

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Regulation (EU) No 576/2013 [[1]](#footnote-1)provides for the compulsory anti-rabies vaccination of pets subject to non-commercial movements into a Member State from territories or third countries.

It also provides for a system of checks on the effectiveness of the anti-rabies vaccination of those animals by a rabies antibody titration test when they are sourced from certain territories or third countries that are not listed in Annex II to Commission Implementing Regulation (EU) No 577/2013[[2]](#footnote-2).

The rabies antibody titration test must be performed in a laboratory approved in accordance with Article 3 of Council Decision 2000/258/EC. Decision 2000/258/EC has been repealed by Regulation (EU) 2016/429[[3]](#footnote-3) and therefore the system to approve laboratories is no longer operational.

This system of checks on the effectiveness of the anti-rabies vaccination was mirrored for the imports into the EU of dogs, cats and ferrets as provided for by the already repealed Council Directive 92/65/EEC[[4]](#footnote-4).

The rules in force applicable to the entry into the Union of dogs, cats and ferrets are laid down in Commission Delegated Regulation (EU) 2020/692[[5]](#footnote-5). It provides for a system whereby consignments of dogs, cats and ferrets are only permitted to enter the Union, amongst other requirements if:

* The animals are sourced from territories or third countries listed in Annex VIII to Commission Implementing Regulation (EU) 2021/404[[6]](#footnote-6); and
* the rabies antibody titration test, when required by Delegated Regulation (EU) 2020/692 has been carried out in a laboratory designated in accordance with Article 37 of Regulation (EU) 2017/625[[7]](#footnote-7) in a listed territory or third country. However, it should also be possible that the test is performed in an official laboratory in a Member State.

As the rabies antibody titration test can be performed in the two types of laboratories mentioned above for the purposes of the entry into the Union, it should also be possible that it is performed in one of these laboratories for the purposes of non-commercial movements of pets into a Member State from territories or third countries.

However, non-commercial movements of pets into a Member State sourced from third countries or territories not listed in Annex VIII to Commission Implementing Regulation (EU) 2021/404 are possible. Those non-commercial movements are subject to rabies antibody titration test. If the test is to be performed in a laboratory placed in a non-listed third country or territory, it is still necessary to design a system replacing and updating the one laid down by the repealed Decision 2000/258/EC to list these laboratories.

For this purpose, this Delegated Regulation establishes a new system to list laboratories that can perform the rabies antibody titration tests and designates the EURL for rabies as responsible for coordinating of the proficiency tests needed for the listing of laboratories in respect of rabies antibody titration tests.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The draft Delegated Regulation was presented to the members of the Expert Group on Animal Health (E00930) on 3 February 2022.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

This Delegated Regulation is to be adopted within the framework of Regulation (EU) 2017/625 and in particular pursuant to Article 99(2) thereof.

COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

(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)[[8]](#footnote-8) and in particular Article 99(2) thereof,

Whereas:

