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Delegations will find attached document C(2023) 7658 final.

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EUROPEAN
COMMISSION

Brussels, 21.11.2023
C(2023) 7658 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 21.11.2023

amending Annex IV to Regulation (EU) No 576/2013 of the European Parliament and of the Council as regards the validity requirements for the rabies antibody titration tests for dogs, cats and ferrets

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Regulation (EU) No 576/2013 of the European Parliament and of the Council[1] provides for the compulsory anti-rabies vaccination of the pet animals listed in Part A of Annex I thereto, namely dogs, cats and ferrets, subject to non-commercial movements into a Member State from territories or third countries. More specifically, it provides that dogs, cats and ferrets are not to be moved into a Member State unless they have received an anti-rabies vaccination and undergone a rabies antibody titration test that comply with the requirements laid down in that Regulation (Article 10). In addition, Regulation (EU) No 576/2013 provides that the Commission is to adopt a list of territories or third countries from which dogs, cats or ferrets moved for non-commercial purposes into a Member State are not required to undergo a rabies antibody titration test. That list is set out in Annex II to Commission Implementing Regulation (EU) No 577/2013[2].

Regulation (EU) No 576/2013 provides for a system of checks on the effectiveness of the anti-rabies vaccination of those pet animals by a rabies antibody titration test when those pet animals come from certain territories or third countries that are not listed in Annex II to Implementing Regulation (EU) No 577/2013.

In addition, Regulation (EU) No 576/2013 provides that the rabies antibody titration test must be performed in a laboratory approved in accordance with Article 3 of Council Decision 2000/258/EC[3]. However, Decision 2000/258/EC has now been repealed by Regulation (EU) 2016/429 of the European Parliament and of the Council[4], and therefore that system for the approval of laboratories is no longer in force. It is necessary to determine which laboratory is to perform the rabies antibody titration test required for the non-commercial movement of dogs, cats and ferrets.

The rules applicable to the entry into the Union of consignments of dogs, cats and ferrets are laid down in Commission Delegated Regulation (EU) 2020/692[5]. That Delegated Regulation provides for a system whereby those consignments are only permitted to enter the Union if, amongst other requirements, the animals come from third countries or territories listed in implementing acts pursuant to Article 230(1) of Regulation (EU) 2016/429, namely in Annex VIII to Commission Implementing Regulation (EU) 2021/404[6], as referred to in Article 3 of

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1 Regulation (EU) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003 (OJ L 178, 28.6.2013, p. 1).

2 Commission Implementing Regulation (EU) No 577/2013 of 28 June 2013 on the model identification documents for the non-commercial movement of dogs, cats and ferrets, the establishment of lists of territories and third countries and the format, layout and language requirements of the declarations attesting compliance with certain conditions provided for in Regulation (EU) No 576/2013 of the European Parliament and of the Council (OJ L 178, 28.6.2013, p. 109).

3 Council Decision 2000/258/EC of 20 March 2000 designating a specific institute responsible for establishing the criteria necessary for standardising the serological tests to monitor the effectiveness of rabies vaccines (OJ L 79, 30.3.2000, p. 4).

4 Regulation (EU) 2016/429[4] 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).

5 Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (OJ L 174, 3.6.2020, p. 379).

6 Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products

that Implementing Regulation; and the animals have undergone a valid rabies antibody titration test (Article 76), unless they come from a third country or territory that is listed in Annex II to Implementing Regulation (EU) No 577/2013.

The rabies antibody titration test, when required by Delegated Regulation (EU) 2020/692, should be carried out in:

- an official laboratory in a Member State designated for the performance of the rabies antibody titration test, in accordance with Article 37 of Regulation EU) 2017/625 of the European Parliament and of the Council[7],
- a laboratory in a third country listed in Annex VIII to Commission Implementing Regulation (EU) 2021/404 designated for the performance of the rabies antibody titration test, in accordance with Article 37 of Regulation (EU) 2017/625 as referred to in Article 9 of that Delegated Regulation.

Therefore, Delegated Regulation (EU) 2020/692 already determines the laboratories that can perform the rabies antibody titration test required for the entry into the Union of dogs, cats and ferrets.

In the interest of consistence of Union rules, the requirements to be complied with by the laboratory where the rabies antibody titration test is to be performed for non-commercial movements of pet animals into a Member State from a third country or territory should be consistent with those which are provided for in Delegated Regulation (EU) 2020/692 as regards the laboratories where the rabies antibody titration test can be performed, and which refer to Article 37 of Regulation (EU) 2017/625 of the European Parliament and of the Council.

Paragraphs 4 and 5 of Article 37 of Regulation (EU) 2017/625 of the European Parliament and of the Council lay down the eligibility requirements for a laboratory to be designated as an official laboratory in a Member State or a third country that is a Contracting Party to the Agreement on the European Economic Area. These eligibility requirements are to be complied with also by laboratories designated in a third country to ensure the same level of performance of rabies antibody titration test for non-commercial movements of pets originating from third counties.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission discussed the contents of this draft Delegated Regulation in a meeting of the Expert Group on Animal Health (E00930) that took place on 3 February 2022.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

This Delegated Regulation is to be adopted within the framework of Regulation (EU) 576/2013, and in particular pursuant to Article 38 thereof.

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and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and the Council (OJ L 114, 31.3.2021, p. 1).

[7] 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).

