
Changes to legislation: *There are outstanding changes not yet made to Regulation (EU) No 576/2013 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

ANNEX III

Validity requirements for anti-rabies vaccinations

1. The anti-rabies vaccine must:
 - (a) be a vaccine other than a live modified vaccine and fall within one of the following categories:
 - (i) an inactivated vaccine of at least one antigenic unit per dose (recommendation from the World Health Organisation); or
 - (ii) a recombinant vaccine expressing the immunising glycoprotein of the rabies virus in a live virus vector;
 - (b) where it is administered in a Member State, it must have been granted a marketing authorisation in accordance with:
 - (i) Article 5 of Directive 2001/82/EC; or
 - (ii) Article 3 of Regulation (EC) No 726/2004;
 - (c) where it is administered in a territory or a third country, have been granted an approval or a licence by the competent authority and meet at least the requirements laid down in the relevant part of the Chapter concerning rabies in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health.

Changes to legislation:

There are outstanding changes not yet made to Regulation (EU) No 576/2013 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.

View outstanding changes

Changes and effects yet to be applied to :

- Regulation repeal by [EUR 2016/429](#) Regulation

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by [S.I. 2019/795 reg. 43\(46\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Signature words omitted by [S.I. 2020/1388 reg. 15\(27\)](#)
- Annex 3 para. 1(d) inserted by [S.I. 2019/795 reg. 43\(47\)\(a\)\(iii\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Annex 3 para. 1(d) inserted by [S.I. 2020/1388 reg. 15\(28\)\(a\)\(iii\)](#)
- Annex 3 para. 1(b)(ii) words inserted by [S.I. 2019/795 reg. 43\(47\)\(a\)\(i\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Annex 3 para. 1(c) words inserted by [S.I. 2019/795 reg. 43\(47\)\(a\)\(ii\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Annex 3 para. 2(e) words inserted by [S.I. 2019/795 reg. 43\(47\)\(b\)\(i\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Annex 3 para. 1(b)(i) words inserted by [S.I. 2020/1388 reg. 15\(28\)\(a\)\(i\)\(bb\)](#)
- Annex 3 para. 1(b)(ii) words inserted by [S.I. 2020/1388 reg. 15\(28\)\(a\)\(i\)\(cc\)](#)
- Annex 3 para. 2(e) words inserted by [S.I. 2020/1388 reg. 15\(28\)\(b\)\(i\)](#)
- Annex 3 para. 2(e) words omitted by [S.I. 2019/795 reg. 43\(47\)\(b\)\(ii\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Annex 3 para. 1(b) words substituted by [S.I. 2020/1388 reg. 15\(28\)\(a\)\(i\)\(aa\)](#)
- Annex 3 para. 1(c) words substituted by [S.I. 2020/1388 reg. 15\(28\)\(a\)\(ii\)](#)
- Annex 3 para. 2(e) words substituted by [S.I. 2020/1388 reg. 15\(28\)\(b\)\(ii\)](#)
- Annex 4 para. 2(a)(i) words inserted by [S.I. 2019/795 reg. 43\(48\)\(a\)\(i\)\(aa\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Annex 4 para. 2(a)(ii) words inserted by [S.I. 2019/795 reg. 43\(48\)\(a\)\(ii\)\(bb\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Annex 4 para. 2(a)(ii) words inserted by [S.I. 2019/795 reg. 43\(48\)\(a\)\(ii\)\(cc\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Annex 4 para. 2(b) words inserted by [S.I. 2019/795 reg. 43\(48\)\(b\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Annex 4 para. 2(c) words inserted by [S.I. 2020/1388 reg. 15\(29\)\(b\)](#)
- Annex 4 para. 2(a)(i) words omitted by [S.I. 2020/1388 reg. 15\(29\)\(a\)\(i\)\(aa\)](#)
- Annex 4 para. 2(a)(i) words omitted by [S.I. 2020/1388 reg. 15\(29\)\(a\)\(ii\)](#)
- Annex 4 para. 2(a)(ii) words omitted by [S.I. 2020/1388 reg. 15\(29\)\(a\)\(iii\)\(bb\)](#)

