Commission Regulation (EC) No 1981/2006 of 22 December 2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the Community reference laboratory for genetically modified organisms (Text with EEA relevance)

Article 1

Subject matter and scope

This Regulation lays down detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 as regards:

(a) the contribution to the costs of the tasks of the Community reference laboratory (CRL) and of the national reference laboratories, as referred to in the Annex to the said Regulation; and

(b) the establishment of national reference laboratories.

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

(a) 'full validation procedure' means the assessment through a ring trial involving national reference laboratories of the method performance criteria set by the applicant as compliant with the document entitled 'Definition of minimum performance requirements for analytical methods of GMO testing' referred to in point 1(B) of Annex I to Regulation (EC) No 641/2004, and the assessment of the repeatability and trueness of the method provided by the applicant;

(b) 'small and medium-sized enterprise (SME)' means small and medium-sized enterprises as defined in Commission Recommendation 2003/361/EC[(1)];

(c) 'developing countries' means beneficiary countries as referred to in Article 2 of Council Regulation (EC) No 980/2005 of 27 June 2005 applying a scheme of generalised tariff preferences[(2)];

(d) 'application' where used without further specification, means an application for authorisation submitted in accordance with Article 5 or 17 of Regulation (EC) No 1829/2003, including applications submitted under other Community legislation which are transformed or supplemented in accordance with Article 46 of that Regulation. It also refers to applications for renewal of authorisations according to Article 11 or 23 of Regulation (EC) No 1829/2003 and modifications of authorisations according to Articles 9(2), 10, 21(2) or 22 of that Regulation, where the CRL is requested to test and validate a method of detection and identification.

Article 3

Contributions

1 For each application, a flat-rate contribution of EUR 30 000 shall be paid by the applicant to the CRL.

2 Where a full validation procedure of a method of detection and identification for a single GMO event according to the requirements laid down in Annex I of Regulation (EC) No 641/2004 is required, the CRL shall request the applicant to pay an additional contribution of EUR 60 000.

This amount shall be multiplied by the number of GMO events to be fully validated.

The CRL shall reduce the amount of the additional contribution, in proportion of the costs saved:

a where the material needed to perform the full validation procedure is supplied by the applicant; and/or

b where the applicant provides data that refer to modules, such as DNA extraction protocols and species specific reference systems, already validated and published by the CRL.

3 Where the costs of the validation of the detection method proposed by the applicant exceed substantially the amount of the financial contributions mentioned under paragraphs 1 and 2, an additional contribution shall be requested.

The additional contribution shall cover 50 % of the part of the costs exceeding the amount of the contributions referred to in paragraphs 1 and 2.

4 The contributions provided for in paragraphs 1 and 2 remain due in case of withdrawal of the application.

Article 4

Reductions and exemptions

1 Where the applicant is a SME or has its head office established in a developing country, the financial contributions referred to in Article 3(1) and (2) shall be reduced by 50 %.

2 Where the same method of detection and identification has already been included in a previous application by the same applicant for products related to the same GMO and that method has been validated and published by the CRL or its validation is pending, that applicant shall be exempted from the payment of the financial contributions referred to Article 3.

However, where costs are incurred by the CRL in carrying out the validation tasks laid down in Regulation (EC) No 1829/2003, the CRL may charge the applicant a maximum contribution of EUR 30 000.

3 Article 3(3) shall not apply where the applicant is a SME or has its head office established in a developing country, nor to applications submitted before the entry into force of this Regulation.

Article 5

Procedure

1 The applicant shall provide evidence that the flat-rate contribution of EUR 30 000 referred to in Article 3(1) has been paid to the CRL when it submits the samples of the food and feed and their control samples to the CRL in accordance with Article 5(3)(j) or Article 17(3)(j) of Regulation (EC) No 1829/2003.

2 Where, as provided for in Article 3(2), a full validation procedure is required, the CRL shall notify the applicant in writing of this fact and require the payment of the amount due in accordance with that provision.

3 Where, as provided for in Article 3(3), the CRL expects the costs of the validation of the detection method proposed by the applicant to exceed substantially the amount of the financial contributions referred to in Article 3(1) and (2), it shall notify the applicant in writing of the estimated amount of the additional costs.

If, within one month of the date of receipt of the notification, the applicant withdraws its application, the additional contribution referred to in Article 3(3) is not due.

After completion of the validation of the detection method, the CRL shall notify the applicant in writing the actual and duly justified costs incurred in carrying out the validation of the detection method and require payment of the contribution due in accordance with Article 3(3).

4 Where, as provided for in Article 4(2), costs are incurred, the CRL shall notify the applicant in writing of the amount of the contribution due, including a justification of that amount.

5 Where an application has been submitted before the date of entry into force of this Regulation, the CRL shall, within three months of that date, notify in writing the applicant of the amount of the financial contribution to be paid according to Article 3(1) and (2) as appropriate.

6 When a reduction of the contribution is claimed in accordance with Article 4(1), the application shall be accompanied by written evidence that the conditions laid down in that Article are fulfilled. The CRL may require supplementary information where appropriate.

7 The contributions mentioned in paragraph 2 to 5 shall be payable by the applicant within 45 days of the date of reception of the notification.

Where the applicant has not provided proof of payment within the set time limit, and where the evaluation report referred to in point 3(e), of the Annex to Regulation (EC) No 1829/2003 has not yet been sent to the European Food Safety Authority (the Authority), the CRL shall not submit it to the Authority until the reception of the due payment. The CRL shall immediately notify the Authority that its report will be delayed, to enable the Authority to inform the applicant and take any further steps required under Articles 6(1) to (2) and 18(1) to (2) of Regulation (EC) No 1829/2003.

Article 6

National reference laboratories assisting the CRL for testing and validating the methods of detection and identification

1 Laboratories which assist the CRL in testing and validating the method of detection and identification, as provided for in Articles 6(3)(d) and 18(3)(d) of Regulation (EC) No 1829/2003, shall fulfil the minimum requirements laid down in Annex I to this Regulation.

The laboratories listed in Annex II, are meeting those requirements, and are hereby appointed as national reference laboratories under Regulation (EC) No 1829/2003 to assist the CRL for testing and validating the method of detection.

2 The CRL and the national reference laboratories listed in Annex II shall enter into a written agreement to define the relations between them, notably in financial matters. In particular, the written agreement shall provide that the CRL is to distribute a share of the financial contributions it receives to the national reference laboratories.

Article 7

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 national reference laboratories under Regulation (EC) No 1829/2003 shall contribute to this annual report.

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

Article 8

Amendment to Regulation (EC) No 1829/2003

The Annex to Regulation (EC) No 1829/2003 is amended in accordance with Annex III to this Regulation.

Article 9

Entry into force

This Regulation shall enter into force on the 20th day following 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, 22 December 2006.

For the Commission

Markos KYPRIANOU

Member of the Commission

(**1**) OJ L 124, 20.5.2003, p. 36.

(**2**) OJ L 169, 30.6.2005, p. 1.