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EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Regulation (EU) 2016/429[[1]](#footnote-2) 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’) lays down rules on transmissible animal diseases and rules for animal health requirements for movements within the Union of terrestrial animals and hatching eggs.

Commission Delegated Regulation (EU) 2020/688[[2]](#footnote-3) supplements the rules for the prevention and control of animal diseases transmissible to animals or to humans laid down in Article 5(1) of Regulation (EU) 2016/429 as regards movements within the Union of kept terrestrial animals, wild terrestrial animals and hatching eggs.

Delegated Regulation (EU) 2020/688 applies from 21 April 2021. Since that date, the epidemiological situation related to infection with epizootic haemorrhagic disease virus has changed, following the notification of outbreaks in several Member States in late 2022.

Due to this new epidemiological situation, the movements to other Member States of certain listed species susceptible to the disease have been affected. Commission Delegated Regulation (EU) 2023/2515[[3]](#footnote-4) provided for alternative risk-mitigating measures while continuing with the prevention of its spreading on account of movements between Member States and to provide for safe movements of susceptible animals.

The experience gained during the application of Delegated Regulation (EU) 2020/688 including its latest amendment, and information from competent authorities of the Member States has shown the neccesity to provide for two more alternative risk mitigating measures:

* requirements related to vaccination;
* a framework for different animal health requirements under derogation that the competent authority of the Member State of destination may wish to specifically establish as they provide enough animal health protection considering their local animal health situation.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission consulted the contents of this draft Delegated Regulation with members of the Expert Group on Animal Health (E00930) on a meeting that took place on 15 March 2024.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

This Delegated Regulation is to be adopted within the framework of Regulation (EU) 2016/429, and in particular pursuant to Article 131(1)(c) and (d).

COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

amending Delegated Regulation (EU) 2020/688 as regards certain animal health requirements for movements within the Union of terrestrial animals

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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’)[[4]](#footnote-5), and in particular to Article 131(1), points (c) and (d) thereof,

Whereas:

1. Regulation (EU) 2016/429 lays down rules for the prevention and control of animal diseases that are transmissible to animals or to humans. That Regulation lays down in its Part IV, Title I, Chapter 3, the animal health requirements for movements within the Union of kept terrestrial animals.
2. Commission Delegated Regulation (EU) 2020/688[[5]](#footnote-6) supplements the rules for the prevention and control of animal diseases transmissible to animals laid down in Article 5(1) of Regulation (EU) 2016/429 as regards movements within the Union of terrestrial animals among them ungulates susceptible to infection with epizootic haemorrhagic disease virus.
3. Infection with epizootic haemorrhagic disease virus is listed in the Annex to Commission Implementing Regulation (EU) 2018/1882[[6]](#footnote-7) as a Category D disease for which measures are needed to prevent it from spreading on account of movements between Member States. The epidemiological situation of the disease in the Union changed since the entry into force of Regulation (EU) 2016/429 and Delegated Regulation (EU) 2020/688, with the first ever notification of outbreaks in the Union in several Member States in late 2022. The spread of the disease continued even after the entry into force of the latest amendment to Delegated Regulation (EU) 2020/688 by Commission Delegated Regulation (EU) 2023/2515[[7]](#footnote-8)..
4. To address that changing epidemiological situation as regards infection with epizootic haemorrhagic disease virus, and to ensure the prevention of its spread on account of movements between Member States, in particular to protect the Member States of destination, additional alternative risk-mitigating measures applicable to those movements are necessary.
5. Vaccination against infection with epizootic haemorrhagic disease virus is considered as a risk mitigating measure in the Terrestrial Animal Health Code of the World Organisation for Animal Health (WOAH). Vaccines are effective to prevent the transmission of the virus via the movement of vaccinated animals irrespective of the virus circulation at the place of origin when the vaccines are applied in accordance with the specifications of the vaccine. Therefore, this Regulation should provide for their use as a risk mitigating measure for movements between Member States.
6. Also, experience has shown that the competent authorities of some Member States, considering the local animal health situation at the places of destination of those animals, wish to use specific animal health risk mitigating measures under derogation, in order to provide enough protection at local level for against this specific disease.
7. Both alternative risk mitigation measures should be added to the relevant articles, regulating movements of bovine, ovine, caprine, camelid, cervid animals, and of other kept ungulates, respectively.
8. Delegated Regulation (EU) 2020/688 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Delegated Regulation (EU) 2020/688

