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) **[**[F1]'full validation procedure' means:

(i) the assessment, through a ring trial according to international standards, 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'[(1)] referred to:

— in the case of genetically modified plants for food or feed uses, food or feed containing or consisting of genetically modified plants and food produced from or containing ingredients produced from genetically modified plants or feed produced from genetically modified plants, in point 3.1.C.4. of Annex III to Commission Implementing Regulation (EU) No 503/2013[(2)];

— in all other cases, in point 1(B) of Annex I to Regulation (EC) No 641/2004;

and

(ii) the assessment of the precision 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[(3)];

(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[(4)];

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

(e) **[**F2**'**GMO containing a single transformation event' means a GMO that has been obtained through a single transformation process;

(f) 'GMO containing stacked transformation events' means a GMO containing more than one single transformation event obtained by conventional crossing, co-transformation or re-transformation.**]**

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) No 120/2014 of 7 February 2014 amending Regulation (EC) No 1981/2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and the Council as regards the Community reference laboratory for genetically modified organisms (Text with EEA relevance).

F2 Inserted by Commission Implementing Regulation (EU) No 120/2014 of 7 February 2014 amending Regulation (EC) No 1981/2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and the Council as regards the Community reference laboratory for genetically modified organisms (Text with EEA relevance).

[F1 Article 3

Contributions

1 For each application for a GMO containing a single transformation event, a flat-rate contribution of EUR 40 000 shall be paid by the applicant to the CRL.

2 The CRL shall request the applicant to pay an additional contribution of EUR 65 000 where a full validation procedure of a method of detection and identification for a GMO containing a single transformation event is required in accordance with the following provisions:

a Annex III to Implementing Regulation (EU) No 503/2013, when the application is related to:

(i) genetically modified plants for food or feed uses;

(ii) food or feed containing or consisting of genetically modified plants;

(iii) food produced from or containing ingredients produced from genetically modified plants or feed produced from such plants; or

b Annex I of Regulation (EC) No 641/2004 in all other cases.

3 For each application for a GMO containing stacked transformation events, where the method of detection and identification of each single transformation event that constitutes the GMO has been validated by the CRL or where the validation is pending, the flat-rate contribution depends on the number (N) of single transformation events that constitute the GMO and shall be calculated as EUR 20 000 + (N × EUR 5 000). Only the GMO containing

stacked transformation events with the highest number of single transformation events is to be considered in this calculation.

4 For each application for a GMO containing stacked transformation events that consists of one or more single transformation event(s) for which the method of detection and identification has not been validated by the CRL or for which no validation is pending, the contribution shall be calculated as follows: Article 3(1) and 3 (2) shall apply to single transformation event(s) for which no validated method exists and Article 3(3) shall apply to the GMO containing stacked transformation events, N corresponding to the number of single transformation events composing the GMO for which a validated method exists.

5 The CRL shall reduce the amount of the additional contribution referred to in paragraph 2, 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 refers to modules, such as DNA extraction protocols and species specific reference systems, already validated and published by the CRL.

6 Where the costs of the validation of the method of detection and identification proposed by the applicant exceed by at least 50 % the amount of the financial contributions mentioned under paragraphs 1, 2 and 3, a further contribution shall be requested. The further contribution shall cover 50 % of the part of the costs exceeding the amount of the contributions referred to in paragraphs 1, 2 and 3.

7 The contributions provided for in paragraphs 1 to 6 remain due in case of withdrawal of the application, without prejudice to Article 5(3).**]**

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) No 120/2014 of 7 February 2014 amending Regulation (EC) No 1981/2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and the Council as regards the Community reference laboratory for genetically modified organisms (Text with EEA relevance).

Article 4

Reductions and exemptions

[F1 1 Where the applicant is a SME, has its head office established in a developing country, or is a public research institution established in the EU whose application relates to a project financed mainly by the public sector, the financial contributions referred to in Article 3(1) to (4) 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.

[F1 3 Article 3(6) shall not apply to applicants referred to in Article 4(1).**]**

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) No 120/2014 of 7 February 2014 amending Regulation (EC) No 1981/2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and the Council as regards the Community reference laboratory for genetically modified organisms (Text with EEA relevance).

Article 5

Procedure

[F1 1 The applicant shall provide evidence that the contribution referred to in Article 3(1), 3(3) and/or 3(4) 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 Articles 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 in accordance with that provision, prior to starting step 4 (collaborative trial) of its validation process.

3 Where, as provided for in Article 3(6), the CRL expects the costs of the validation of the detection method proposed by the applicant to exceed by at least 50 % the amount of the financial contributions referred to in Article 3(1) to (4), it shall notify the applicant in writing of the estimated amount of the further costs.

If, within one month of the date of receipt of the notification, the applicant withdraws its application, the further contribution referred to in Article 3(6) shall not be 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 method of detection and require payment of the contribution due in accordance with Article 3(6).**]**

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.

F3 5 . . . . . .

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 **[**F1 The contributions provided for in paragraph 2 and 3 shall be payable by the applicant within 45 days of the date of reception of the notification. Step 4 (collaborative trial) of the validation process shall not be started before those contributions are received.**]**

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.

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) No 120/2014 of 7 February 2014 amending Regulation (EC) No 1981/2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and the Council as regards the Community reference laboratory for genetically modified organisms (Text with EEA relevance).

F3 Deleted by Commission Implementing Regulation (EU) No 120/2014 of 7 February 2014 amending Regulation (EC) No 1981/2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and the Council as regards the Community reference laboratory for genetically modified organisms (Text with EEA relevance).

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.

[[F1]2 The national reference laboratories listed in Annex II shall be selected randomly for participation in an international collaborative validation trial and shall receive 2 400 EUR from the CRL as a contribution to the costs for their participation. In case of Article 4(1) this amount shall be proportionally reduced.

3 The CRL and those national reference laboratories listed in Annex II that participate in a validation study shall enter into a written agreement to define the relations between them, notably in financial matters.**]**

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) No 120/2014 of 7 February 2014 amending Regulation (EC) No 1981/2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and the Council as regards the Community reference laboratory for genetically modified organisms (Text with EEA relevance).

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.

(1) **[**[F1]http://gmo-crl.jrc.ec.europa.eu/doc/Min_Perf_Requirements_Analytical_methods.pdf, CRL and European Network of GMO laboratories, 13 October 2008.**]**

(2) **[**[F1]OJ L 157, 8.6.2013, p. 1.**]**

(3) OJ L 124, 20.5.2003, p. 36.

(4) OJ L 169, 30.6.2005, p. 1.

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) No 120/2014 of 7 February 2014 amending Regulation (EC) No 1981/2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and the Council as regards the Community reference laboratory for genetically modified organisms (Text with EEA relevance).

Changes to legislation:
There are outstanding changes not yet made to Commission Regulation (EC) No 1981/2006. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Regulation revoked by S.I. 2019/705 reg. 390 (This amendment not applied to legislation.gov.uk. Reg. 390 substituted by regs. 389-477 immediately before IP completion day by virtue of S.I. 2020/1504, regs. 1(2), 17(21)(22))
- Regulation revoked by S.I. 2019/705, reg. 477 (as substituted) by S.I. 2020/1504 reg. 17(22)