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)

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;

(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)**[**F1;**]**

(d) **[**F2if requested by the CRL, submitting an amendment to the evaluation report concerning the supplementary data submitted by the applicant to the CRL or to the Authority.**]**

Textual Amendments

F1 Substituted by 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).

F2 Inserted by 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).

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.

Status:
Point in time view as at 31/12/2020.

Changes to legislation:
There are outstanding changes not yet made to Commission Regulation (EC) No 378/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.