

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<sup>(1)</sup>, 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<sup>(2)</sup>.
- (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<sup>(3)</sup> 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) <sup>[F1]</sup>‘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’<sup>(4)</sup> referred to:

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- 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<sup>(5)</sup>;
- 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<sup>(6)</sup>;
- (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<sup>(7)</sup>;
- (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<sup>[F1]</sup>;
- (e) <sup>[F2]</sup>‘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).

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## *l<sup>F1</sup>* 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).]

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### Article 4

#### Reductions and exemptions

[<sup>F1</sup> 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.

[<sup>F13</sup> 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

[<sup>F1</sup> 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

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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.

F<sup>3</sup>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 [F<sup>1</sup>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

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- 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.

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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.

[<sup>F12</sup> 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.



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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) <sup>[F1]</sup>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;]

- (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.

## <sup>[F1]</sup>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);

#### **Bulgaria**

- Национален център по обществено здраве и анализи (НЦОЗА), София, Сектор ГМО;

#### **Česká republika**

- Výzkumný ústav rostlinné výroby, v.v.i. (VÚRV), Praha;

#### **Danmark**

- Danmarks Tekniske Universitet, DTU Fødevareinstituttet, Afdeling for Toksikologi og Risikovurdering<sup>(8)</sup>,
- Ministeriet for Fødevarer, Landbrug og Fiskeri, Fødevarestyrelsen, Sektion for Plantediagnostik, Ringsted;

#### **Deutschland**

- Chemisches und Veterinäruntersuchungsamt (CVUA) Freiburg,

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- Landwirtschaftliches Technologiezentrum Augustenberg (LTZ),
  - Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit (LGL),
  - Landeslabor Berlin-Brandenburg, Berlin,
  - Landeslabor Berlin-Brandenburg, Frankfurt/Oder,
  - Institut für Hygiene und Umwelt der Hansestadt Hamburg,
  - Landesbetrieb Hessisches Landeslabor — Standort Kassel,
  - Landesamt für Landwirtschaft, Lebensmittelsicherheit und Fischerei (LALLF) Mecklenburg-Vorpommern,
  - Niedersächsisches Landesamt für Verbraucherschutz und Lebensmittelsicherheit (LAVES) — Lebensmittel- und Veterinärinstitut Braunschweig/Hannover,
  - Landesuntersuchungsamt Rheinland-Pfalz — Institut für Lebensmittelchemie Trier,
  - Landwirtschaftliche Untersuchungs- und Forschungsanstalt (LUFA) Speyer,
  - Landesamt für Verbraucherschutz — Abteilung D Veterinärmedizinische, mikro- und molekularbiologische Untersuchungen, Saarland,
  - Staatliche Betriebsgesellschaft für Umwelt und Landwirtschaft, Geschäftsbereich Labore Landwirtschaft, Sachsen,
  - Landesuntersuchungsanstalt für das Gesundheits- und Veterinärwesen Sachsen (LUA),
  - Landesamt für Verbraucherschutz Sachsen-Anhalt — Fachbereich Lebensmittelsicherheit,
  - Landeslabor Schleswig-Holstein,
  - Thüringer Landesamt für Verbraucherschutz (TLV),
  - Bundesinstitut für Risikobewertung (BfR),
  - Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL);
- Eesti**
- Tallinna Tehnikäilikooli (TTÜ) geenitehnoloogia instituut, DNA analüüsi labor;
- Éire**
- Food and Environment Research Agency (FERA) Sand Hutton, York;
- Elláda**
- Ελληνικός Γεωργικός Οργανισμός ‘ΔΗΜΗΤΡΑ’, Γενική Διεύθυνση Αγροτικής Έρευνας, Ινστιτούτο Τεχνολογίας Γεωργικών Προϊόντων, Εργαστήριο Γενετικής Ταυτοποίησης, Αθήνα,
  - Υπουργείο Οικονομικών, Γενική Γραμματεία Δημοσίων Εσόδων, Γενική Διεύθυνση Γενικού Χημείου του Κράτους (ΓΧΚ), Διεύθυνση Τροφίμων; Αθήνα;
- España**
- Centro Nacional de Alimentación, Agencia Española de Seguridad Alimentaria y Nutrición (CNA-AESAN),
  - Laboratorio Arbitral Agroalimentario del Ministerio de Agricultura, Alimentación y Medio Ambiente (LAA-MAGRAMA);
- France**
- Groupement d’Intérêt Public — Groupe d’Etude et de contrôle des Variétés et des Semences (GIP-GEVES),
  - Laboratoire du Service Commun des Laboratoires (SCL) d’Illkirch-Graffenstaden,
  - Laboratoire de la Santé des Végétaux (ANSES), Angers;
- Hrvatska**
- Odsjek za kvantifikaciju GMO i procjenu rizika, Hrvatski zavod za javno zdravstvo;
- Italia**