1. Regulation (EU) 2017/625 lays down, inter alia, rules for the designation, responsabilities and tasks of European Union reference laboratories. It provides for delegated acts to be adopted in certain cases in order to lay down rules supplementing the requirements, responsabilities and tasks of the European Union reference laboratories.
2. Commission Delegated Regulation (EU) 2020/692[[9]](#footnote-9) lays down supplementing animal health rules concerning the entry into the Union of consignments of certain species and categories of animals. Article 9 provides, inter alia, for a system whereby 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 a laboratory designated in accordance with Article 37 of Regulation (EU) 2017/625 in a third country or territory. However, it is also possible that the laboratory tests have been carried out in an official laboratory in a Member State. Article 76 requires a valid rabies antibody titration test for consignments of dogs, cats and ferrets that are being moved into a Member State from territories or third countries that are not listed in Annex II to Implementing Regulation (EU) No 577/2013[[10]](#footnote-10).
3. Commission Implementing Regulation (EU) 2021/404[[11]](#footnote-11) lays down the lists of third countries, territories or zones or compartments thereof from which the entry into the Union of consignments of the species and categories of animals falling within the scope of Delegated Regulation (EU) 2020/692 is permitted. Consignments of dogs, cats and ferrets are only permitted to enter into the Union from third countries or territories listed in Annex VIII to that Implementing Regulation. When required by Delegated Regulation (EU) 2020/692, the rabies antibody titration test may be performed either in a laboratory designated in accordance with Article 37 of Regulation (EU) 2017/625 by the competent authority of the third country or territory listed in Annex VIII to Implementing Regulation (EU) 2021/404, or in an official laboratory in a Member State.
4. Regulation (EU) No 576/2013[[12]](#footnote-12) lays down 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. The definition of pet animal in that Regulation covers dogs, cats and ferrets. Regulation (EU) No 576/2013 has now been repealed by Regulation (EU) 2016/429 of the European Parliament and of the Council[[13]](#footnote-13) 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.
5. In addition, Regulation (EU) No 576/2013 provides for the compulsory anti-rabies vaccination of certain pet animals subject to non-commercial movements into a Member State from territories or third countries. It also 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 they are sourced from certain territories or third countries that are not listed in Annex II to Commission Implementing Regulation (EU) No 577/2013.
6. Annex IV to Regulation (EU) No 576/2013 lays down 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[[14]](#footnote-14). Decision 2000/258/EC has now been repealed by Regulation (EU) 2016/429.
7. As for the purposes of entry into the Union of dogs, cats and ferrets into a Member State from a territory or third country listed in Annex II to Implementing Regulation (EU) 577/2013 or in Annex VIII to Implementing Regulation 2021/404, the rabies antibody titration test can be performed in a laboratory designated in accordance with Article 37 of Regulation (EU) 2017/625 by a competent authority of that territory or third country or in an official laboratory in a Member State, for reasons of consistency it should also be possible to allow the performance of the rabies antibody titration test required for non-commercial movements of pet animals in those laboratories.
8. However, the non-commercial movements of pet animals into a Member State from third countries or territories nor listed in Annex II to Implementing Regulation (EU) 577/2013 neither in Annex VIII to Implementing Regulation (EU) 2021/404 is possible and they are subject to the rabies antibody titration test that may be performed in a laboratory located in one of these third countries or territories. These laboratories should demonstrate their capacity to perform the rabies antibody titration test. Therefore, a listing procedure of those laboratories that replaces and updates the one laid down by the repealed Decision 2000/258/EC should be set up.
9. The listing procedure should be based on the participation with favourable results of the laboratory in a proficiency test organised by a laboratory designated by the Commission.
10. Commission Regulation (EC) No 737/2008[[15]](#footnote-15) designated the ANSES Laboratoire d’études sur la rage et la pathologie des animaux sauvages in Nancy, France as the EU reference laboratory for rabies. The repealed Decision 2000/258/EC designated that laboratory as the specific institute responsible for establishing the criteria necessary for standardising the serological tests to monitor the effectiveness of rabies vaccines. One of the tasks of that institute was to organise a proficiency test and appraise the results of the laboratories for their possible approval for the purposes of their authorisation to carry out the serological tests to monitor the effectiveness of the anti-rabies vaccination.
11. Considering the experience that the Laboratoire d’études sur la rage et la pathologie des animaux sauvages in Nancy has obtained since it was designated by Decision 2000/258/EC and due to the new legal requirements introduced by Delegated Regulation (EU) 2020/692, it is appropriate to designate it as the laboratory responsible for the organisation and coordination of the proficiency test and the appraisal of the laboratories for the purposes of their listing to carry out the serological tests to monitor the effectiveness of the anti-rabies vaccination.
12. Upon arrival in the Union, the validity of a rabies antibody titration test must be easily verifiable to detect non-compliance with the validity of the rabies antibody titration test. For this purpose, the contact details of the official laboratories in member states and designated or listed laboratories in third countries or territories performing the test should be made publicly available by the Commission,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

