Annex 3

EU comment on the September 2014 meeting report of the OIE Biological Standards Commission

Referring to point 5.1. of the above report regarding the inclusion of the BOVIGAM® *Mycobacterium bovis* Gamma interferon test kit for cattle in the OIE register of diagnostic kits, the EU kindly requests a copy of the dossier submitted by the kit manufacturer and the final report of the expert evaluation panel, in order to be in a position to prepare the EU position should a resolution to this effect be proposed for adoption at the OIE General Session in May 2015.

Indeed, should that test kit be included in the OIE register, it would be very important for countries using that kit to do so in a harmonised manner, e.g. as regards the use of tuberculin from different sources or of new generation peptides.

Furthermore, it would be important to interpret the test results in a consistent way. Indeed, depending on the purpose of the test (i.e. for pre-export testing or disease free certification purposes), it would be crucial to establish harmonised and appropriate cut-off points and threshold values, which would need to be determined through well-designed scientific trials.

Finally, it would also be important to clarify the status of the test, i.e. as an ancillary or alternative test to the classical intradermal tuberculin test, which according to the OIE Terrestrial Manual is the prescribed test for international trade.

In order to assess the implications related to the possible use of this test kit, it would be important for EU experts to review the relevant documentation available at the OIE.