

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.

2. An anti-rabies vaccination must fulfil the following conditions:

- (a) the vaccine was administered by an authorised veterinarian;
- (b) the pet animal was at least 12 weeks old at the date on which the vaccine was administered;
- (c) the date of administration of the vaccine is indicated by an authorised veterinarian or an official veterinarian in the appropriate section of the identification document;
- (d) the date of administration referred to in point (c) does not precede the date of application of the transponder or tattoo or the date of reading of the transponder or the tattoo indicated in the appropriate section of the identification document;
- (e) the period of validity of the vaccination starts from the establishment of protective immunity, which shall not be less than 21 days from the completion of the vaccination protocol required by the manufacturer for the primary vaccination, and continues until the end of the period of protective immunity, as prescribed in the technical specification of the marketing authorisation referred to in point 1(b) or the approval or licence referred to in point 1(c) for the anti-rabies vaccine in the Member State or territory or third country where the vaccine is administered.

The period of validity of the vaccination is indicated by an authorised veterinarian or an official veterinarian in the appropriate section of the identification document;

- (f) a revaccination must be considered a primary vaccination if it was not carried out within the period of validity referred to in point (e) of the previous vaccination.
