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)

COMMISSION IMPLEMENTING REGULATION (EU) No 120/2014

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[(1)], and in particular Article 32, second subparagraph and fifth subparagraph, thereof,

Whereas:

(1) Detailed rules for implementing Article 32 of Regulation (EC) No 1829/2003 were set out by Commission Regulation (EC) No 1981/2006[(2)], as amended by Implementing Regulation (EU) No 503/2013[(3)]. It is necessary to update those rules, in particular regarding the financial contributions of applicants, in order to take into account changes in the costs incurred when testing and validating methods for detection, and changes in the allocation of tasks in the Member States.

(2) The Regulation should also take into account the growing number of GMOs containing stacked transformation events with an increasing combination of single transformation events.

(3) It is necessary to update the list of designated national reference laboratories to assist the Community Reference Laboratory referred to in in the first paragraph of Article 32 of Regulation (EC) No 1829/2003 (CRL) for testing and validation of detection methods in order to take account of changes of designation of national reference laboratories by Member States and to include those in the Member States which recently joined the Union.

(4) Transitional measures should be laid down to allow applicants who have received the acknowledgement of the application for an authorisation by the national competent authority according to Regulation (EC) No 1829/2003 before the entry into force of this Regulation to pay the financial contributions according to Regulation (EC) No 1981/2006.

(5) Due consideration should be given to public research institutions established in the EU applying for GMO authorisations related to projects mainly financed by the public sector, and a reduction of the amount of the financial contribution should therefore be foreseen in such cases.

(6) Regulation (EC) No 1981/2006 should therefore be amended accordingly.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1981/2006 is amended as follows:

(1) In Article 2, point (a) is replaced by the following:

(a) "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"[(4)] 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[(5)];

— 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.

(2) In Article 2, the following definitions are added:

(e) "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.

(3) Article 3 is replaced by the following:

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).

(4) Article 4 is amended as follows:

(a) Paragraph 1 is replaced by the following:

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 %.

(b) Paragraph 3 is replaced by the following:

3. Article 3(6) shall not apply to applicants referred to in Article 4(1).

(5) Article 5 is amended as follows:

(a) Paragraphs 1, 2 and 3 are replaced by the following:

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).

(b) Paragraph 5 is deleted.

(c) The first subparagraph of paragraph 7 is replaced by the following:

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.

(6) In Article 6, paragraph 2 is replaced by the following paragraphs 2 and 3:

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.

(7) In Annex I, point (a) is replaced by the following:

(a) be accredited according to EN ISO/IEC 17025 on "General requirements for the competence of testing and calibration laboratories", or an equivalent international standard which ensures that the laboratories:

— have suitably qualified staff with adequate training in analytical methods used for the detection and identification of GMOs and GM food and feed,

— possess the equipment needed to carry out the required analysis,

— have an adequate administrative infrastructure,

— have sufficient data-processing capacity to produce technical reports and to enable rapid communication with the other laboratories participating in the testing and validation of detection methods;

Laboratories listed in Annex II to this Regulation which are not yet accredited are admitted until 31 December 2014 if the laboratory declares to be in the process of accreditation and provides proof of technical competences to the CRL.

(8) Annex II is replaced by the Annex to this Regulation.

Article 2

Transitional measures

Articles 3 to 5 of Regulation (EC) No 1981/2006 on financial contributions shall continue to apply to applicants who have received the acknowledgement of the application for an authorisation by the national competent authority according to Regulation (EC) No 1829/2003 before the entry into force of this Regulation.

Article 3

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.