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- Centro di Ricerca per la Sperimentazione in Agricoltura, Centro di Sperimentazione e Certificazione delle Sementi (CRA-SCS), Sede di Tavazzano — Laboratorio,
- Istituto Superiore di Sanità, Dipartimento di Sanità Pubblica Veterinaria e Sicurezza Alimentare — Reparto OGM e xenobiotici di origine fungina (ISS-DSPVSA),
- Istituto Zooprofilattico Sperimentale delle Regioni Lazio e Toscana, Centro di Riferenza Nazionale per la Ricerca di OGM (CROGM);

**Kypros**

- Γενικό Χημείο του Κράτους (ΓΧΚ);

**Latvija**

- Pārtikas drošības, dzīvnieku veselības un vides zinātniskais institūts 'BIOR';

**Lietuva**

- Nacionalinio maisto ir veterinarijos rizikos vertinimo instituto Molekulinės biologijos ir Genetiškai modifikuotų organizmų tyrimų skyrius;

**Luxembourg**

- Laboratoire National de Santé (LNS), Division du contrôle des denrées alimentaires;

**Magyarország**

- Nemzeti Élelmiszerlánc-biztonsági Hivatal (NÉBIH);

**Malta**

- LGC Limited UK;

**Nederland**

- RIKILT — Wageningen UR,
- Nederlandse Voedsel en Waren Autoriteit (NVWA);

**Österreich**

- Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH — Institut für Lebensmittelsicherheit Wien, Abteilung für Molekular- und Mikrobiologie (AGES — MOMI),
- Umweltbundesamt GmbH;

**Polska**

- Instytut Hodowli i Aklimatyzacji Roślin (IHAR); Laboratorium Kontroli Genetycznie Modyfikowanych Organizmów, Błonie,
- Instytut Zootechniki — Państwowy Instytut Badawczy, Krajowe Laboratorium Pasz, Lublin,
- Państwowy Instytut Weterynaryjny — Państwowy Instytut Badawczy, Puławy,
- Regionalne Laboratorium Badań Żywności Genetycznie Modyfikowanej w Tarnobrzegu;

**Portugal**

- Laboratório de OGM, Instituto Nacional de Investigação Agrária e Veterinária (INIAV), Unidade Estratégica de Investigação e Serviços de Sistemas Agrários e Florestais e Sanidade Vegetal (UEIS-SAFSV);

**România**

- Laboratorul Național de Referință pentru OMG din alimente și furaje, Institutul de Diagnostic și Sănătate Animală, București;

**Slovenija**

- Kmetijski inštitut Slovenije (KIS), Ljubljana,
- Nacionalni inštitut za biologijo (NIB), Ljubljana;

**Slovensko**

- Ústredný kontrolný a skúšobný ústav poľnohospodársky, Oddelenie molekulárnej biológie NRL Bratislava,

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- Štátny veterinárny a potravinový ústav, Dolný Kubín (State Veterinary and Food Institute Dolný Kubín);

**Suomi/Finland**

- Tullilaboratorio,
- Elintarviketurvallisuusvirasto Evira;

**Sverige**

- Livsmedelsverket (SLV);

**United Kingdom**

- Food and Environment Research Agency (FERA),
- LGC Limited (LGC),
- Science and Advice for Scottish Agriculture (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<sup>(9)</sup>, 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.
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.

**Status:** Point in time view as at 31/12/2020.

**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. (See end of Document for details)

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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) [<sup>F1</sup>[http://gmo-crl.jrc.ec.europa.eu/doc/Min\\_Perf\\_Requirements\\_Analytical\\_methods.pdf](http://gmo-crl.jrc.ec.europa.eu/doc/Min_Perf_Requirements_Analytical_methods.pdf), CRL and European Network of GMO laboratories, 13 October 2008.]
- (5) [<sup>F1</sup>OJ L 157, 8.6.2013, p. 1.]
- (6) OJ L 124, 20.5.2003, p. 36.
- (7) OJ L 169, 30.6.2005, p. 1.
- (8) [<sup>F1</sup>Until 1 January 2014.]
- (9) OJ L 165, 30.4.2004, p. 1, as corrected by OJ L 191, 28.5.2004, p. 1.’

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#### **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).

**Status:**

Point in time view as at 31/12/2020.

**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.