

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

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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.

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- (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:

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;

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- (b) ‘small and medium-sized enterprise (SME)’ means small and medium-sized enterprises as defined in Commission Recommendation 2003/361/EC⁽⁴⁾;
- (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⁽⁵⁾;
- (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 %.

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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

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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.

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Done at Brussels, 22 December 2006.

For the Commission

Markos KYPRIANOU

Member of the Commission

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ANNEX I

Requirements for laboratories assisting the Community reference laboratory for testing and validation of methods for detection, as referred to in Article 6(1)

Laboratories assisting the Community reference laboratory for testing and validating the method for detection, as set out in point 3(d) of the Annex to Regulation (EC) No 1829/2003, must:

- (a) be accredited, or being in the process of accreditation 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 analysis of GMOs and GM food and feed,
 - 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;
- (b) provide assurance that their staff respect the confidential nature of subjects, data, results or communications involved in the handling of applications for authorisation, for renewal of authorisations or for modification of authorisations submitted in accordance with Regulation (EC) No 1829/2003 and in particular the confidential information referred to in Article 30 of that Regulation.

ANNEX II

National reference laboratories assisting the CRL for testing and validation of methods for detection, as referred to in Article 6(1)

Belgique/België

- Centre wallon de Recherches agronomiques (CRA-W),
- Institut Scientifique de Santé Publique (ISP) — Wetenschappelijk Instituut Volksgezondheid (WIV),
- Instituut voor Landbouw- en Visserijonderzoek (ILVO);

Česká republika

- Státní veterinární ústav Jihlava (SVU Jihlava),
- Státní zdravotní ústav (SZÚ), Laboratoř pro molekulárně biologické metody (LMBM), Centrum hygieny potravinových řetězců v Brně,
- Státní zemědělská a potravinářská inspekce (SZPI),
- Vysoká škola chemicko-technologická v Praze (VŠCHT),
- Výzkumný ústav rostlinné výroby (VÚRV), Praha;

Danmark

- Danmarks Fødevareforskning (DFVF),
- Ministeriet for Fødevarer, Landbrug og Fiskeri, Plantedirektoratet, Laboratorium for Diagnostik i Planter, Frø og Foder;

Deutschland

- Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit (LGL),

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- Berliner Betrieb für Zentrale Gesundheitliche Aufgaben (BBGes) — Institut für Lebensmittel, Arzneimittel und Tierseuchen (ILAT),
- Bundesinstitut für Risikobewertung,
- Chemisches und Veterinäruntersuchungsamt (CVUA) Freiburg,
- Chemisches und Veterinäruntersuchungsamt Ostwestfalen-Lippe,
- Institut für Hygiene und Umwelt der Hansestadt Hamburg,
- Landesamt für Landwirtschaft, Lebensmittelsicherheit und Fischerei — Mecklenburg-Vorpommern (LALLF MV),
- Landesamt für Soziales, Gesundheits- und Verbraucherschutz — Abteilung F: Verbraucherschutz, Veterinärmedizin, Lebensmittelhygiene und Molekularbiologie,
- Landesamt für Umweltschutz Sachsen-Anhalt,
- Landesamt für Verbraucherschutz Sachsen-Anhalt — Fachbereich Lebensmittelsicherheit,
- Landesbetrieb Hessisches Landeslabor — Standort Kassel,
- Landeslabor Brandenburg,
- Landeslabor Schleswig-Holstein,
- Landesuntersuchungsamt Rheinland-Pfalz — Institut für Lebensmittelchemie Trier,
- Landesuntersuchungsanstalt für das Gesundheits- und Veterinärwesen Sachsen (LUA),
- Landwirtschaftliche Untersuchungs- und Forschungsanstalt Rostock der LMS Mecklenburg-Vorpommern,
- Niedersächsisches Landesamt für Verbraucherschutz und Lebensmittelsicherheit (LAVES) — Lebensmittelinstitut (LI) Braunschweig,
- Sächsische Landesanstalt für Landwirtschaft — Fachbereich Landwirtschaftliches Untersuchungswesen,
- Staatliche Landwirtschaftliche Untersuchungs- und Forschungsanstalt Augustenberg (Baden-Württemberg),
- Thüringer Landesamt für Lebensmittelsicherheit und Verbraucherschutz (TLLV);
- Eesti
- DNA analüüsi laboratoorium, Geenitehnoloogia Instituut (GTI), Tallinna Tehnikaülikool (TTÜ),
- Keemilise ja Bioloogilise Füüsika Instituut (KBFI), Molekulaargeneetika laboratoorium (MG),
- Veterinaar-ja Toidulaboratoorium (VTL);
- Elláda
- Εθνικό Ίδρυμα Αγροτικής Έρευνας Εργαστήριο Γενετικής Ταυτοποίησης Γεωργικών Προϊόντων, Μικροοργανισμών και Ελέγχου Σπόρων Σποράς για την Ανίχνευση, Γενετικών Τροποποιήσεων,
- Υπουργείο Οικονομίας και Οικονομικών, Γενική Διεύθυνση Γενικού Χημείου του Κράτους (ΓΧΚ), Διεύθυνση Τροφίμων — Αθήνα;
- España
- Centro Nacional de Alimentación, Agencia Española de Seguridad Alimentaria (CNA-AESA),
- Laboratorio Arbitral Agroalimentario del Ministerio de Agricultura, Pesca y Alimentación (LAA-MAPA);
- France
- Groupement d'Intérêt Public — Groupe d'Etude et de contrôle des Variétés et des Semences (GIP-GEVES),

