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)

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)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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, fifth sub-paragraph, thereof,

Whereas:

(1) Regulation (EC) No 1829/2003 provides for a Community reference laboratory (CRL) to carry out certain duties and tasks set out in that Regulation. It also provides that the CRL is to be assisted by national reference laboratories.

(2) Methods of detection and identification which have to be tested and validated by the CRL and samples and control samples have to meet the requirements laid down in Commission Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation[(2)].

(3) It is necessary to provide detailed rules for implementing Article 32 of Regulation (EC) No 1829/2003.

(4) The financial contribution to be paid by applicants in accordance with Article 32 of Regulation (EC) No 1829/2003 should be used only towards supporting the costs of the duties and tasks as set out in the Annex to that Regulation. The CRL should be authorised to charge a financial contribution to applicants for new authorisations, for renewal of authorisations and in the case of modification of authorisations where appropriate.

(5) The determination of the amount of the financial contribution should take into account the burden of work to be carried out by the CRL in each case, depending on the level

of method testing and validation already carried out prior to the submission of the application for authorisation.

(6) Applicants should be encouraged to provide data that refer to modules which have already been validated and published by the CRL in order to facilitate both the establishment of the application dossier and the validation of the detection method.

(7) A financial contribution should be levied on a flat-rate basis in order to contribute to supporting the costs incurred in the comprehensive data analysis and in-house laboratory verification of the method and samples received to be carried out by the CRL in all cases where a new method is submitted.

(8) An additional financial contribution should be charged to applicants where the validation of the proposed method requires the performance of a collaborative study involving national reference laboratories in order to comply with the criteria referred to in Annex I of Regulation (EC) No 641/2004.

(9) The amount of the financial contributions should cover the costs directly associated with the validation tasks to be performed. Those include in particular the manpower, the reagents and other associated disposable material, the distribution of material to members of the European Network of GMO laboratories (ENGL) where appropriate and the administrative costs. They should be calculated on the basis of the experience gained by the Commission's Joint Research Centre in carrying out validations of detection methods, including collaboration with members of the ENGL where appropriate, and should not exceed the actual costs incurred in carrying out that validation.

(10) Where the validation costs for a specific application for authorisation exceeds substantially the amount of the financial contributions provided for in this Regulation, the CRL should be able to charge an additional contribution to the applicant. In that case, the applicant should have the right to be exempted from the payment of the additional contribution if he withdraws its application within a set time limit.

(11) Due consideration should be given to the specific case of biotechnological research originating in developing countries. A reduction of the amount of the financial contribution should therefore be provided where the head office of the applicant for authorisation is established in a developing country.

(12) In order to facilitate the participation of small and medium-sized enterprises (SMEs) to the Community procedure for authorisation of genetically modified (GM) food and feed, it is appropriate to provide for a reduced financial contribution where applicants are SMEs. The model declaration on the information relating to the qualification of an enterprise as an SME[(3)] could serve for the written evidence to be provided by applicants as to their SME status.

(13) Regulation (EC) No 1829/2003 already lays down the rule that applicants should make a financial contribution, so any applicants who have lodged applications before the entry into force of this Regulation will be aware of this rule. Consequently, the financial contribution should also be required for applications for authorisation submitted before the date of entry into force of this Regulation.

(14) National reference laboratories assisting the CRL for the duties and tasks set out in the Annex to Regulation (EC) No 1829/2003 should be part of the European Network of GMO Laboratories (ENGL), whose members represent the state-of-the-art in GMO detection, including expertise in method development, performance and validation, sampling and management of biological and analytical uncertainties. They should also meet specific requirements where they have to assist the CRL specifically for testing and validation of detection methods in the context of collaborative studies according to international standards.

(15) In the interests of stability and efficacy and in order to make the validation procedure operational in accordance with this Regulation, it is necessary to designate the national reference laboratories apt to assist the CRL for testing and validation of detection methods.

(16) The relationship between the national reference laboratories assisting the CRL for testing and validation of detection methods and between them and the CRL should be defined by a written agreement.

(17) The Annex to Regulation (EC) No 1829/2003 should be amended accordingly.

(18) 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:

(**1**) OJ L 268, 18.10.2003, p. 1.

(**2**) OJ L 102, 7.4.2004, p. 14.

(**3**) Commission communication 2003/C 118/03 (OJ C 118, 20.5.2003, p. 5). Corrigendum published in OJ C 156, 4.7.2003, p. 14.

Status:
Point in time view as at 28/02/2014.

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.