fee = Component 1 + Component 2 = EUR 6000’.

Article 2

Correction to Regulation (EC) No 378/2005

The title of Annex I to Regulation (EC) No 378/2005 is replaced by the following:

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

Article 3
Entry into force

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