EUROPEAN
COMMISSION

Brussels, 17.9.2021
C(2021) 6673 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 17.9.2021

supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council by establishing the European Union reference laboratory for Rift Valley fever

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Rift Valley fever (RVF) is an emerging zoonotic vector-borne disease of wild and domestic ruminants caused by a virus and representing a potential cross-border threat. RVF is characterised by high rates of abortion and neonatal mortality in domestic ruminants. In humans, the disease mainly develops as an influenza-like illness, where a minority of patients may develop encephalitis or even a severe hepatic disease with haemorrhagic manifestations, which is generally fatal. RVF is on the list of notifiable animal diseases[1] of the World Organisation for Animal Health (OIE).

Rules for the prevention and control of RVF, including adequate surveillance and control measures against this disease, are laid down in accordance with Regulation (EU) 2016/429 of the European Parliament and of the Council[2] on transmissible animal diseases, which establishes a legislative framework for the prevention and control of listed diseases. In accordance with the Annex to Commission Implementing Regulation (EU) 2018/1882[3], RVF is considered as a category A, D and E disease, for which immediate eradication measures are to be taken as soon as it is detected.

The effectiveness of the surveillance, control and eradication measures to be taken by the competent authorities depends on the quality, uniformity and reliability of the methods of analysis, test or diagnosis employed by the official laboratories designated in accordance with Article 37(1) of Regulation (EU) 2017/625. European Union reference laboratories promote uniform practices in the development or use of the methods of analysis and ensure the quality, uniformity and reliability of the results of the methods of analysis, test or diagnosis performed by those official laboratories.

Regulation (EU) 2017/625 of the European Parliament and of the Council[4] on official controls lays down rules on establishing European Union reference laboratories.

So far, the Union has not established a European Union reference laboratory for RVF. The measures taken *in response to* previous outbreaks indicate that official laboratories designated in accordance with Article 37(1) of Regulation (EU) 2017/625 promote uniform practices in the development or use of the methods of analysis, test or diagnosis employed by those official laboratories, and in the interpretation of results.

---

1 OIE list of notifiable terrestrial and aquatic animal diseases (https://www.oie.int/en/what-we-do/animal-health-and-welfare/animal-diseases).

2 Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84, 31.3.2016, p. 1).

3 Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases (OJ L 308, 4.12.2018, p. 21).

4 Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

It is therefore necessary to establish a European Union reference laboratory for RVF with a view to contribute to the improvement and harmonisation of the methods of analysis, test or diagnosis, the development of validated methods and the coordinated assistance to those official laboratories.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission consulted with the Expert Group on animal health (E00930) by a written consultation on 23/02/2021. The draft Delegated Regulation was also made available to the European Parliament and the Council. The Commission received no comments.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

This Delegated Regulation is to be adopted pursuant to Regulation (EU) 2017/625, and in particular Article 92(4) thereof.

COMMISSION DELEGATED REGULATION (EU) …/...

of 17.9.2021

supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council by establishing the European Union reference laboratory for Rift Valley fever

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)[5], and in particular Article 92(4) thereof,

Whereas:

(1) Rift Valley fever (RVF) is an emerging zoonotic vector-borne disease of wild and domestic ruminants caused by a virus and representing a potential cross-border threat. RVF is characterised by high rates of abortion and neonatal mortality in domestic ruminants. In humans, the disease mainly develops as an influenza-like illness, where a minority of patients may develop encephalitis or even severe hepatic disease with haemorrhagic manifestations. RVF is on the list of notifiable animal diseases[6] of the World Organisation for Animal Health (OIE).

(2) In March 2019, the European Centre for Disease Prevention and Control (ECDC) published a rapid risk assessment to address the risk of importation of RVF virus and further spread of the virus within the Union and the European Economic Area (EEA) in relation to the increase in cases reported in Mayotte[7]. The assessment highlighted that, although the risk from these outbreaks was very low for the Union and the EEA in terms of introduction of RVF virus through the legal trade of animals and animal products, the illegal transport of fresh meat, unpasteurised milk and untreated products from infected ruminants in personal luggage could pose a risk. The ECDC concluded that if the virus was introduced into the continental part of the Union and the EEA, further vector-borne transmission among animals could not be excluded.

---

5 OJ L 95, 7.4.2017, p. 1.

6 OIE list of notifiable terrestrial and aquatic animal diseases (https://www.oie.int/en/what-we-do/animal-health-and-welfare/animal-diseases).

7 European Centre for Disease Prevention and Control. Rapid risk assessment: Rift Valley fever outbreak in Mayotte, France – 7 March 2019. Stockholm: ECDC; 2019.

(3) In addition, the European Food Safety Authority (EFSA) adopted a scientific opinion on RVF on 23 January 2020[8], indicating that the risk of spread of RVF into countries neighbouring the Union and the risk of possible introduction of infected vectors into the Union should not be ignored.

(4) The risk of RVF entering the Union means that the Union should establish adequate surveillance and control measures against this disease, in accordance with Regulation (EU) 2016/429 of the European Parliament and of the Council[9], which establishes a legislative framework for the prevention and control of listed diseases. In accordance with the Annex to Commission Implementing Regulation (EU) 2018/1882[10], RVF is considered as a category A, D and E disease, for which immediate eradication measures are to be taken as soon as it is detected.

(5) The Union has in place adequate surveillance and disease control measures against RVF to ensure its immediate eradication if the disease enters into the Union. In order for these measures to continue being effective, they should also include appropriate preparedness and available resources to fight against the disease, taking also into account the zoonotic potential of the disease. In that respect, it is considered necessary to provide sufficient laboratory testing capacity, since the good quality of such testing capacity is essential to implement the surveillance and disease control measures and avoid, therefore, that the disease enters the Union.

(6) So far, the Union has not established a European Union reference laboratory for RVF. The designation of a reference laboratory is essential to be able to apply surveillance and disease control measures on a scientific basis and in a homogeneous manner throughout the Union territory.

(7) This Regulation should therefore establish a European Union reference laboratory for RVF to contribute to ensure the effectiveness of official controls and to coordinate assistance to official laboratories,

HAS ADOPTED THIS REGULATION:

Article 1

The European Union reference laboratory for Rift Valley fever is hereby established.

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*.

[8] EFSA Journal 2020;18(3):6041.

[9] Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84, 31.3.2016, p. 1).

[10] Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases (OJ L 308, 4.12.2018, p. 21).

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

Done at Brussels, 17.9.2021

For the Commission
The President
Ursula VON DER LEYEN