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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.

### 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).

## [<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;

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## Danmark

- Danmarks Tekniske Universitet, DTU Fødevareinstituttet, Afdeling for Toksikologi og Risikovurdering<sup>(1)</sup>,
- Ministeriet for Fødevarer, Landbrug og Fiskeri, Fødevarestyrelsen, Sektion for Plantediagnostik, Ringsted;

## Deutschland

- Chemisches und Veterinäruntersuchungsamt (CVUA) Freiburg,
- 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 Tehnikaülikooli (TTÜ) geenitehnoloogia instituut, DNA analüüs 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

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- 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 procjenju rizika, Hrvatski zavod za javno zdravstvo;
- Italia**
- 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 Scurezza Alimentare — Reparto OGM e xenobiotici di origine fungina (ISS-DSPVSA),
- Istituto Zooprofilattico Sperimentale delle Regioni Lazio e Toscana, Centro di Referenza 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 Genetiskai 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 Genetycznej 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;

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### **Slovenija**

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

### **Slovensko**

- Ústredný kontrolný a skúšobný ústav poľnohospodársky, Oddelenie molekulárnej biológie NRL Bratislava,
- 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>(2)</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;

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- (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.

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- (1) [<sup>F1</sup>Until 1 January 2014.]
- (2) [OJ L 165, 30.4.2004, p. 1.](#), as corrected by [OJ L 191, 28.5.2004, p. 1.](#)<sup>2</sup>

#### 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 \(Text with EEA relevance\).](#)

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