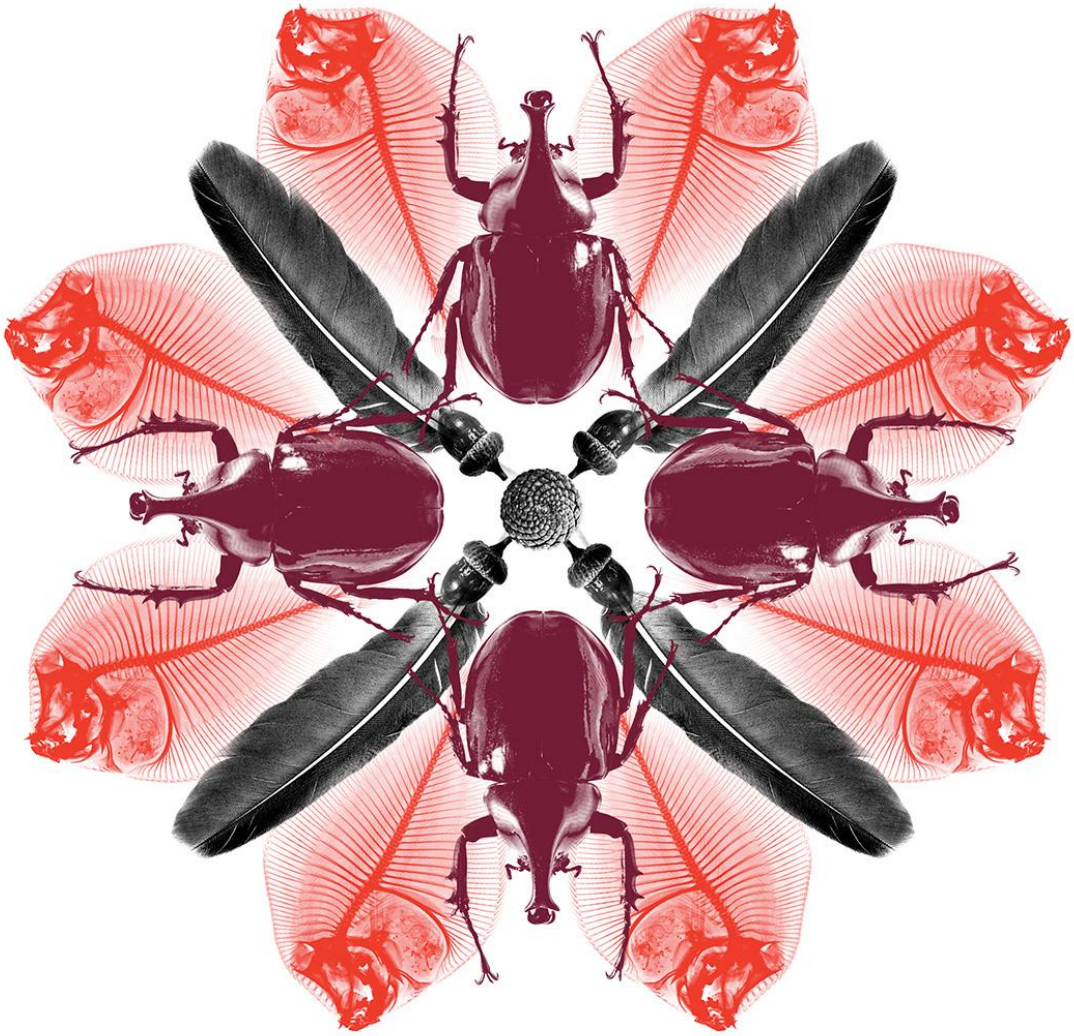
Australian Government
Department of Agriculture, Fisheries and Forestry

Requirements for facilities to export tissue cultures free of media to Australia

Version 1.0



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Version history

Date	Version	Changes
1 March 2023	1.0	Initial version of this document

Contents

1 Introduction

Imported live plants for planting (nursery stock) may provide a pathway for exotic plant diseases and insect pests to be introduced into Australia, and can become infected or infested at any step along the export pathway. This includes from culturing infected motherstock, throughout the production process itself, during storage and packaging, during transport to the point of export, and in-transit from the point of export to the first point of entry in Australia.

Tissue cultured plantlets can either be imported into Australia established in growing media (i.e. agar), or free of growth media from a facility that has been assessed and recognised as an approved source by the Department of Agriculture, Fisheries and Forestry (the department). Importantly, the presence of a nutrient rich growing media provides a medium favourable for the expression of bacterial and fungal contamination associated with tissue culture plantlets, and enables better visualisation of infection during on-arrival inspection in Australia. Accordingly, importing tissue culture plantlets without growing media makes it more difficult to identify any potential bacterial and fungal contamination. Given this, the department applies additional requirements to ensure sufficient measures are implemented offshore by the production facility to appropriately manage the risks.

This document is designed to assist facilities in developing systems, processes and procedures to manage contamination risks and ensure that products are produced and handled in a manner to meet Australia's import conditions. The department will reference this document when assessing applications from facilities to become approved or re-approved to export tissue cultures free of media to Australia, or in the auditing of facilities to ensure ongoing compliance.

For more information on how the department manages the biosecurity risks associated with live plants, please see the Approved sources of tissue cultures free of media and Plant pests and disease pages on the department's webpage. For more information on the import conditions and testing requirements, please review the information on the Australian Biosecurity Import Conditions (BICON).

