ANNEX I

Requirements for laboratories participating, as referred to in Article 8

Laboratories participating in the consortium must satisfy the following minimum requirements:

(a) have been proposed as a national reference laboratory by a Member State for the purpose of taking part in the consortium referred to in Annex II to Regulation (EC) No 1831/2003;

(b) have suitable qualified staff that are adequately trained in analytical methods used for the feed additives on which they are involved;

(c) possess the equipment needed to carry out the analysis of feed additives, in particular the ones on which they are carrying tasks under this Regulation;

(d) have an adequate administrative infrastructure;

(e) have sufficient data-processing capacity to produce technical reports and to enable rapid communication with the other laboratories participating in the consortium;

(f) provide assurance that their staff respect the confidential aspects of issues, results or communications involved in the handling of applications for authorisation submitted in accordance with Regulation (EC) No 1831/2003 and in particular the information referred to in Article 18 of that Regulation;

(g) have sufficient knowledge of international standards and practices in laboratory work;

(h) must be accredited, or being in the process of accreditation according to international standards such as ISO 17025.

[F1ANNEX II

Community reference laboratory and consortium of national reference laboratories, as referred to in Article 6(2)

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) 2015/1761 of 1 October 2015 amending Commission Regulation (EC) No 378/2005 as regards the Community Reference Laboratory reports, fees and the laboratories listed in Annex II thereto (Text with EEA relevance).

COMMUNITY REFERENCE LABORATORY

Joint Research Centre of the European Commission. Institute for Reference Materials and Measurements. Geel, Belgium.

NATIONAL REFERENCE LABORATORIES OF THE MEMBER STATES

Belgique/België

— Federaal Laboratorium voor de Voedselveiligheid Tervuren (FLVVT –FAVV);

— Vlaamse Instelling voor Technologisch Onderzoek (VITO), Mol;

— Centre wallon de Recherches agronomiques (CRA-W), Gembloux.

Česká republika

— Ústřední kontrolní a zkušební ústav zemědělský (ÚKZÚZ), Praha.

Danmark

— Fødevarestyrelsens Laboratorie Aarhus (kemisk);

— Fødevarestyrelsens Laboratorie Ringsted (kemisk og mikrobiologisk).

Deutschland

— Sachgebiet Futtermittel des Bayrischen Landesamtes für Gesundheit und Lebensmittelsicherheit (LGL), Oberschleißheim;

— Landwirtschaftliche Untersuchungs- und Forschungsanstalt (LUFA), Speyer;

— Staatliche Betriebsgesellschaft für Umwelt und Landwirtschaft. Geschäftsbereich 6 — Labore Landwirtschaft, Nossen;

— Thüringer Landesanstalt für Landwirtschaft (TLL). Abteilung Untersuchungswesen. Jena.

Eesti

— Põllumajandusuuringute Keskus (PMK). Jääkide ja saasteainete labor, Saku, Harjumaa;

— Põllumajandusuuringute Keskus (PMK), Taimse materjali labor, Saku, Harjumaa.

España

— Laboratorio Arbitral Agroalimentario. Ministerio de Agricultura, Alimentación y Medio Ambiente, Madrid;

— Laboratori Agroalimentari, Departament d'Agricultura, Ramaderia, PESCA, Alimentació i Medi Natural. Generalitat de Catalunya, Cabrils.

France

— Laboratoire de Rennes (SCL L35), Service Commun des Laboratoires DGCCRF et DGDDI, Rennes.

Éire/Ireland

— The State Laboratory, Kildare.

Ελλάδα

— Εργαστήριο Ελέγχου Κυκλοφορίας Ζωοτροφών Θεσσαλονίκης.

Italia

— Istituto Superiore di Sanità. Dipartimento di Sanità Pubblica Veterinaria e Sicurezza Alimentare, Roma;

— Centro di referenza nazionale per la sorveglienza ed il controllo degli alimenti per gli animali (CReAA), Torino.

