

CTO Direction to MPI Inspector

Movement of uncleared goods (not covered by an import health standard) to a containment facility

CTO direction code for recording in Quantum: CTO Plants: 20180005

This direction applies to the importation of high-THC *Cannabis sativa* seeds for sowing for the purposes of making medicines for use in approved clinical trials, imported by Zealand Health Manufacturing Limited from any country:

Pursuant to section 104(1) of the Biosecurity Act 1993 I, _____, Deputy Chief Technical Officer, Ministry for Primary Industries, appointed under section 101 of the Biosecurity Act 1993 (the Act) give the following directions to all Inspectors appointed by a Chief Technical Officer at the Ministry for Primary Industries, or any of its predecessors, and exercising powers under section 25 and section 30A of the Act:

1. The goods may be authorised under section 25(4) of the Act to move to the listed containment facility by issuing a Biosecurity Authority/Clearance Certificate (BACC) to the operator of the containment facility, any person in charge of the goods, or any person in possession of the goods:

Facility name: Bio-Protection Research Centre at Lincoln University
Facility standard: Containment facilities for Plants: 2007
Facility number: CV489
Facility operator: Tracey Nelson

2. All of the following must apply to the goods:

- (a) **This CTO direction is valid for a period of two years from the date of signing of this document, or until revoked (whichever comes first).**
- (b) All consignments must be transported in accordance with the requirements specified in section 8.2.7 of the Containment Facilities for Plants standard.

3. The authorisation must be given to the facility operator, any person in charge of the goods, and any person in possession of the goods.

4. The following conditions in relation to the goods must be included in the authorisation:

- (a) Seed packets must not be opened at the Border, but directed to the Operator of the MPI-containment Facility listed on this direction.
- (b) On arrival all documents associated with the consignment will be inspected by a MPI Inspector to ensure compliance with this direction.
- (c) All seed for sowing must be clearly identified with the scientific name (e.g. genus and species);
- (d) All packaging associated with seed for sowing must be clean, free from soil and other contaminants;
- (e) The goods must be kept in the containment facility.
- (f) The goods can only be moved from this containment facility after it has met all the requirements listed in this direction.
- (g) The goods must be held in accordance with the conditions set out in Table 1 "Requirements in the containment facility", as specified on the CTO direction to MPI Inspector 'CTOPlants:' by including the following statement in the 'Authority Conditions' section of the BACC 'Further conditions must be followed as per table 1 of CTO Plants:'

Note: If any of the above conditions are not complied with, a BACC must not be issued and a non-compliance must be forwarded to the Plant Germplasm (Imports) team

Table 1: Requirements in the containment facility

Condition	
1.	On arrival at the containment facility all seeds lines must be given a 100% inspection for pests, weeds and diseases by an accredited person nominated by the facility operator.
2.	A record must be kept of all seeds (including quantity, scientific name/description of the goods, country of origin and date of arrival) and the current status of the material (i.e. held/in use/destroyed). Upon request, this record must be made available to the MPI inspector at all reasonable times.
3.	The seeds must be stored and used at the containment facility in accordance with the quality operating system approved by the facility inspector, and must not leave the facility without further authorisation from the facility inspector. Leaf material can be sent for analysis at the Institute of Environmental Science and Research (ESR) for determination of levels of cannabinoids as required for this project.
4.	<p>The goods must be managed in the following manner:</p> <ul style="list-style-type: none"> i) The seeds must be treated prior to germination using a hot water dip for the removal of bacterial organisms under supervision by a MPI-inspector. The hot water treatment must be conducted either at 50°C for 30 minutes or at 60°C for 10 minutes. ii) All plants must be inspected for pest and disease symptoms during the quarantine period by a MPI inspector. iii) The quarantine period begins once the plants have two fully expanded leaves. iv) During growth in quarantine seed lots must be inspected by the MPI inspector at the following stages of growth: a) after two fully expanded leaves emerged; b) 4 weeks after two fully expanded leaves emerged; c) 4 weeks later; d) and a final inspection before flowering. v) Fungicides or any other chemical are not to be used on plants without prior approval from a MPI inspector. vi) Records must be maintained detailing the results of all inspections, inspector name and the dates of the inspections for each seed lot. vii) Only seed from plants screened and plants screened and found to be free of any regulated disease may be given biosecurity clearance by a MPI Inspector. No material (except samples to ESR) which has not undergone a PEQ growth period and release can be removed from the containment facility (i.e. un-germinated seed from original imports).
5.	Any material remaining after analysis is to be incinerated/autoclaved for disposal unless otherwise stated in the operating system with further authorisation from the facility inspector
6.	All non-regulated pests (those occurring in New Zealand), regulated pests (not occurring in New Zealand), and vermin present as a contaminant must be reported to the MPI inspector as soon as possible. Seeds and/or seedlings associated with a contaminant will be destroyed appropriately under MPI supervision.

This direction takes effect from the date of signing.

Deputy Chief Technical Officer

Date: 5/3/18