- Annex 4 para. 2(a)(i) words substituted by [S.I. 2019/795 reg. 43\(48\)\(a\)\(i\)\(bb\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Annex 4 para. 2(a)(ii) words substituted by [S.I. 2019/795 reg. 43\(48\)\(a\)\(ii\)\(aa\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Annex 4 para. 2(a)(i) words substituted by [S.I. 2020/1388 reg. 15\(29\)\(a\)\(i\)\(bb\)](#)
- Annex 4 para. 2(a)(ii) words substituted by [S.I. 2020/1388 reg. 15\(29\)\(a\)\(iii\)\(aa\)](#)
- Annex 4 para. 2(a)(ii) words substituted by [S.I. 2020/1388 reg. 15\(29\)\(a\)\(iii\)\(cc\)](#)
- Annex 4 para. 2(a)(ii) words substituted by [S.I. 2020/1388 reg. 15\(29\)\(a\)\(iii\)\(dd\)](#)
- Annex 4(2)(b) words inserted by [S.S.I. 2022/131 reg. 2\(a\)](#)
- Annex 4(2)(b) words inserted (temp.) by [S.I. 2022/445 reg. 2\(2\)\(a\)](#)
- Annex 4(2A) inserted by [S.S.I. 2022/131 reg. 2\(b\)](#)
- Annex 4(2A) inserted (temp.) by [S.I. 2022/445 reg. 2\(2\)\(b\)](#)
- Art. 2(2)(b) words substituted by [S.I. 2019/795 reg. 43\(2\)\(b\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 2(2)(b) words substituted by [S.I. 2020/1388 reg. 15\(2\)\(b\)](#)
- Art. 3(f) word substituted in earlier amending provision S.I. 2019/795, reg. 43(3)(a) by [S.I. 2019/813 reg. 5\(8\)\(a\)](#) (This amendment not applied to legislation.gov.uk. Reg. 5 omitted (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(a), 37)
- Art. 3(f) words substituted by [S.I. 2019/795 reg. 43\(3\)\(a\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 3(f) words substituted by [S.I. 2020/1388 reg. 15\(3\)\(a\)](#)
- Art. 3(g) words substituted by [S.I. 2019/795 reg. 43\(3\)\(b\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 3(g) words substituted by [S.I. 2020/1388 reg. 15\(3\)\(b\)](#)
- Art. 3(k) words substituted by [S.I. 2019/795 reg. 43\(3\)\(c\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 3(k) words substituted by [S.I. 2020/1388 reg. 15\(3\)\(c\)](#)
- Art. 3(l)-(p) inserted by [S.I. 2019/795 reg. 43\(3\)\(d\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 3(l)-(r) inserted by [S.I. 2020/1388 reg. 15\(3\)\(d\)](#)
- Art. 3(p) words substituted by [S.I. 2021/1229 reg. 5](#)
- Art. 3A inserted by [S.I. 2019/795 reg. 43\(4\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 3A inserted by [S.I. 2020/1388 reg. 15\(4\)](#)
- Art. 6(c) words inserted by [S.I. 2019/795 reg. 43\(7\)\(b\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 9(2)(a) words substituted by [S.I. 2019/795 reg. 43\(10\)\(b\)\(ii\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 9(2)(b) words substituted by [S.I. 2019/795 reg. 43\(10\)\(b\)\(ii\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 10(1)(d) words substituted by [S.I. 2019/795 reg. 43\(12\)\(a\)\(ii\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 10(1)(d) words substituted by [S.I. 2020/1388 reg. 15\(7\)\(a\)\(ii\)](#)
- Art. 10(3)(a) words substituted by [S.I. 2019/795 reg. 43\(12\)\(c\)\(ii\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))

- Art. 10(3)(a) words substituted by [S.I. 2020/1388 reg. 15\(7\)\(c\)\(ii\)](#)
- Art. 12(1)(b) words omitted by [S.I. 2020/1463 reg. 8\(4\)\(a\)\(ii\)](#)
- Art. 12(1)(c) words inserted by [S.I. 2019/795 reg. 43\(14\)\(a\)\(ii\)\(aa\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 12(1)(c) words inserted by [S.I. 2019/795 reg. 43\(14\)\(a\)\(ii\)\(bb\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 12(1)(c) words omitted by [S.I. 2020/1463 reg. 8\(4\)\(a\)\(iii\)\(aa\)](#)
- Art. 12(1)(c) words substituted by [S.I. 2020/1463 reg. 8\(4\)\(a\)\(iii\)\(bb\)](#)
- Art. 14(2)(a) words substituted by [S.I. 2019/795 reg. 43\(16\)\(b\)\(ii\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 14(2)(a) words substituted by [S.I. 2020/1388 reg. 15\(8\)\(b\)\(ii\)](#)
- Art. 14(2)(b) words substituted by [S.I. 2019/795 reg. 43\(16\)\(b\)\(ii\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 14(2)(b) words substituted by [S.I. 2020/1388 reg. 15\(8\)\(b\)\(iii\)](#)
- Art. 14(2)(d) words omitted by [S.I. 2020/1388 reg. 15\(8\)\(b\)\(iv\)](#)
- Art. 19(3)(a) omitted by [S.I. 2020/1463 reg. 8\(8\)\(c\)\(ii\)](#)
- Art. 19(3)(a) words substituted by [S.I. 2019/795 reg. 43\(21\)\(c\)\(ii\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 19(3)(b) omitted by [S.I. 2020/1463 reg. 8\(8\)\(c\)\(ii\)](#)
- Art. 19(3)(b) words substituted by [S.I. 2019/795 reg. 43\(21\)\(c\)\(iii\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 26a inserted by [S.I. 2020/1388 reg. 15\(13\)\(f\)](#)
- Art. 27(a) words inserted by [S.I. 2019/795 reg. 43\(30\)\(b\)\(i\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 27(a) words inserted by [S.I. 2019/795 reg. 43\(30\)\(b\)\(ii\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 27(b) words inserted by [S.I. 2019/795 reg. 43\(30\)\(c\)\(ii\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 27(b) words substituted by [S.I. 2019/795 reg. 43\(30\)\(c\)\(i\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 27(b) words substituted by [S.I. 2019/795 reg. 43\(30\)\(c\)\(iii\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 32(1)(a) words substituted by [S.I. 2019/795 reg. 43\(36\)\(a\)\(ii\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 32(1)(a) words substituted by [S.I. 2020/1388 reg. 15\(18\)\(b\)\(ii\)](#)
- Art. 34(4)(a) word inserted by [S.I. 2020/1388 reg. 15\(20\)\(e\)\(ii\)\(bb\)](#)
- Art. 34(4)(a) word substituted by [S.I. 2020/1388 reg. 15\(20\)\(e\)\(ii\)\(aa\)](#)
- Art. 34(4)(b) word substituted by [S.I. 2020/1388 reg. 15\(20\)\(e\)\(iii\)](#)
- Art. 34(4)(c) word substituted by [S.I. 2020/1388 reg. 15\(20\)\(e\)\(iv\)\(aa\)](#)
- Art. 34(4)(c) words omitted by [S.I. 2019/795 reg. 43\(38\)\(e\)\(ii\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 34(4)(c) words omitted by [S.I. 2020/1388 reg. 15\(20\)\(e\)\(iv\)\(bb\)](#)
- Art. 34(4)(c) words substituted by [S.I. 2020/1388 reg. 15\(20\)\(e\)\(iv\)\(cc\)](#)
- Art. 35(1)(b) words omitted by [S.I. 2020/1388 reg. 15\(21\)\(a\)\(ii\)](#)