Delegated Regulation (EU) 2020/688 is amended as follows:

1. Article 10, paragraph 1 is amended as follows:

(a) the following is added after point (f)(ii) sub-point 2:

‘3. the animals have been vaccinated against all serotypes of infection with epizootic haemorrhagic disease virus reported during the past 2 years in an area of at least 150 km radius around the establishment of origin, the animals are within the immunity period guaranteed in the specifications of the vaccine and meet at least one of the following requirements:

* they have been vaccinated more than 60 days before the date of movement;
* they have been vaccinated with an inactivated vaccine and subject to a PCR test, with negative results on samples collected at least 14 days after the onset of the immunity set in the specifications of the vaccine’;

(b) last subparagraph of paragraph 1 is replaced by the following:

‘By way of derogation from point (f)(ii), the competent authority of the Member State of origin may authorise the following movements to another Member State or area thereof:

(a) movements which do not meet one of the requirements laid down in that point; or

(b) movements that comply with specific animal health requirements defined by the competent authority of the Member State of destination.

Prior to the use of any of the derogations, the competent authority of the Member State of destination shall:

(a) inform the Commission and the other Member States that such movements are authorised; and

(b) accept the animals regardless of the Member State or area thereof of their origin’.

2. Article 15, paragraph 1 is amended as follows:

(a) the following is added after point (e)(ii) sub-point 2:

‘3. the animals have been vaccinated against all serotypes of infection with epizootic haemorrhagic disease virus reported during the past 2 years in an area of at least 150 km radius around the establishment of origin, the animals are within the immunity period guaranteed in the specifications of the vaccine and meet at least one of the following requirements:

* they have been vaccinated more than 60 days before the date of movement;
* they have been vaccinated with an inactivated vaccine and subject to a PCR test, with negative results on samples collected at least 14 days after the onset of the immunity set in the specifications of the vaccine’;

(b) last subparagraph of paragraph 1 is replaced by the following:

‘By way of derogation from point (e)(ii), the competent authority of the Member State of origin may authorise the following movements to another Member State or area thereof:

(a) movements which do not meet one of the requirements laid down in that point; or

(b) movements that comply with specific animal health requirements defined by the competent authority of the Member State of destination.

Prior to the use of any of the derogations, the competent authority of the Member State of destination shall:

(a) inform the Commission and the other Member States that such movements are authorised; and

(b) accept the animals regardless of the Member State or area thereof of their origin’;

3. Article 23, paragraph 1 is amended as follows:

(a) the following is added after point (g)(ii) sub-point 2:

‘3. the animals have been vaccinated against all serotypes of infection with epizootic haemorrhagic disease virus reported during the past 2 years in an area of at least 150 km radius around the establishment of origin, the animals are within the immunity period guaranteed in the specifications of the vaccine and meet at least one of the following requirements:

* they have been vaccinated more than 60 days before the date of movement;
* they have been vaccinated with an inactivated vaccine and subject to a PCR test, with negative results on samples collected at least 14 days after the onset of the immunity set in the specifications of the vaccine’;

(b) last subparagraph of paragraph 1 is replaced by the following:

‘By way of derogation from point (g)(ii), the competent authority of the Member State of origin may authorise the following movements to another Member State or area thereof:

(a) movements which do not meet one of the requirements laid down in that point; or

(b) movements that comply with specific animal health requirements defined by the competent authority of the Member State of destination.

Prior to the use of any of the derogations, the competent authority of the Member State of destination shall:

(a) inform the Commission and the other Member States that such movements are authorised; and

(b) accept the animals regardless of the Member State or area thereof of their origin’.

