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OIE ACTIONS

OIE project to replace International Standard Bovine Tuberculin

KEYWORDS

#ad hoc group, *#*bovine tuberculosis, *#*international collaborative study, *#*International Standard Bovine Tuberculin (ISBT), *#*preliminary evaluation, *#*purified protein derivative (PPD) bovine tuberculin, *#*tuberculin, *#World* Organisation for Animal Health (OIE).

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An OIE ad hoc Group of bovine tuberculosis (bTB) experts is coordinating a project to evaluate, calibrate and validate a replacement for the OIE's International Standard Bovine Tuberculin (ISBT). The ISBT is used as a reference standard for quality control tests for purified protein derivative (PPD) bovine tuberculins that are used in bTB surveillance, diagnosis and export certification. The current reference standard was produced in 1986 and is becoming depleted, so it must be replaced.

The ISBT replacement project [1] involves participants from OIE Headquarters; an *ad hoc* Group of bTB experts from <u>the OIE Reference Laboratories for bTB</u> (from France, Argentina and the United Kingdom); <u>the United Kingdom</u> <u>National Institute for Biological Standards and Control (NIBSC)</u> for preparation, storage and distribution of the tuberculins; and collaborating scientists from approximately 15 other national laboratories.

In the candidate tuberculin validation studies, two candidate tuberculins will be tested in guinea pigs and cattle, in comparison with the current ISBT, to evaluate and calibrate the candidate tuberculins' potency and specificity, and assess the candidates' overall 'fitness for purpose'.

A preliminary evaluation has been completed with satisfactory results

The laboratory testing is scheduled in two phases. A preliminary evaluation was conducted in guinea pigs, and has now been completed with satisfactory results. A larger-scale international collaborative study is scheduled for September 2018 to June 2019 in which the performance of the two candidate tuberculins will be further assessed in guinea pigs to evaluate potency and specificity, as well as in experimentally infected cattle and naturally sensitised 'reactor' cattle to evaluate 'fitness for purpose'.

When the tests have been completed, provided the data are satisfactory, the *ad hoc* Group will prepare a comprehensive report and submit it for approval/endorsement through the OIE governance processes that include endorsement by <u>experts of the OIE Biological Standards Commission</u>, and adoption by <u>OIE Member Country</u> <u>Delegates</u> at the OIE General Session.

Once the study has been endorsed by the Delegates, the *ad hoc* Group will prepare a summary report for publication in a peer-reviewed scientific journal, and the NIBSC will be able to begin distributing the new ISBT.



http://dx.doi.org/10.20506/bull.2019.1.2922

OIE ad hoc Group reports

REFERENCES

1. World Organisation for Animal Health (OIE) (2017). - <u>Report of the meeting of the OIE ad hoc Group on replacement of the international standard bovine tuberculin</u>, Paris, 6–8 June 2017.



The OIE is an international organisation created in 1924 with a mandate from its 182 Member Countries to improve animal health and welfare. Its activities are permanently supported by 301 centres of scientific expertise and 12 regional offices with a presence on every continent.





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