# COMMISSION REGULATION (EU) No 415/2013

## of 6 May 2013

## laying down additional responsibilities and tasks for the EU reference laboratories for rabies, bovine tuberculosis and bee health, amending Regulation (EC) No 737/2008 and repealing Regulation (EU) No 87/2011

**(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 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules [1], and in particular Article 32(6) thereof,

Whereas:

(1) Regulation (EC) No 882/2004 lays down the general functions and duties for the EU reference laboratories for food and feed and for animal health set out in Annex VII thereto. In addition, Regulation (EC) No 882/2004 provides that the Commission may include in Annex VII thereto other EU reference laboratories relevant to the areas falling within the scope of that Regulation.

(2) Regulation (EC) No 882/2004 also provides that, in addition to the general functions and duties of EU reference laboratories in the animal health sector laid down therein, additional responsibilities and tasks for those EU reference laboratories may be laid down by the Commission.

(3) By Commission Regulation (EC) No 737/2008 of 28 July 2008 designating the Community reference laboratories for crustacean diseases, rabies and bovine tuberculosis, laying down additional responsibilities and tasks for the Community reference laboratories for rabies and bovine tuberculosis and amending Annex VII to Regulation (EC) No 882/2004 of the European Parliament and of the Council [2], the Commission designated, inter alia, the EU reference laboratories for rabies and bovine tuberculosis and, consequently, inserted the relevant entries concerning those laboratories in Annex VII to Regulation (EC) No 882/2004. In addition, Annexes I and II to Regulation (EC) No 737/2008 set out certain specific responsibilities and tasks linked to the characteristics of the pathogens. Those responsibilities and tasks are additional to those laid down in Regulation (EC) No 882/2004.

(4) By Commission Regulation (EU) No 87/2011 of 2 February 2011 designating the EU reference laboratory for bee health, laying down additional responsibilities and tasks for that laboratory and amending Annex VII to Regulation (EC) No 882/2004 of the European Parliament and of the Council [3], the Commission designated the EU reference laboratory for bee health and, consequently, inserted the relevant entry concerning that laboratory in Annex VII to Regulation (EC) No 882/2004. In addition, the Annex to Regulation (EU) No 87/2011 sets out certain specific responsibilities and tasks linked to the characteristics of the agents liable to affect bee health. Those responsibilities and tasks are additional to those laid down in Regulation (EC) No 882/2004.

(5) The definition of certain tasks of the EU reference laboratory for bee health in the Annex to Regulation (EU) No 87/2011 needs to be amended as regards serological tests because they are not applicable to testing on bees. As well the mention of colony collapse disorder (CCD) should be modified in order to ensure consistency with the terminology used in the surveillance studies on bee mortality established in Commission Implementing Decision 2012/362/EU [4].

(6) In the interest of clarity and simplification of Union legislation, it is appropriate that the provisions concerning those additional responsibilities and tasks of the EU reference laboratories for rabies, bovine tuberculosis and bee health be set out in only one act.

(7) Regulation (EC) No 737/2008 should therefore be amended accordingly and Regulation (EU) No 87/2011 be repealed.

(8) 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*

In addition to the general functions and duties of EU reference laboratories in the animal health sector laid down in Article 32(2) of Regulation (EC) No 882/2004, the EU

[1] OJ L 165, 30.4.2004, p. 1.
[2] OJ L 201, 30.7.2008, p. 29.
[3] OJ L 29, 3.2.2011, p. 1.
[4] OJ L 176, 6.7.2012, p. 65.

reference laboratory for rabies set out in point 16 of Part II of Annex VII to that Regulation shall also have the responsibilities and tasks set out in Annex I to this Regulation.

*Article 2*

In addition to the general functions and duties of EU reference laboratories in the animal health sector laid down in Article 32(2) of Regulation (EC) No 882/2004, the EU reference laboratory for bovine tuberculosis set out in point 17 of Part II of Annex VII to that Regulation shall also have the responsibilities and tasks set out in Annex II to this Regulation.

*Article 3*

In addition to the general functions and duties of EU reference laboratories in the animal health sector laid down in Article 32(2) of Regulation (EC) No 882/2004, the EU reference laboratory for bee health set out in point 18 of Part II of Annex VII to that Regulation shall also have the responsibilities and tasks set out in Annex III to this Regulation.

*Article 4*

Regulation (EC) No 737/2008 is amended as follows:

(1) Articles 2 and 3 are deleted;

(2) Annexes I and II are deleted.

