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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

(OJ L 201, 30.7.2008, p. 29)

Amended by:

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Commission Regulation (EU) No 208/2011 of 2 March 2011

Official Journal

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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

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 animal welfare rules ⁽¹⁾, and in particular Article 32(5) and (6) thereof,

Having regard to Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals ⁽²⁾, and in particular Article 55(1) thereof,

Whereas:

- (1) Regulation (EC) No 882/2004 lays down the general tasks, duties and requirements for Community reference laboratories for food and feed and for animal health. The Community reference laboratories for animal health and live animals are listed in Part II of Annex VII to that Regulation.
- (2) Directive 2006/88/EC lays down the animal health requirements for the placing on the market, and the importation and the transit through the Community of aquaculture animals and products thereof, and certain minimum preventive and control measures for certain diseases in those animals. Pursuant to that Directive, the Community reference laboratories for aquatic animal diseases are to comply with the functions and duties laid down in Part I of Annex VI thereto.
- (3) Following the completion of the selection procedure of a call for designation, the Centre for Environment, Fisheries & Aquaculture Science (Cefas), Weymouth Laboratory, United Kingdom, should be designated as the Community reference laboratory for crustacean diseases.
- (4) Following the completion of the selection procedure of a call for designation, the Laboratoire d'études sur la rage et la pathologie des animaux sauvages of the Agence Française de Sécurité Sanitaire des Aliments (AFSSA), Nancy, France, should be designated as the Community reference laboratory for rabies.
- (5) Following the completion of the selection procedure of a call for designation, the Laboratorio de Vigilancia Veterinaria (VISAVET) of the Facultad de Veterinaria, Universidad Complutense de Madrid, Madrid, Spain, should be designated as the Community reference laboratory for bovine tuberculosis.

⁽¹⁾ OJ L 165, 30.4.2004, p. 1, as corrected by OJ L 191, 28.5.2004, p. 1. Regulation as last amended by Council Regulation (EC) No 301/2008 (OJ L 97, 9.4.2008, p. 85).

⁽²⁾ OJ L 328, 24.11.2006, p. 14. Directive as amended by Commission Directive 2008/53/EC (OJ L 117, 1.5.2008, p. 27).

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- (6) The Community reference laboratories for crustacean diseases, rabies and bovine tuberculosis should be designated for an initial period of five years from 1 July 2008 in order to enable the assessment of their performance and compliance.
- (7) In addition to the general functions and duties laid down in Article 32(2) of Regulation (EC) No 882/2004, certain specific responsibilities and tasks linked to the characteristics of the agents causing the disease should be carried out at Community level to ensure enhanced coordination. Therefore, these additional specific responsibilities and tasks should be laid down in the present Regulation for the Community reference laboratories for rabies and bovine tuberculosis.
- (8) Part II of Annex VII to Regulation (EC) No 882/2004 should therefore be amended accordingly.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee of the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The Centre for Environment, Fisheries & Aquaculture Science (Cefas), Weymouth Laboratory, United Kingdom, is hereby designated as the Community reference laboratory for crustacean diseases from 1 July 2008 until 30 June 2013.

Article 2

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The Laboratoire de la rage et de la faune sauvage de Nancy of the Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES), France, is hereby designated as the EU reference laboratory for rabies from 1 July 2008 until 30 June 2013.

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Certain responsibilities and tasks for that laboratory are set out in Annex I.

Article 3

The Laboratorio de Vigilancia Veterinaria (VISAVET), Facultad de Veterinaria, Universidad Complutense de Madrid, Madrid, Spain, is hereby designated as the Community reference laboratory for bovine tuberculosis from 1 July 2008 until 30 June 2013.

Certain responsibilities and tasks for that laboratory are set out in Annex II.

Article 4

In Part II of Annex VII to Regulation (EC) No 882/2004, the following points 15, 16 and 17 are added:

‘15. Community reference laboratory for crustacean diseases

Centre for Environment, Fisheries & Aquaculture Science
(Cefas)

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- Weymouth Laboratory
The Nothe
Barrack Road
Weymouth
Dorset DT4 8UB
United Kingdom
16. Community reference laboratory for rabies
AFSSA — Laboratoire d'études sur la rage et la pathologie des animaux sauvages, Nancy, France
54220 Malzéville
France
17. Community reference laboratory for bovine tuberculosis
VISAVET — Laboratorio de vigilancia veterinaria, Facultad de Veterinaria, Universidad Complutense de Madrid
Avda. Puerta de Hierro, s/n. Ciudad Universitaria
28040 Madrid
Spain'

Article 5

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.



ANNEX I

**CERTAIN RESPONSIBILITIES AND TASKS OF THE COMMUNITY
REFERENCE LABORATORY FOR RABIES**

In addition to the general functions and duties of Community reference laboratories in the animal health sector pursuant to Article 32(2) of Regulation (EC) No 882/2004, the Community reference laboratory for rabies shall have the responsibilities and tasks set out in points 1 to 5.

1. To 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 Community, including typing;
 - (e) organising periodical comparative tests of diagnostic procedures at Community 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 Community;
 - (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. To facilitate the harmonisation of techniques throughout the Community, in particular specifying standard test methodologies.
3. To organise workshops for the benefit of national reference laboratories as agreed in the work-programme and annual budget referred to in Articles 2 to 4 of Commission Regulation (EC) No 156/2004⁽¹⁾, including training of experts from the Member States and, as appropriate, from third countries, in new analytical methodologies.
4. To provide technical assistance to the Commission and, upon its request, to participate in international fora relating to rabies, concerning in particular the standardisation of analytical diagnostic methods and their implementation.
5. To 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 Community reference laboratory.

⁽¹⁾ OJ L 27, 30.1.2004, p. 5.



ANNEX II

**CERTAIN RESPONSIBILITIES AND TASKS OF THE COMMUNITY
REFERENCE LABORATORY FOR BOVINE TUBERCULOSIS**

In addition to the general functions and duties of Community reference laboratories in the animal health sector pursuant to Article 32(2) of Regulation (EC) No 882/2004, the Community reference laboratory for bovine tuberculosis shall have the responsibilities and tasks set out in points 1 to 5.

- (1) To 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 tuberculin 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 Community including typing;
 - (e) organising periodical comparative tests of diagnostic procedures at Community 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 Community;
 - (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) To facilitate the harmonisation of techniques throughout the Community, in particular specifying standard test methodologies.
- (3) To organise workshops for the benefit of national reference laboratories as agreed in the work-programme and annual budget referred to in Articles 2 to 4 of Regulation (EC) No 156/2004, including training of experts from the Member States and, as appropriate, from third countries, in new analytical methodologies.
- (4) To provide technical assistance to the Commission and, upon its request, to participate in international fora relating to the diagnostic of bovine tuberculosis, concerning in particular the standardisation of analytical diagnostic methods and their implementation.
- (5) To perform research activities and, whenever possible, co-ordinate 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 Community reference laboratory.