Kypros

— Feedingstuffs Analytical Laboratory, Department of Agriculture, Nicosia.

Latvija

— Pārtikas drošības, dzīvnieku veselības un vides zinātniskais institūts BIOR, Rīga.

Lietuva

— Nacionalinis maisto ir veterinarijos rizikos vertinimo institutas, Vilnius.

Luxembourg

— Laboratoire de Contrôle et d'essais — ASTA, Ettelbruck.

Magyarország

— Nemzeti Élelmiszerlánc-biztonsági Hivatal, Élelmiszer- és Takarmánybiztonsági Igazgatóság, Takarmányvizsgáló Nemzeti Referencia Laboratórium, Budapest.

Nederland

— RIKILT Wageningen UR, Wageningen.

Österreich

— Österreichische Agentur für Gesundheit und Ernährungssicherheit (AGES), Wien.

Polska

— Instytut Zootechniki — Państwowy Instytut Badawczy, Krajowe Laboratorium Pasz, Lublin;

— Państwowy Instytut Weterynaryjny, Pulawy.

Portugal

— Instituto Nacional de Investigação Agrária e Veterinária, I.P. (INIAV,IP), Lisboa.

Slovenija

— Univerza v Ljubljani. Veterinarska fakulteta. Nacionalni veterinarski inštitut. Enota za patologijo prehrane in higieno okolja, Ljubljana;

— Kmetijski inštitut Slovenije, Ljubljana.

Slovensko

— Skúšobné laboratórium analýzy krmív, Ústredný kontrolný a skúšobný ústav poľnohospodársky, Bratislava.

Suomi/Finland

— Elintarviketurvallisuusvirasto/Livsmedelssäkerhetsverket (Evira), Helsinki/ Helsingfors.

Sverige

— Avdelningen för kemi, miljö och fodersäkerhet, Statens Veterinärmedicinska Anstalt (SVA), Uppsala.

United Kingdom

— LGC Ltd, Teddington.

NATIONAL REFERENCE LABORATORIES OF EFTA COUNTRIES

Norway

— The National Institute of Nutrition and Seafood Research (NIFES), Bergen.**]**

ANNEX III

Text replacing paragraphs 2 and 3 of Annex II to Regulation (EC) No 1831/2003

2. For the duties and tasks set out in this Annex, the CRL may be assisted by a consortium of national reference laboratories.

The CRL shall be responsible for:

2.1. the reception, storage and maintenance of the samples of the feed additive sent by the applicant as provided for in Article 7(3)(f);

2.2. evaluating the method of analysis of the feed additive, and of other relevant methods of analysis related to it, on the basis of the data provided in the application for authorisation of the feed additive as regards its suitability for official control in accordance with the requirements of the implementing rules referred to in Article 7(4) and (5) and the guidance of the Authority referred to in Article 7(6);

2.3. submitting a full evaluation report to the Authority on the results of the duties and tasks referred to in this Annex;

2.4. where necessary, the testing of the method(s) of analysis.

3. The CRL shall be responsible for coordination of the validation of the method(s) of analysis of the additive, in accordance with the procedure provided for in Article 10 of Regulation (EC) No 378/2005[(1)]. This task may involve the preparation of food or feed test material.

4. The CRL shall provide scientific and technical assistance to the Commission, especially in cases where Member States contest the results of analyses related to the duties and tasks referred to in this Annex, without prejudice to any role defined for it under Articles 11 and 32 of Regulation (EC) No 882/2004 of the European Parliament and of the Council[(2)].

5. On request by the Commission, the CRL may also be responsible for conducting special analytical or other related studies in a manner similar to the duties and tasks referred to in point 2. This may be the case, in particular, for existing products notified under Article 10 and included in the Register and for the period until an application for authorisation under Article 10(2) is submitted in accordance with Article 10(2).

6. The CRL shall be responsible for the overall coordination of the consortium of national reference laboratories. The CRL shall ensure that the relevant data concerning the applications are made available to the laboratories.

