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 III

TESTING AND VALIDATION OF METHODS OF ANALYSIS, REPORTING AND GUIDANCE

Article 10

Testing of methods of analysis and validation of methods of analysis

1 The CRL shall indicate in its evaluation report to the Authority, as provided for in Article 5(2), and shall inform the applicant and the Commission, if it considers that the following are necessary:

a testing of methods of analysis;

b validation of methods of analysis.

In doing so, the CRL shall provide the applicant with a document describing the work to be carried out through the consortium including a time schedule and an estimate of a special fee to be paid by the applicant. The applicant shall inform the CRL about his agreement to the document within 15 days of receipt of the communication.

2 The CRL shall supplement the report to the Authority, as provided for in Article 5(1), with an addendum concerning the outcome of the application of the procedure foreseen in paragraph 1 within 30 days of the availability to the CRL of the results of the testing and validation work.

Article 11

Reporting

The CRL shall be responsible for preparing an annual report on each year's activities carried out for the implementation of this Regulation and shall submit it to the Commission. The consortium shall contribute to this annual report.

The CRL may also organise an annual meeting with the consortium, in view of the establishment of the annual report.

Article 12

Guidance

1 The CRL may establish detailed guidance for applicants concerning:

a reference samples;

b the testing of methods of analysis, including in particular criteria about when such testing may be required;

c the validation of methods of analysis, including in particular criteria about when such validation may be required**[**F1**;]**

[F2**** d requirements concerning methods of analysis submitted in accordance with paragraph 2.6. of Annex II to Regulation (EC) No 429/2008.**]**

2 The CRL shall establish detailed guidance for laboratories, including criteria for appointing rapporteur laboratories.

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).

Status:
Point in time view as at 16/10/2009.

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.