Commission Regulation (EU) 2018/221 of 15 February 2018 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the European Union reference laboratory for transmissible spongiform encephalopathies (Text with EEA relevance)

COMMISSION REGULATION (EU) 2018/221

of 15 February 2018

amending Regulation (EC) No 999/2001 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the European Union reference laboratory for transmissible spongiform encephalopathies

(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 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies[(1)], and in particular Article 23a(m) thereof,

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[(2)], and in particular Article 32(5) thereof,

Whereas:

(1) Regulation (EC) No 882/2004 lays down the general tasks, duties and requirements for European Union (EU) reference laboratories for food and feed and for animal health. The designated EU reference laboratories are listed in Annex VII to that Regulation, including that responsible for transmissible spongiform encephalopathies (TSEs).

(2) Regulation (EC) No 999/2001 establishes the EU reference laboratory for TSEs and its specific tasks.

(3) The designation of the EU reference laboratory for TSEs, currently located in the United Kingdom, will be discontinued on 31 December 2018 as a consequence of the United Kingdom notification in accordance with Article 50 of the Treaty on European Union.

(4) It is necessary to maintain an EU reference laboratory for TSEs in order to ensure the high quality and reliability of diagnosis techniques for TSEs as well as their uniform application throughout the Union. The Commission therefore launched on 29 May 2017 a call for applications to select and designate an EU reference laboratory for TSEs. Following completion of the selection procedure, the selected consortium between the Istituto Zooprofilattico Sperimentale del Piemonte, Liguria e Valle d'Aosta

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2018/221. (See end of Document for details)*

(IZSPLVA) and the Istituto Superiore di Sanità (ISS), led by the former, should be designated as EU reference laboratory for TSEs.

(5) Regulations (EC) No 999/2001 and (EC) No 882/2004 should therefore be amended accordingly.

(6) In order to avoid any disruption of activities of the EU reference laboratory for TSEs and to allow the newly designated EU reference laboratory sufficient time to be fully operational, it is appropriate that the measures provided for in this Regulation apply as from 1 January 2019.

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

HAS ADOPTED THIS REGULATION:

Article 1

In Chapter B of Annex X to Regulation (EC) No 999/2001, point 1 is replaced by the following:

1. The EU reference laboratory for TSEs is a consortium between the Istituto Zooprofilattico Sperimentale del Piemonte, Liguria e Valle d'Aosta (IZSPLVA) and the Istituto Superiore di Sanità (ISS), led by IZSPLVA:

Istituto Zooprofilattico Sperimentale del Piemonte, Liguria e Valle d'Aosta (IZSPLVA)

Via Bologna 148

10154 Torino

Italy

Istituto Superiore di Sanità (ISS)

Viale Regina Elena 299

00161 Roma

Italy.

Article 2

In Part I of Annex VII to Regulation (EC) No 882/2004, point 13 is replaced by the following:

13. **EU reference laboratory for transmissible spongiform encephalopathies (TSEs)**

The laboratory referred to in point 1 of Chapter B of Annex X to Regulation (EC) No 999/2001.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2019.

This Regulation shall be binding in its entirety and directly applicable in all Member States.