This Regulation lays down rules on:

(a) the listing of laboratories in third countries or territories not listed in Annex VIII to Implementing Regulation (EU) 2021/404 for the purposes of carrying out a rabies antibody titration test for the non-commercial movement of dogs, cats and ferrets into a Member State from a third country or territory;

(b) the proficiency test whereby laboratories in third countries or territories not listed in Annex VIII to Implementing Regulation (EU) 2021/404 participate and obtain a favourable result to qualify for listing;

(c) the requirements for the listed laboratories in third countries or territories, not listed in Annex VIII to Implementing Regulation (EU) 2021/404 to remain on the list;

(d) designating an EU laboratory for the proficiency testing, and its tasks and responsibilities;

(e) the obligation of the competent authority of the laboratories performing rabies antibody titration tests to submit the contact details of those laboratories to the Commission.

Article 2

Listing of laboratories in third countries or territories not listed in Annex VIII to Implementing Regulation (EU) 2021/404

1. The Commission may list laboratories in third countries or territories not listed in Annex VIII to Implementing Regulation (EU) 2021/404 for the purpose of carrying out a rabies antibody titration test for the non-commercial movement of dogs, cats and ferrets into a Member State from a third country or territory subject to compliance with the following conditions:

(a) the laboratory participates in the proficiency test provided for in Article 3 and obtains a favourable result;

(b) the competent authority of the third country or territory responsible for the laboratory submits to the Commission an application for listing the laboratory containing at least the name of the laboratory, the name of the responsible of the laboratory, and the address, telephone number and e-mail.

2. Laboratories listed in accordance with paragraph 1 of this Article shall only remain on the list if they participate in the proficiency test provided for in Article 3 with a favourable result every two years following the date of their initial listing or subsequent prolongation.

Article 3

Proficiency test

1. The proficiency test for the laboratories applying for the listing referred to in Article 2(1) shall be carried out by the EU laboratory listed in Annex I.

2. The first proficiency test shall take place in 2022 and it shall be repeated every two years from the date of the previous test.

3. Following each proficiency test, the EU laboratory listed in Annex I shall submit an appraisal report, at the latest by 31 October of the same year, to:

(a) the corresponding laboratory which underwent the proficiency test;

(b) the Commission.

4. By way of derogation from the deadline referred to in paragraph 3, an unfavourable report shall be submitted within a period of 30 days following the date of the appraisal.

Article 4

Tasks and responsibilities of the laboratory listed in Annex I

The tasks and responsibilities of the EU laboratory referred to in Article 3(1) are laid down in Annex II.

Article 5

Publicly available information in the Commission website

1. The competent authority responsible for the laboratory shall send the Commission the information provided for in Article 2(1), point (b), of the following laboratories that may perform a valid rabies antibody titration test:

(a) official laboratories in a Member State;

(b) laboratories in third countries or territories designated in accordance with Article 37 of Regulation (EU) 2017/625;

(c) laboratories in a third country or territory listed in accordance with Article 2.

2. The Commission shall make the contact details of the laboratories referred to in paragraph 1 publicly available on the Commission’s website.

Article 6

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. 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). [↑](#footnote-ref-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). [↑](#footnote-ref-2)
3. 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). [↑](#footnote-ref-3)
4. Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC (OJ L 268, 14.9.1992, p. 54). [↑](#footnote-ref-4)
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). [↑](#footnote-ref-5)
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 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). [↑](#footnote-ref-6)
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). [↑](#footnote-ref-7)
8. OJ L 95, 7.4.2017, p. 1. [↑](#footnote-ref-8)
9. 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). [↑](#footnote-ref-9)
10. 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). [↑](#footnote-ref-10)
11. 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 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). [↑](#footnote-ref-11)
12. [↑](#footnote-ref-12)
13. 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). [↑](#footnote-ref-13)
14. 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). [↑](#footnote-ref-14)
15. [↑](#footnote-ref-15)