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)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([1]), and in particular the first subparagraph of Article 7(4) and the third paragraph of Article 21 thereof,

After consulting the European Food Safety Authority,

Whereas:

(1) Regulation (EC) No 1831/2003 establishes the procedure for authorising the placing on the market and use of feed additives in animal nutrition. It provides that any person seeking authorisation for a feed additive or a new use of a feed additive is to submit an application for authorisation in accordance with that Regulation.

(2) Commission Regulation (EC) No 378/2005 ([2]) lays down detailed rules for the implementation of Regulation (EC) No 1831/2003 as regards applications for authorisation of a feed additive or for a new use of a feed additive and the duties and tasks of the Community Reference Laboratory ('CRL').

(3) Article 5 of Regulation (EC) No 378/2005 provides that the CRL is to submit a full evaluation report to the European Food Safety Authority ('the Authority') for each application for authorisation of a feed additive. Exceptions to the requirement to submit an evaluation report are made for applications for a new use of a feed additive or applications for changing the terms of an existing authorisation, provided that the proposed conditions for the new use or for the change in the terms of the authorisation fall within the scope of the method of analysis previously submitted in accordance with the requirements laid down in Annex II to Commission Regulation (EC) No 429/2008 ([3]) and already evaluated. Furthermore, Article 4 of that Regulation provides that the CRL is to charge applicants fees for submitting applications for authorisation. Exception is made where no samples are required and the CRL does not need to issue a report, as the method of analysis has already been evaluated. However, applications for renewal of authorisations of feed additives do not benefit from those exceptions.

(4) Experience has shown that the exceptions to the requirements concerning evaluation reports and submission fees should also be extended to the applications for renewal of authorisations of feed additives. Article 5 of and Annex IV to Regulation (EC) No 378/2005 should therefore be amended accordingly.

(5) Annex II to Regulation (EC) No 378/2005 sets out a list of national reference laboratories assisting the CRL in its duties and tasks. Several Member States have informed the Commission that their national reference laboratories taking part in the consortium have changed because other laboratories have been designated for that purpose or the name or address of the laboratories have changed. Annex II to Regulation (EC) No 378/2005 should therefore be adapted accordingly.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) OJ L 268, 18.10.2003, p. 29.

([2]) Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8).

([3]) Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 378/2005 is amended as follows:

(1) Article 5(4) is replaced by the following:

'4. An evaluation report shall not be required for:

(a) applications for a new use of a feed additive submitted in accordance with Article 4(1) of Regulation (EC) No 1831/2003, when the proposed conditions for placing the feed additive on the market for the new use fall within the scope of the method of analysis previously submitted in accordance with paragraph 2.6 of Annex II to Regulation (EC) No 429/2008 and already evaluated by the CRL;

(b) applications for changing the terms of an existing authorisation submitted in accordance with Article 13(3) of Regulation (EC) No 1831/2003, when the proposed change or the new conditions for placing the feed additive on the market fall within the scope of the method of analysis previously submitted in accordance with paragraph 2.6 of Annex II to Regulation (EC) No 429/2008 and already evaluated by the CRL;

(c) applications for renewal of an existing authorisation submitted in accordance with Article 14 of Regulation (EC) No 1831/2003, when the conditions for placing the feed additive on the market fall within the scope of the method of analysis previously submitted in accordance with paragraph 2.6 of Annex II to Regulation (EC) No 429/2008 and already evaluated by the CRL.

Notwithstanding paragraph 4, the Commission, the CRL or the Authority may, on the basis of legitimate factors relevant to the application, consider that a new evaluation of the methods of analysis is necessary. In such cases the applicant shall be informed by the CRL.';

(2) Annex II is replaced by the text as set out in the Annex to this Regulation;

(3) in Annex IV, under the title 'Rates according to the type of application for authorisations of feed additives in accordance with Regulation (EC) No 1831/2003', point 5 is replaced by the following:

'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.'

Article 2

This Regulation shall enter into force on the twentieth day following that of 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.

Done at Brussels, 1 October 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

'ANNEX II

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

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.'