*Article 5*

Regulation (EU) No 87/2011 is repealed.

References to the repealed Regulation shall be construed as references to this Regulation.

*Article 6*

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, 6 May 2013.

*For the Commission*
*The President*
José Manuel BARROSO

*ANNEX I*

**Responsibilities and tasks of the EU reference laboratory for rabies, additional to those laid down in Article 32(2) of Regulation (EC) No 882/2004**

1. The EU reference laboratory for rabies shall coordinate, in consultation with the Commission, the methods employed in the Member States for diagnosing rabies, in particular by:

   (a) typing, storing and supplying strains of rabies virus;

   (b) preparing, controlling and supplying international standard sera and other reference reagents to the national reference laboratories in order to standardise the tests and reagents used in the Member States;

   (c) validating reference reagents including antigens and national standard sera submitted by the national reference laboratories;

   (d) building up and maintaining a sera bank and a collection of rabies virus, and maintaining a database of strains isolated across the Union, including typing;

   (e) organising periodical comparative tests of diagnostic procedures at Union level and operating laboratory proficiency tests of national reference laboratories;

   (f) collecting and collating data and information on the methods of diagnosis used and the results of tests carried out in the Union;

   (g) characterising rabies virus by the most up-to-date methods available to allow a greater understanding of the epidemiology of that disease;

   (h) keeping abreast of developments in rabies surveillance, epidemiology and prevention throughout the world;

   (i) acquiring a thorough knowledge of the preparation and use of the products of veterinary immunology used to eradicate and control rabies including the evaluation of vaccines.

2. The EU reference laboratory for rabies shall also:

   (a) facilitate the harmonisation of techniques throughout the Union, in particular by specifying standard test methodologies;

   (b) organise workshops for the benefit of national reference laboratories as agreed in the work programme and estimated budget referred to in Article 2 of Commission Implementing Regulation (EU) No 926/2011 [1], including training of experts from the Member States and, as appropriate, from third countries, in new analytical methodologies;

   (c) provide technical assistance to the Commission and, upon its request, participate in international forums relating to rabies, concerning in particular the standardisation of analytical diagnostic methods and their implementation.

3. In addition, the EU reference laboratory for rabies shall perform research activities and, whenever possible, coordinate research activities directed towards the improved control and eradication of rabies, in particular by:

   (a) carrying out or collaborating with national reference laboratories in carrying out test validation trials;

   (b) providing scientific advice to the Commission and collecting information and reports associated with the activities of the EU reference laboratory.

[1] OJ L 241, 17.9.2011, p. 2.

*ANNEX II*

**Responsibilities and tasks of the EU reference laboratory for bovine tuberculosis, additional to those laid down in Article 32(2) of Regulation (EC) No 882/2004**

1. The EU reference laboratory for bovine tuberculosis shall coordinate, in consultation with the Commission, the methods employed in the Member States for diagnosing bovine tuberculosis, in particular by:

   (a) typing, storing and supplying strains of Mycobacterium sp. causing tuberculosis in animals;

   (b) preparing, controlling and supplying reference reagents to the national reference laboratories in order to standardise the tests and reagents used in the Member States;

   (c) validating reference reagents including antigens and tuberculins submitted by the national reference laboratories for bovine tuberculosis;

   (d) building up and maintaining a collection of Mycobacterium sp. causing tuberculosis in animals, and maintaining a database of strains isolated across the Union including typing;

   (e) organising periodical comparative tests of diagnostic procedures at Union level and operating laboratory proficiency tests of national reference laboratories;

   (f) collecting and collating data and information on the methods of diagnosis used and the results of tests carried out in the Union;

   (g) characterising Mycobacterium sp. causing tuberculosis in animals by the most up-to-date methods available to allow a greater understanding of the epidemiology of that disease;

   (h) keeping abreast of developments in bovine tuberculosis surveillance, epidemiology and prevention throughout the world;

   (i) acquiring a thorough knowledge of the preparation and use of the products of veterinary immunology used to eradicate and control bovine tuberculosis including the evaluation of vaccines.

2. The EU reference laboratory for bovine tuberculosis shall also:

   (a) facilitate the harmonisation of techniques throughout the Union, in particular by specifying standard test methodologies;

   (b) organise workshops for the benefit of national reference laboratories as agreed in the work programme and estimated budget referred to in Article 2 of Implementing Regulation (EU) No 926/2011, including training of experts from the Member States and, as appropriate, from third countries, in new analytical methodologies;

   (c) provide technical assistance to the Commission and, upon its request, to participate in international forums relating to the diagnostic of bovine tuberculosis, concerning in particular the standardisation of analytical diagnostic methods and their implementation.