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- Laboratoire de Phytopathologie et de méthodologies de la détection (INRA Versailles),
- Laboratoire Direction Générale de la Consommation, de la Concurrence et de la Répression des Fraudes de Strasbourg (Laboratoire de la DGCCRF de Strasbourg),
- Laboratoire National de la Protection des Végétaux d'Orléans (LNPV Orléans);
- Ireland
 - The State Laboratory (SL), Celbridge;
- Italia
 - Ente Nazionale Sementi Elette (E.N.S.E.), Laboratorio Analisi Sementi,
 - Istituto Superiore di Sanità, Centro Nazionale per la Qualità degli Alimenti e per i Rischi Alimentari (CNQARA),
 - Istituto Zooprofilattico Sperimentale delle Regioni Lazio e Toscana, Centro di Riferenza Nazionale per la Ricerca di OGM (CROGM);
- Kypros
 - Γενικό χημείο του κράτους (γγκκ);
- Latvija
 - Pārtikas un veterinārā dienesta Nacionālais diagnostikas centrs (PVD NDC);
- Lietuva
 - Nacionalinė Veterinarijos Laboratorija, GMO Tyrimų Skyrius;
- Luxembourg
 - Laboratoire National de Santé (LNS), Division du contrôle des denrées alimentaires;
- Magyarország
 - Országos Élelmiszerbiztonsági és Táplálkozástudományi Intézet (OÉTI),
 - Országos Mezőgazdasági Minőség Intézet, Központi Laboratórium (OMMI);
- Nederland
 - RIKILT Instituut voor Voedselveiligheid,
 - Voedsel en Waren Autoriteit (VWA);
- Österreich
 - Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH — Kompetenzzentrum Biochemie (AGES - CC BIOC),
 - Umweltbundesamt GmbH;
- Polska
 - Instytut Biochemii i Biofizyki Polskiej Akademii Nauk, Laboratorium Analiz Modyfikacji Genetycznych Instytutu Biochemii i Biofizyki Polskiej Akademii Nauk (GMOIBB), Warszawa,
 - Instytut Hodowli i Aklimatyzacji Roślin (IHAR); Laboratorium Kontroli Genetycznie Modyfikowanych Organizmów, Błonie,
 - Instytut Zootechniki (National Feed Laboratory – NFL), Lublin,
 - Państwowego Instytutu Weterynaryjnego – Państwowego Instytutu Badawczego w Puławach, Puławy,
 - Regionalne Laboratorium Badań Żywności Genetycznie Modyfikowanej (RLG);
- Portugal
 - Direcção-Geral de Protecção das Culturas (DGPC), Laboratório de Caracterização de Materiais de Multiplicação de Plantas (LCMMP),
 - Instituto Nacional de Engenharia Tecnologia e Inovação (INETI), Laboratório para a Indústria Alimentar (LIA);
- Slovenija
 - Kmetijski inštitut Slovenije (KIS), Ljubljana,
 - Nacionalni inštitut za biologijo (National institute of Biology, NIB), Ljubljana;
- Slovensko

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- Štátny veterinárny a potravinový ústav, Dolný Kubín (State Veterinary and Food Institute Dolný Kubín),
 - Ústav molekulárnej biológie SAV (Molecular Biology Institute of the Slovak Academy of Slovakia),
 - Ústredný kontrolný a skúšobný ústav poľnohospodársky, Oddelenie molekulárnej biológie Bratislava, (Central Control and Testing Institute of Agriculture);
- Suomi/Finland
- Tullilaboratorio
- Sverige
- Livsmedelsverket (SLV)
- United Kingdom
- Central Science Laboratory (CSL),
 - LGC Limited (LGC),
 - Scottish Agricultural Science Agency (SASA).

ANNEX III

Amendments to the Annex to Regulation (EC) No 1829/2003

Points 2, 3 and 4 are replaced by the following:

2. For the duties and tasks outlined in this Annex, the Community reference laboratory shall be assisted by the national reference laboratories referred to in Article 32, which shall consequently be considered as members of the consortium referred to as the “European Network of GMO laboratories”.
3. The Community reference laboratory shall be responsible, in particular, for:
 - (a) the reception, preparation, storage, maintenance and distribution to the members of the European Network of GMO laboratories of the appropriate positive and negative control samples, subject to assurance given by such members of the respect of the confidential nature of the data received where applicable;
 - (b) without prejudice to the responsibilities of the Community reference laboratories laid down in Article 32 of Regulation (EC) No 882/2004 of the European Parliament and of the Council⁽⁶⁾, the distribution to national reference laboratories within the meaning of Article 33 of that Regulation of the appropriate positive and negative control samples, subject to assurance given by such laboratories of the respect of the confidential nature of the data received where applicable;
 - (c) evaluating the data provided by the applicant for authorisation for placing the food or feed on the market, for the purpose of testing and validation of the method for sampling and detection;
 - (d) testing and validating the method for detection, including sampling and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food or feed;
 - (e) submitting full evaluation reports to the Authority.

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4. The Community reference laboratory shall play a role in dispute settlements concerning the results of the tasks outlined in this Annex, without prejudice to the responsibilities of the Community reference laboratories laid down in Article 32 of Regulation (EC) No 882/2004.

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- (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.
- (4) OJ L 124, 20.5.2003, p. 36.
- (5) OJ L 169, 30.6.2005, p. 1.
- (6) OJ L 165, 30.4.2004, p. 1, as corrected by OJ L 191, 28.5.2004, p. 1.'

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