7. Without prejudice to the responsibilities of the Community reference laboratories laid down in Article 32 of Regulation (EC) No 882/2004, the CRL may create and maintain a database of methods of analysis available for control of feed additives and make it available to official control laboratories from Member States and other interested parties.

[F2 ANNEX IV

RATES FOR FEES AS REFERRED TO IN ARTICLE 4(1)

Textual Amendments

F2 Inserted by Commission Regulation (EC) No 885/2009 of 25 September 2009 amending Regulation (EC) No 378/2005 as regards reference samples, fees and the laboratories listed in Annex II (Text with EEA relevance).

Composition of the fee

For the purpose of the calculation of the fee, the fee is composed of the following two components:

1. The first component is intended to support the CRL administrative costs and the costs related to the handling of the reference samples. This first component amounts to EUR 2 000.

2. The second component is intended to support the costs of the Rapporteur Laboratory for the scientific evaluation and preparation of the evaluation report. This second component amounts to EUR 4 000.

The two components are applied as detailed below to calculate the fee rates.

Rates according to the type of application for authorisations of feed additives in accordance with Regulation (EC) No 1831/2003

1. Authorisation of a new feed additive (Article 4(1) of Regulation (EC) No 1831/2003):

Fee = Component 1 + Component 2 = EUR 6 000

2. Authorisation of a new use of a feed additive (Article 4(1) of Regulation (EC) No 1831/2003):

— when Article 3 (4)(a) and Article 5(4)(a) apply:

Fee = EUR 0

— when only Article 3 (4)(a) applies, only Component 2 is applicable:

Fee = EUR 4 000

3. Authorisation of an already authorised feed additive (Article 10(2) of Regulation (EC) No 1831/2003):

Fee = Component 1 + Component 2 = EUR 6 000

— For groups of applications concerning more than one feed additive submitted simultaneously belonging to the same category of feed additives, functional group and sub classification, if applicable, and other than chemically defined flavourings, zootechnical additives, coccidiostats and histomonostats, and when the methods of analysis used for these feed additives are of the multi-analyte type of methods of analysis, the fee shall be calculated as follows:

The first component is multiplied by the number (n) of feed additives in the group:

Component 1 = (EUR 2 000 × n) = N

The second component is multiplied by the number (m) of methods of analysis to be evaluated by the CRL:

Component 2 = (EUR 4 000 × m) = M

The fee shall be the sum of the two components:

Fee = N + M

— For groups of applications concerning more than one chemically defined flavouring submitted simultaneously and when the methods of analysis used for these feed additives are of the multi-analyte type of methods of analysis, the fee shall be calculated as follows:

The first component is multiplied by the number (n) of reference samples, as specified in Article 3 paragraph 1, submitted to the CRL:

Component 1 = (EUR 2 000 × n) = N

The second component is multiplied by the number (m) of methods of analysis to be evaluated by the CRL:

Component 2 = (EUR 4 000 × m) = M

The fee shall be the sum of the two components:

Fee = N + M

4. Applications for changing the terms of an existing authorisation (Article 13(3) of Regulation (EC) No 1831/2003):

— when Article 3(4)(b) and Article 5(4)(b) apply:

Fee = EUR 0

— when only Article 3(4)(b) applies, only Component 2 applies:

Fee = EUR 4 000

[[F1]5. Renewal of an authorisation of a feed additive (Article 14 of Regulation (EC) No 1831/2003):

— Fee = component 2 = EUR 4 000

— when Article 5(4)(c) applies: Fee = EUR 0.**]**

(**1**) OJ L 59, 5.3.2005, p. 8.

(**2**) OJ L 165, 30.4.2004, p. 1. Corrigendum OJ L 191, 28.5.2004, p. 1.’

Status:
Point in time view as at 31/01/2020.

Changes to legislation:
There are outstanding changes not yet made to Commission Regulation (EC) No 378/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.