4. Article 26, paragraph 1 is amended as follows:

(a) the following is added after point (g)(ii) sub-point 2:

‘3. the animals have been vaccinated against all serotypes of infection with epizootic haemorrhagic disease virus reported during the past 2 years in an area of at least 150 km radius around the establishment of origin, the animals are within the immunity period guaranteed in the specifications of the vaccine and meet at least one of the following requirements:

* they have been vaccinated more than 60 days before the date of movement;
* they have been vaccinated with an inactivated vaccine and subject to a PCR test, with negative results on samples collected at least 14 days after the onset of the immunity set in the specifications of the vaccine’;

(b) last subparagraph of paragraph1 is replaced by the following:

‘By way of derogation from point (g)(ii), the competent authority of the Member State of origin may authorise the following movements to another Member State or area thereof:

(a) movements which do not meet one of the requirements laid down in that point; or

(b) movements that comply with specific animal health requirements defined by the competent authority of the Member State of destination.

Prior to the use of any of the derogations, the competent authority of the Member State of destination shall:

(a) inform the Commission and the other Member States that such movements are authorised; and

(b) accept the animals regardless of the Member State or area thereof of their origin’.

5. Article 29, paragraph 1 is amended as follows:

(a) the following is added after point (f)(ii) sub-point 2:

‘3. the animals have been vaccinated against all serotypes of infection with epizootic haemorrhagic disease virus reported during the past 2 years in an area of at least 150 km radius around the establishment of origin, the animals are within the immunity period guaranteed in the specifications of the vaccine and meet at least one of the following requirements:

* they have been vaccinated more than 60 days before the date of movement;
* they have been vaccinated with an inactivated vaccine and subject to a PCR test, with negative results on samples collected at least 14 days after the onset of the immunity set in the specifications of the vaccine’;

(b) last subparagraph of paragraph 1 is replaced by the following:

‘By way of derogation from point (f)(ii), the competent authority of the Member State of origin may authorise the following movements to another Member State or area thereof:

(a) movements which do not meet one of the requirements laid down in that point; or

(b) movements that comply with specific animal health requirements defined by the competent authority of the Member State of destination.

Prior to the use of any of the derogations, the competent authority of the Member State of destination shall:

(a) inform the Commission and the other Member States that such movements are authorised; and

(b) accept the animals regardless of the Member State or area thereof of their origin’.

Article 2

Entry into force

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,

 For the Commission

 The President

 Ursula VON DER LEYEN

1. OJ L 84, 31.3.2016, p. 1, ELI: <http://data.europa.eu/eli/reg/2016/429/oj>. [↑](#footnote-ref-2)
2. Commission Delegated Regulation (EU) 2020/688 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs (OJ L 174, 3.6.2020, p. 140), ELI: <https://eur-lex.europa.eu/eli/reg_del/2020/688/oj>. [↑](#footnote-ref-3)
3. Commission Delegated Regulation (EU) 2023/2515 of 8 September 2023 amending Delegated Regulation (EU) 2020/688 as regards certain animal health requirements for movements within the Union of terrestrial animals, ELI: <https://eur-lex.europa.eu/eli/reg_del/2023/2515/oj>. [↑](#footnote-ref-4)
4. OJ L 84, 31.3.2016, p. 1, ELI: <http://data.europa.eu/eli/reg/2016/429/oj>. [↑](#footnote-ref-5)
5. Commission Delegated Regulation (EU) 2020/688 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs (OJ L 174, 3.6.2020, p. 140), ELI: <https://eur-lex.europa.eu/eli/reg_del/2020/688/oj>. [↑](#footnote-ref-6)
6. 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), ELI: <https://eur-lex.europa.eu/eli/reg_impl/2018/1882/oj>. [↑](#footnote-ref-7)
7. Commission Delegated Regulation (EU) 2023/2515 of 8 September 2023 amending Delegated Regulation (EU) 2020/688 as regards certain animal health requirements for movements within the Union of terrestrial animals , ELI: <https://eur-lex.europa.eu/eli/reg_del/2023/2515/oj>. [↑](#footnote-ref-8)