

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;

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**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. (See end of Document for details) [View outstanding changes](#)

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- 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<sup>[F1];</sup>
  - <sup>[F2]</sup>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 \(Text with EEA relevance\)](#).

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**Changes and effects yet to be applied to the whole legislation item and associated provisions**

- Signature words omitted by [S.I. 2019/654 reg. 75](#)
- Art. 3(1)(a) words omitted by [S.I. 2022/1351 reg. 10\(2\)\(a\)\(ii\)\(bb\)](#)
- Art. 3(1)(a) words substituted by [S.I. 2019/654 reg. 65\(b\)](#)
- Art. 4(4)-(9) inserted by [S.I. 2019/654 reg. 66\(c\)](#)
- Art. 4(5)(c) omitted in earlier amending provision S.I. 2019/654, reg. 66(c) by [S.I. 2020/1504 reg. 12\(14\)\(a\)](#)
- Art. 4(8) words substituted in earlier amending provision S.I. 2019/654, reg. 66(c) by [S.I. 2020/1504 reg. 12\(14\)\(b\)\(i\)](#)
- Art. 4(8)(b) words substituted in earlier amending provision S.I. 2019/654, reg. 66(c) by [S.I. 2020/1504 reg. 12\(14\)\(b\)\(ii\)](#)
- Art. 4(8)(d) omitted in earlier amending provision S.I. 2019/654, reg. 66(c) by [S.I. 2020/1504 reg. 12\(14\)\(b\)\(iii\)](#)
- Art. 4(8)(d) words substituted by [S.I. 2019/1013 reg. 56](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/1013 revoked immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 21(e))
- Art. 4(9)(d) omitted in earlier amending provision S.I. 2019/654, reg. 66(c) by [S.I. 2020/1504 reg. 12\(14\)\(c\)](#)