Ref: CTO 2016 059 [1]
Invertebrates: *Necator americanus* for human use

CTO direction to biosecurity inspectors for the clearance of *Necator americanus* (human tapeworm) for human use

Pursuant to section 27(1)(d)(iii) of the Biosecurity Act 1993 I, Lucy Johnston, Manager Animal Imports, Ministry for Primary Industries (under delegated authority), give the following directions for *Necator americanus* (human tapeworm), shipped from James Cook University (Cairns), to be given clearance in accordance with the following measures, different from those in the applicable import health standard for the importation of invertebrates into New Zealand (INVNONIC.ALL):

Clauses 11.1 and 11.2
Clauses 11.1 and 11.2 of INVNONIC.ALL state:

11.1 Following biosecurity authorisation being given, the container must proceed to the approved registered transitional facility which must be operated according to the MAF Standard 154.02.08: Transitional and containment facility for invertebrates.

11.2 On arrival in the transitional facility the culture must be subjected to such disease testing, identity confirmation, treatments or procedures as required by the permit to import, the MAF Standard 154.02.08 and the Animal Imports/Exports Group Manager.

The *Necator americanus* shipped from James Cook University (Cairns) for a human clinical trial does not need to be imported into a transitional facility approved to, and operating under, 154.02.18 (Transitional and Containment Facilities for Invertebrates) if the importation of the product is accompanied by validated import permit as well as a signed and dated manufacturer's declaration that verifies the following:

a) *N. americanus* are laboratory raised; and
b) *N. americanus* are for human use only; and
c) the species being sent to New Zealand have been identified as *N. americanus* and not another species.

The manufacturer's declaration must be linked to the specific consignment it is accompanying.

The reason for directing clearance is that the biosecurity risks associated with this CTO direction have been assessed and are managed effectively. Advice was provided from Medsafe (Ministry of Health) which stated no Medsafe approval is required for this trial.

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

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