COMMISSION DELEGATED REGULATION (EU) …/...

of 21.11.2023

amending Annex IV to Regulation (EU) No 576/2013 of the European Parliament and of the Council as regards the validity requirements for the rabies antibody titration tests for dogs, cats and ferrets

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003[1], and in particular Article 38 thereof,

Whereas:

(1) Regulation (EU) No 576/2013 lays down, inter alia, the animal health requirements applicable to non-commercial movements of pet animals into a Member State from a territory or a third country, and the rules for compliance checks on such non-commercial movements. Regulation (EU) No 576/2013 has been repealed by Regulation (EU) 2016/429 of the European Parliament and of the Council[2] but, as a transitional measure, it continues to apply until 21 April 2026 in respect of non–commercial movements of pet animals, in place of Part VI of Regulation (EU) 2016/429.

(2) Regulation (EU) No 576/2013 provides for the compulsory anti-rabies vaccination of certain pet animals, namely dogs, cats and ferrets, subject to non-commercial movements into a Member State from territories or third countries. More specifically, it provides that dogs, cats and ferrets are not to be moved into a Member State unless they have received an anti-rabies vaccination and have undergone a rabies antibody titration test that both comply with the requirements laid down in that Regulation. In addition, Regulation (EU) No 576/2013 provides that the Commission is to adopt a list of territories or third countries from which dogs, cats or ferrets moved for non-commercial purposes into a Member State are not required to undergo a rabies antibody titration test. That list is duly set out in Annex II to Commission Implementing Regulation (EU) No 577/2013[3].

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1 OJ L 178, 28.6.2013, p. 1.

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) No 577/2013 of 28 June 2013 on the model identification documents for the non-commercial movement of dogs, cats and ferrets, the establishment of lists of territories and third countries and the format, layout and language requirements of the declarations attesting compliance with certain conditions provided for in Regulation (EU) No 576/2013 of the European Parliament and of the Council (OJ L 178, 28.6.2013, p. 109).

(3) Moreover, when a rabies antibody titration test is compulsory, it must comply with the validity requirements set out in Annex IV to Regulation (EU) No 576/2013. That Annex lays down the validity requirements for the rabies antibody titration test and it establishes that, for the purposes of the non-commercial movement of pet animals from third countries or territories, the rabies antibody titration test must be performed in a laboratory approved in accordance with Article 3 of Council Decision 2000/258/EC[4]. However, that Decision has been repealed by Regulation (EU) 2016/429. It is therefore necessary to determine which laboratory is to perform the rabies antibody titration test required for the non-commercial movement of dogs, cats and ferrets.

(4) Commission Delegated Regulation (EU) 2020/692[5] lays down supplementing animal health rules concerning the entry into the Union of consignments of certain species and categories of animals. It therefore applies to commercial movements of those species and categories of animals. It results from Article 3 of that Delegated Regulation that consignments of dogs, cats and ferrets are only permitted to enter the Union if the third country or territory of origin of the consignment, or zone or compartment thereof, is listed in Annex VIII to Implementing Regulation (EU) 2021/404. Article 9 of Delegated Regulation (EU) 2020/692 provides that consignments of dogs, cats and ferrets are only permitted to enter the Union if the laboratory tests required by that Delegated Regulation have been carried out in an official laboratory designated in accordance with Article 37 of Regulation (EU) 2017/625 of the European Parliament and of the Council[6]. Article 76 of Delegated Regulation (EU) 2020/692 requires a valid rabies antibody titration test for consignments of dogs, cats and ferrets that are entering the Union from third countries or territories, unless they are listed in Annex II to Implementing Regulation (EU) No 577/2013. Therefore, Delegated Regulation (EU) 2020/692 already determines the laboratories that can perform the rabies antibody titration test required for the entry into the Union of dogs, cats and ferrets.

(5) Accordingly, in the interest of consistency of Union rules, the requirements to be complied with by the laboratory where the rabies antibody titration test is to be performed for non-commercial movements of pet animals into a Member State from a third country or territory should be consistent with the requirements laid down in Delegated Regulation (EU) 2020/692 as regards the laboratories where the rabies

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4 Council Decision 2000/258/EC of 20 March 2000 designating a specific institute responsible for establishing the criteria necessary for standardising the serological tests to monitor the effectiveness of rabies vaccines (OJ L 79, 30.3.2000, p. 40).

5 Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (OJ L 174, 3.6.2020, p. 379).

6 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).

antibody titration test can be performed, and which refer to Article 37 of Regulation (EU) 2017/625.

(6) Article 37(4) and (5) of Regulation (EU) 2017/625 lays down the eligibility requirements for a laboratory to be designated as an official laboratory in a Member State or a third country that is a Contracting Party to the Agreement on the European Economic Area. These eligibility requirements are to be complied with also by laboratories designated in a third country to ensure the same level of performance of rabies antibody titration test for non-commercial movements of pets originating from third counties.

(7) Therefore, Regulation (EU) No 576/2013 should be amended as regards the laboratories that may perform valid rabies antibody titration tests for the purposes of non-commercial movements of dogs, cats and ferrets into a Member State,

HAS ADOPTED THIS REGULATION:

Article 1

Annex IV to Regulation (EU) No 576/2013 is amended in accordance with the Annex to this Regulation.

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*.

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

Done at Brussels, 21.11.2023

For the Commission
The President
Ursula VON DER LEYEN