

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 Decision 2000/258/EC has been repealed by Regulation (EU) 2016/429[[3]](#footnote-3) and therefore the system to approve laboratories is no longer operational.

Draft Delegated Regulation[[4]](#footnote-4) SANTE 7274/2021 updates the provisions laid down in Decision 2000/258/EC laying down new rules as regards the laboratory where the test can be performed.

Therefore, Regulation (EU) No 576/2013 should be amended in line with the provisons of Draft Delegated Regulation[[5]](#footnote-5) SANTE 7274/2021.

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) 576/2013, and in particular pursuant to Article 38 thereof.

COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

**amending Regulation (EU) No 576/2013 of the European Parliament and of the Council of as regards the validity requirements for the rabies antibody titration tests**

**(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[[6]](#footnote-6) and in particular Article 38 thereof,

Whereas:

1. Regulation (EU) No 576/2013 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. Regulation (EU) No 576/2013 has now been repealed by Regulation (EU) 2016/429 of the European Parliament and of the Council[[7]](#footnote-7) but, as a transitional measure, it continues to apply until 21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. 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[[8]](#footnote-8).
3. 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[[9]](#footnote-9). Decision 2000/258/EC has now been repealed by Regulation (EU) 2016/429.
4. The provisions of Council Decision 2000/258/EC are updated by those provided for in Draft Delegated Regulation[[10]](#footnote-10) SANTE 7274/2021 whereby the rabies antibody titration test may be performed in different types of laboratories.
5. Therefore, Annex IV to Regulation (EU) No 576/2013 should be amended accordingly.

HAS ADOPTED THIS REGULATION:

Article 1

Amendment to Annex IV of Regulation (EU) 576/2013

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,

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. Draft Delegated Regulation (SANTE 7274/2021) supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards the designation of an EU laboratory to organise the proficiency testing for carrying out rabies antibody titration tests for the purposes of non-commercial movements of pet animals from third countries and territories and setting up a system to list laboratories that can perform these tests [↑](#footnote-ref-4)
5. Draft Delegated Regulation (SANTE 7274/2021) supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards the designation of an EU laboratory to organise the proficiency testing for carrying out rabies antibody titration tests for the purposes of non-commercial movements of pet animals from third countries and territories and setting up a system to list laboratories that can perform these tests [↑](#footnote-ref-5)
6. [↑](#footnote-ref-6)
7. 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-7)
8. 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-8)
9. 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-9)
10. Draft Delegated Regulation (SANTE 7274/2021) supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards the designation of an EU laboratory to organise the proficiency testing for carrying out rabies antibody titration tests for the purposes of non-commercial movements of pet animals from third countries and territories and setting up a system to list laboratories that can perform these tests [↑](#footnote-ref-10)