- Art. 36(1)(a) words omitted by [S.I. 2019/795 reg. 43\(40\)\(a\)\(i\)\(bb\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 36(1)(a) words substituted by [S.I. 2020/1388 reg. 15\(22\)\(a\)\(i\)\(bb\)](#)
- Art. 36(1)(b) words omitted by [S.I. 2019/795 reg. 43\(40\)\(a\)\(i\)\(cc\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 36(1)(b) words omitted by [S.I. 2020/1388 reg. 15\(22\)\(a\)\(ii\)](#)
- Art. 36(1)(b) words substituted by [S.I. 2020/1388 reg. 15\(22\)\(a\)\(i\)\(cc\)](#)
- Art. 37(2)(a) omitted by [S.I. 2020/1388 reg. 15\(23\)\(b\)\(i\)](#)
- Art. 37(2)(a) words omitted by [S.I. 2019/795 reg. 43\(41\)\(b\)\(i\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 37(2)(b) word substituted by [S.I. 2020/1388 reg. 15\(23\)\(b\)\(ii\)](#)
- Art. 37(2)(c) words substituted by [S.I. 2019/795 reg. 43\(41\)\(b\)\(ii\)\(aa\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 37(2)(c) words substituted by [S.I. 2020/1388 reg. 15\(23\)\(b\)\(iii\)\(aa\)](#)
- Art. 37(2)(c)(i) word substituted by [S.I. 2020/1388 reg. 15\(23\)\(b\)\(iii\)\(bb\)](#)
- Art. 37(2)(c)(ii) omitted by [S.I. 2019/795 reg. 43\(41\)\(b\)\(ii\)\(bb\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 37(2)(c)(ii) omitted by [S.I. 2020/1388 reg. 15\(23\)\(b\)\(iii\)\(cc\)](#)
- Art. 37(2)(e) words omitted by [S.I. 2019/795 reg. 43\(41\)\(b\)\(iii\)\(cc\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 37(2)(e) words omitted by [S.I. 2020/1388 reg. 15\(23\)\(b\)\(iv\)\(cc\)](#)
- Art. 37(2)(e) words substituted by [S.I. 2019/795 reg. 43\(41\)\(b\)\(iii\)\(aa\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 37(2)(e) words substituted by [S.I. 2019/795 reg. 43\(41\)\(b\)\(iii\)\(bb\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 37(2)(e) words substituted by [S.I. 2020/1388 reg. 15\(23\)\(b\)\(iv\)\(aa\)](#)
- Art. 37(2)(e) words substituted by [S.I. 2020/1388 reg. 15\(23\)\(b\)\(iv\)\(bb\)](#)
- Art. 37(2)(f) words omitted by [S.I. 2019/795 reg. 43\(41\)\(b\)\(iv\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/795 revoked (31.12.2020) by virtue of S.I. 2020/1462, regs. 1(2)(b), 73(1))
- Art. 37(2)(f) words omitted by [S.I. 2020/1388 reg. 15\(23\)\(b\)\(v\)](#)
- Art. 44(2)(b) substituted by [S.I. 2020/1388 reg. 15\(26\)\(b\)\(ii\)](#)