EUROPEAN
COMMISSION

Brussels, XXX
PLAN/2024/2894 CIS
(POOL/G5/2024/2894/2894-EN
CIS.docx)
[…](2025) XXX draft

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)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

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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)

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 the first subparagraph of Article 7(4) and the third subparagraph of Article 21 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 feed additives. 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) Annex II to Regulation (EC) No 1831/2003 provides that the Community reference laboratory ('CRL') may be assisted by a consortium of national references laboratories ('consortium') for the duties and tasks set out in that Annex and confers upon the CRL the responsibility for the overall coordination of that 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 and the fee rates to be charged by the CRL on applicants. 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 for its

[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).

duties and tasks and Annex II to that Regulation provides for the list of those national reference laboratories.

(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 or for changing the terms of an existing authorisation, where such applications do not modify the form in which the feed additive is intended to be placed on the market and for which reference samples had been previously sent to the CRL. Experience has shown that the exceptions to the requirement concerning the submission of reference samples should be extended to the applications for renewal of an existing authorisation, provided that the reference samples previously submitted 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. However, the exceptions to the requirement to supply reference samples should not affect the obligations on the applicant, laid down in Article 3(3) of Regulation (EC) No 378/2005, to supply new or additional reference samples to replace those expired or where requested by the CRL. Article 3(4) of Regulation (EC) No 378/2005 should therefore be amended accordingly.

(5) The exception to the requirement to submit reference samples for applications for renewal of authorisation should be reflected in the calculation of the fees according to the type of application. Point 5 of Annex IV to 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 fees on applicants in accordance with rates that 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 that procedure concerning the application for authorisation, which may affect the deriving tasks of the CRL. In order to take into account the costs of those actual tasks, the CRL should have the possibility to adapt the fee rates where such modification occurs. Articles 4 and 5(4) of Regulation (EC) No 378/2005 should therefore be amended accordingly.

(7) Article 5(4), second subparagraph, of Regulation (EC) No 378/2005 provides that a new evaluation of the methods of analysis may be considered as necessary for applications for a new use of a feed additive, for changing the terms of an authorisation or for renewal of an authorisation, on the basis of legitimate factors relevant to the application. For legal certainty purpose, it should be clarified that such factors may include the need to adapt the analysis methods to take account of scientific and technological developments and that any related impact on the calculation of the fees rates is to be considered where appropriate. The second subparagraph of Article 5(4) of Regulation (EC) No 378/2005 should therefore be amended accordingly.

(8) 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 timely adapt the list to the modifications requested by the Member States. 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 laboratories designation 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. Furthermore, it is appropriate to clarify that the relations between the members of the consortium, including the CRL, are the subject of an agreement rather than a contract stricto sensu. Article 6 and Annex I of Regulation (EC) No 378/2005 should therefore be amended accordingly.

(9) As a result of the above amendment, the remaining reference in Annex II to Regulation (EC) No 378/2005 concerning the Joint Research Centre of the Commission which is acting as CRL should rather be included in the enacting terms of that Regulation.

(10) Article 9(2) of Regulation (EC) No 378/2005 requires the annual communication by each national reference laboratory to the CRL of the estimated number of applications for which the national reference laboratory could act as rapporteur laboratory for the year concerned. According to 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 organised directly by the CRL in the context of its permanent exchanges with the consortium without the need for formal annual communications from each national reference laboratory. Consequently, in order 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.

(11) 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.

(12) 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) In Article 3(4),

– the first sentence is replaced by the following:

‘Unless the applicant is required to maintain or to supply reference samples in accordance with paragraph 3, reference samples shall not be required for:’

– 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, when reference samples held by the CRL in relation to the existing authorisation of the feed additive are still 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 the rates for fees relevant to the type of application concerned differ from those calculated at the time of the submission of the application, it shall inform the applicant thereof and adapt the fee charge accordingly. Should the applicant notify his disagreement to the change of fees rates within 15 days of receipt of the communication, the CRL shall indicate in the report referred to in Article 5(1) 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 CRL may consider that the existing 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 where appropriate.'

(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 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. The members of the consortium, including the CRL, shall enter into an agreement to define the relations between them, particularly in financial matters. In particular, the agreement 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 agreement, 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 national reference laboratories complying with the requirements set out in Annex I to take part in the consortium. The Commission shall forward those requests 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 between the members of the consortium shall be adjusted to reflect any changes to the consortium.'

(6) Article 9(2) is deleted.

(7) 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;’

(8) In Annex II, the title and the provisions included therein are deleted.

(9) In Annex IV, point 5 is replaced by the following:

‘5. 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 4000.’

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

Transitional measure concerning the national reference laboratories

The national reference laboratories on the list published by the CRL by the date of entry into force of this Regulation are hereby appointed national reference laboratories to take part in the consortium referred to in Article 6(1) of Regulation (EC) No 378/2005.

Article 4

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