



Ref: CTO 2016 043 [B]

Invertebrates: *Necator americanus* for human use

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

Replaces CTO direction(s): CTO 2016 031 [B]

Pursuant to section 27(1)(d)(iii) of the Biosecurity Act 1993 I, Vicki Melville, Manager Animal Imports, Ministry for Primary Industries (under delegated authority), give the following directions for *Necator americanus* (human hookworm), produced by Wormswell in the United Kingdom 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 5.1, 5.2 and 8

Under INVNONIC.ALL, clauses 5.1, 5.2 and 8 state that an import permit is required for any importation:

- 5.1 *Application for a permit to import must be made before the proposed date of importation in writing to:
Animal Imports Team
MAF Biosecurity New Zealand
PO Box 2526
Wellington
New Zealand.
Email: animalimports@maf.govt.nz*
- 5.2 *A permit to import will be issued for multiple consignments for a period of up to six months.*
- 8 *The permit to import accompanying the consignment must identify the eligible invertebrate species which must not be a new organism as defined by the Hazardous Substances and New Organisms Act 1996.*

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* produced by Wormswell (United Kingdom) for human use does not need to be accompanied by an import permit nor 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 a manufacturer's declaration (on Wormswell letterhead) where Wormswell verify 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* (human hookworm) and not another species; and
- d) *N. americanus* is in purified water.

The manufacturer's declaration must link to the batch number of the *N. americanus* being imported.

The reason for directing clearance is that the biosecurity risks associated with this CTO direction have been assessed and are managed effectively. Advice was received from MedSafe (Ministry of Health) which requires the distribution of hookworms to be in compliance with the requirements of the Medicines Act 1981 if intended to be administered to a person for a therapeutic purpose.

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