



Ref: CTO 2014 028 [G]

Cell line: Vero Cell Line (*Chlorocebus aethiops*)

**CTO direction to biosecurity inspectors for the clearance of vero cell line (*Chlorocebus aethiops*).**

Pursuant to section 27(1)(d)(iii) of the Biosecurity Act 1993 I, Marnie Thomas, Manager Animal Imports, Ministry for Primary Industries (under delegated authority), give the following directions for vero cell line (*Chlorocebus aethiops*) imported by South Pacific Sera Limited for the purposes of vaccine production only to be given clearance in accordance with the following measures, different from those in the applicable import health standard for cell cultures from all countries (CELLCULIC.ALL):

Each consignment of vero cells must be accompanied by an original letter from the manager of the facility, linking the imported batch back to the original tested master cell stock, batch number 111287. On presentation of the letter, biosecurity clearance may be granted.

Under CELLCULIC.ALL (clause 6.3), all not new organisms must be imported into a transitional facility approved and operating according to the MPI / EPA standard 154.03.02 (Facilities for Microorganisms and Cell Cultures: 2007a). However, this cell line is required for the production of a vaccine to protect sheep from toxoplasmosis. Detailed information has been provided that outlines the testing and negative results the cell line has been tested for and it has been assessed that the biosecurity risk is mitigated by the procedures South Pacific Sera Limited uses.

The reason for directing clearance is that the biosecurity risks associated with this CTO direction have been assessed and are managed effectively.

This direction takes effect from the date of signing and continues in effect until amended or revoked.