3. In addition, the EU reference laboratory for bovine tuberculosis shall perform research activities and, whenever possible, coordinate research activities directed towards the improved control and eradication of bovine tuberculosis, in particular by:

   (a) carrying out or collaborating with national reference laboratories in carrying out test validation trials;

   (b) providing scientific advice to the Commission and collecting information and reports associated with the activities of the EU reference laboratory.

*ANNEX III*

**Responsibilities and tasks of the EU reference laboratory for bee health, additional to those laid down in Article 32(2) of Regulation (EC) No 882/2004**

1. The EU reference laboratory for bee health shall coordinate, in consultation with the Commission, the methods employed in the Member States for diagnosing the relevant bee diseases, as necessary, in particular by:

   (a) typing, storing and, where appropriate, supplying strains of the pathogenic agents to facilitate the diagnostic service in the Union;

   (b) typing and antigenic and genomic characterisation of pathogenic agents, where relevant and necessary, for example for epidemiological follow-ups or verification of diagnosis;

   (c) supplying standard sera and other reference reagents to the national reference laboratories in order to standardise the test and the reagents used in each Member State, where reference reagents are required;

   (d) organising periodic comparative tests of diagnostic procedures at Union level with the national reference laboratories, in order to provide information on the methods of diagnosis used and the result of the tests carried out in the Union;

   (e) retaining expertise on the Tropilaelaps mites and the small hive beetle (*Aethina tumida*) and other pertinent pathogenic agents to enable rapid differential diagnosis;

   (f) determining the identity of the causative pathogenic agents, where necessary in close collaboration with regional reference laboratories designated by the World Organisation for Animal Health (OIE);

   (g) building up and maintaining an up-to-date collection of pathogenic agents and their strains and an up-to-date collection of other reagents against bee disease pathogens when or if available;

   (h) carrying out an inventory of the currently used techniques in the various laboratories;

   (i) proposing standardised tests and test procedures or reference reagents for internal quality control;

   (j) advising the Commission on scientific aspects related to bee health.

2. The EU reference laboratory for bee health shall also:

   (a) assist actively in the diagnosis of outbreaks of the relevant disease in Member States by receiving pathogen isolates for confirmatory diagnosis, characterisation and epizootic studies and communicating without delay the results of any investigations to the Commission, the Member States and the national reference laboratories concerned;

   (b) facilitate the training or retraining of experts in laboratory diagnosis with a view to harmonising diagnostic techniques throughout the Union;

   (c) organise workshops for the benefit of national reference laboratories as agreed in the work programme and estimated budget referred to in Article 2 of Regulation (EU) No 926/2011, including training of experts from the Member States and, as appropriate, from third countries, in new analytical methodologies;

   (d) provide technical assistance to the Commission and, at its request, participate in international forums concerning, in particular, the standardisation of analytical methods and their implementation;

   (e) develop monitoring activities and whenever possible coordinate activities directed towards an improvement of the bee health status in the Union, in particular by:

      (i) carrying out or collaborating with national reference laboratories concerned in carrying out test validation trials;

      (ii) providing scientific and technical support to the Commission and collecting information and reports associated with the activities of the EU reference laboratory;

      (iii) establishing and coordinating a survey on honeybee colony losses in the Union with regard to establishing a baseline for 'normal' seasonal mortality of bees;

   (f) collaborate with the relevant competent laboratories in third countries where those diseases are prevalent as regards methods of diagnosing bee diseases;

   (g) collaborate with the relevant regional laboratories designated by the OIE with regard to exotic diseases (Tropilaelaps mites and the small hive beetle (*Aethina tumida*) and any other disease exotic to the Union);

   (h) collate and forward information to the Commission and to national reference laboratories concerned on exotic and endemic diseases or pests that are potentially emerging and could affect the Union, including honeybee colony losses.

3. In addition, the EU reference laboratory for bee health shall:

(a) perform experiments and field trials, in consultation with the Commission, directed towards an improved control of specific bee diseases;

(b) review at the annual meeting of national reference laboratories the relevant requirements for testing laid down in the OIE Terrestrial Animal Health Code and Manual of Diagnostic Tests and Vaccines for Terrestrial Animals;

(c) assist the Commission in reviewing the OIE's recommendations in the Terrestrial Animal Health Code and Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.