Ref: CTO 2015 079[B] **Commodity: Biological Products: Human Clinical Trials**

CTO direction to biosecurity inspectors for the clearance of *biological products for human clinical trials*.

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 biological products for human clinical trials to be given clearance in accordance with the following measures, different from those in the applicable import health standard for biological products (including samples – BIOPRODIC.ALL):

For clause 19 of BIOPRODIC.ALL, biological products intended to be used on or in humans such as, but not limited to; antibiotics, vaccines, and surgical implants/equipment, are eligible to receive biosecurity clearance provided that

- They are commercially manufactured **or manufactured in a GMP facility for non-commercially manufactured products**; and
- The packaging identifies that the products are intended for human use **or the import is accompanied by a signed and dated manufacturer's declaration stating the products are intended for human use, linking the batch numbers of the product to those being imported**; and
- The packaging of surgical implants also identifies that the product(s) is sterile.

The goods given clearance by this CTO direction are only for biological products for human clinical trials.

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.

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