Annex II

TECHNICAL CRITERIA FOR IDENTIFICATION OF BULK MATERIAL FOR THE REPLACEMENT OF THE INTERNATIONAL STANDARD AVIAN TUBERCULIN (ISAT-2)

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1. Quantity per single batch production:

Each ampoule contains 10 to 12 mg PPD powder and phosphate salts. By definition each ampoule contains 500 000 IU of PPD of M. avium tuberculin. The concentration must be suitable for dilution further for filling at 2 mg/ 1 ml / ampoule in glucose-phosphate buffer (pH 6.5 —7.5). The bulk material should be sufficient to fill 2000 ampoules. The product must be presented as a single homogenous bulk or filled in clear/neutral glass ampoules. All documentation and labelling should be in English.

2. POTENCY

The stated potency is not less than 20 000 IU/ml. The estimated potency is not less than 75 per cent and not more than 133 per cent of the stated potency. The estimated potency per mg must be as close as possible to the old ISAT-1, ± 20 000 I International Units (I.U.) per mg. as estimated in guinea pigs. The potency of field preparations currently in use, depending on local legislation, is variable. Contents of each ampoule must be ± 2mg, allowing the present dilution schemes in use to remain in place.

3. SPECIFICITY

Specificity must comply with the requirements given by the WOAH Terrestrial Manual of Diagnostic Tests and Vaccines for Terrestrial Animals .

4. LYOPHILISATION

For lyophilization, the bulk material must not contain phenol, glycerol and glucose. Traditionally, bulk material is stored often at +4°C in the presence of phenol, used as preservative. It is recognized that companies may need to adapt procedures specifically in order to supply bulk material without phenol, glycerol and glucose.

5. PRODUCTION STRAIN - *M. avium* strain D4ER

A certified seed lot system should be in place to guarantee future continuity of the ISAT-2. Avian PPD production strain must be sequenced. The origin and passage history of the M. avium strain D4 must be provided.

6. SELECTION

The initial selection will be made by WOAH using the detailed testing data supplied by the companies. To allow a valid comparison of candidates the basic product data complying with the WOAH Terrestrial Manual of Diagnostic Tests and Vaccines for Terrestrial Animals or other standards such as European Pharmacopeia) must be provided. In particular a Latin square design must be used for allocation of guinea pig inoculation sites.