ANNEX 3

EU POSITION

ON THE DRAFT OIE *TERRESTRIAL MANUAL*

CHAPTER 2.1.17. ON RABIES

PROPOSED FOR ADOPTION IN MAY 2018

The EU cannot support the adoption of the draft OIE *Terrestrial Manual* Chapter 2.1.17. on rabies as circulated to member countries on 23 March 2018.

Indeed, whereas Chapter 2.1.17. has been thoroughly revised by an OIE *ad hoc* group in May 2017 which has updated and improved the entire chapter in many aspects, and though many comments the EU had submitted to the OIE in December 2017 on the version of the draft revised chapter that was circulated in October 2017 have been taken into account by the OIE, the March 2018 version of that draft chapter includes numerous additional changes, some of which could have significant negative consequences for rabies surveillance and for the international movement of dogs and cats.

In fact, the present version of the draft chapter on rabies contains new elements which are scientifically and technically not robust in the view of the EU. These relate mainly to Part B of the chapter ("Diagnostic techniques").

As many of these elements have only been introduced in the March 2018 version of the draft chapter, it is unclear to what extent they have thoroughly been discussed among the experts of the OIE Reference Laboratories for Rabies and whether there was a consensus among those experts as to their inclusion in the OIE *Terrestrial Manual*. Furthermore, the February 2018 meeting report of the Biological Standards Commission curiously does not mention these significant changes at all; the changes to the draft chapter mentioned in the relevant section of Annex 3 to the report pertain to changes on other issues.

Our main concern relates to the diagnostic methods recommended in the draft chapter for rabies surveillance and for pre-movement testing of individual animals.

In Table 1 of Part B of the draft chapter, which summarises the different test methods available for rabies diagnosis and their purpose, two tests have been added in the March 2018 draft version of the chapter, namely the ELISA and the RIAD antigen detection tests. While the former's description had

previously been included in Chapter 2.1.17., the latter's description was newly added in the March 2018 draft revised version. We understand that the RIAD antigen detection test has not followed the usual procedure for inclusion in the *Terrestrial Manual*, i.e. it has not been formally submitted to the OIE for consideration by the Biological Standard Commission. Furthermore, we understand there was no consensus among the experts of the OIE Reference Laboratories for Rabies as to the inclusion of that test in the draft chapter.

Indeed, the RIAD antigen detection test has been the subject of only one publication in 2017 with very little validation data from only one laboratory. These data are largely insufficient to support the inclusion of this test in the OIE *Terrestrial Manual*, as this would require a full validation of the test in accordance with Chapter 1.1.6. on *Principles and methods of validation of diagnostic assays for infectious diseases*.

Furthermore, ELISA tests are now presented in Section B 2 as well as in Table 1 of draft revised Chapter 2.1.17. as tests that can be used to determine antibody responses in individual dog and cat serum specimens following vaccination prior to international travel. However, these tests have an important limitation in that they measure the total antibody content and not the level of antibodies responsible for rabies virus neutralisation. Indeed, it is current custom internationally to require a test measuring the level of rabies virus-neutralising antibody in the serum of vaccinated pet animals, with 0.5 IU per ml considered to represent a reasonable level of seroconversion and an adequate response to vaccination prior to international travel in line with the recommendations of the current version of the OIE *Terrestrial Manual*.

As stated in draft revised Chapter 2.1.17., use of ELISA tests for such pre-travel serology testing would require that the specific assay formulation has been validated as fit for this purpose, including a comparison with neutralisation tests, and that this be internationally accepted. As that information is not provided, we cannot support these changes.

Finally, we note that Seller's staining method (histological staining for "Negri bodies") is no longer recommended for diagnosis, as mentioned in several parts of the draft chapter. Yet it is still included in Table 1, albeit with only one "+", which might still cause confusion. For reasons of consistency and clarity, we suggests deleting that method from Table 1. Similarly, the mouse inoculation test (MIT) is no longer recommended for routine use in the draft chapter, which states that it should be replaced by cell culture techniques which are as sensitive, more rapid, less expensive and avoid the use of animals. However, the MIT is still included in Table 1 as recommended method ("+++"). This seems inconsistent and could cause confusion; we thus suggest also deleting the MIT from Table 1.

For the reasons explained above, the EU cannot support the adoption of this draft revised Chapter 2.1.17. at the May 2018 General Session, and requests that it be circulated for another round of member country comments before being submitted for adoption by the World Assembly.