1.1 Scope

This document provides general requirements for overseas facilities to be approved to export tissue cultures free of growth media to Australia. These are in addition to specific import conditions set by the department. The following key components are addressed in the following sections:

- process for submitting and supporting an application
- how applications are prioritised for assessment
- key criteria and requirements for a facility to be approved
- certification and review periods, including non-compliances.

The requirements outlined in this document are the minimum criteria that must be met by an offshore facility in order to become an approved source. The department may request additional information or assurances be implemented at the facility or by the exporting NPPO to manage biosecurity risks identified during the audit.

Should the department grant approval to the facility, the tissue cultures may be imported free of media, without the requirement to undergo post-entry quarantine growth, provided that all of the other import conditions have been met.

The requirements provided in this document do not apply to overseas facilities manufacturing and exporting:

- tissue cultures **in** growth media; and
- nursery stock operating under alternative high-health arrangements; and
- plants species that belong agriculturally significant food, fibre and energy crops and are associated with significant pests and/diseases of biosecurity concern. Such imports are managed under more tightly regulated systems on-arrival in Australia and have distinct clearance pathways such as testing and screening through the Australian government post-entry quarantine facility prior to being released from biosecurity control.

1.2 Overview of application process

How to apply?

To become certified as an approved source, facilities must lodge a formal application in writing to the department and be assessed through a desktop audit process to ensure they have the appropriate systems, processes, expertise and oversight to manage the risks in accordance with Australia's appropriate level of protection (ALOP). The assessment process comprises a full end-to-end systems review spanning from the sourcing of mother stock material through to the point of export.

Formal application can be made via email to imports@aff.gov.au or through the export country's National Plant Protection Organisation (NPPO) representative.

The application must include:

- Documentation attesting to their ability to meet the requirements outlined in this document.
- Where applicable, evidence of how the facility meets the requirements. This should include formal procedures (i.e. quality assurance manuals or quality management system documents) and/or records and processes undertaken.
- Endorsement letter from the export countries NPPO attesting to their support of the facility, and that a site visit has been undertaken to confirm adherence with the requirements outlined in section 12 of this document.
- Letter of endorsement from an Australian importer

Prioritisation of applications

Following the receipt of an application, the department will undertake a preliminary review of the submission to ensure all the required supporting information has been provided. Applications will only be accepted if all required documentation has been received.

New applications will be reviewed through a prioritisation process, and will be informed by a number of factors including, but not limited to the following:

- available resourcing – new application requests will be assessed according to available personnel, budgeting, and appropriate expertise required to make a comprehensive assessment

- complexity of an application
- balancing with other program priorities/responsibilities
- order of applications received
- endorsement by Australian importers and the exporting country NPPO

Based on a balance of the above factors, an audit will be scheduled into the department's work program for completion. It is worth emphasising that not all criteria outlined above contribute equally to the prioritisation process and the department will exercise flexibility in how work is scheduled for completion.

Timeframe for completion of assessment

Once the application commences assessment, the timeframes for completion can vary substantially and is case-by-case, contingent on the following:

- the complexity of the request as above
- quality of information to support an assessment
- the need for ongoing engagement with the applicant to resolve outstanding issues
- balancing with other high priority work as noted above
- level of cooperation from key parties associated with the application e.g. the exporting country NPPO, testing facilities etc.

Given the above, the department does not explicitly prescribe assessment timeframes for completion of an approved source application.

Note: The department may request further documentary evidence (e.g. records) to support the assessment process.

Certification periods, non-compliance and review

Facilities that become recognised as an approved source for export of tissue cultures free of media to Australia will initially be certified for a defined period (e.g. three years). The applicant will be advised of this validity period by the department in writing following a successful audit outcome. Certification status is however subject to compliance activity by the exporting facility and the department may conduct periodic reviews to determine if measures continue to remain fit-for-purpose. Accordingly, major non-compliances may result in suspension of certification status, as can ongoing lesser non-compliances that are not suitably actioned in line with departmental requirements.

Certification periods and assessment requirements may vary for facilities seeking to re-certify their status after the initial establishment period has elapsed. This will again be contingent on a range of factors and the department will engage with the applicant to inform them of re-certification requirements and certification validity periods.

Documentation requirements

All information or documentation supplied in support of an application for a facility to become an approved source to export tissue cultures free of growth media to Australia must meet the department's Minimum documentary and import declaration requirements.

This policy outlines the minimum documentary requirements that must be met when lodging information to the department in support of an application.

1.3 Key definitions

The following words are used throughout this document to describe requirements, recommendations, allowances and guidance for offshore facilities wishing to be approved to export tissue cultures free of growth media to Australia.

- 'must' indicates a mandatory requirement.

Failure to meet these will be considered a non-conformance.

- 'should' indicates that the requirement is expected to be implemented unless there is a valid reason for not implementing it. A valid reason could be that it is not applicable to the facility or has been replaced by an alternative demonstrated to provide an equivalent outcome.

Failure to meet these requirements will result in a non-conformance unless demonstrated to be inapplicable or an acceptable alternative is in place.

- 'may' indicates an allowance for the facility to decide how to achieve the desired outcome of a requirement.

How the facility chooses to meet the desired outcome will be assessed at audit and may result in a non-conformance being issued if the desired outcome is not met.

1.4 Glossary

Term	Definition
BICON	Australian Biosecurity Import Conditions database
biosecurity	Managing risks to Australia's economy, environment and community of pests and diseases entering, emerging, establishing or spreading in Australia.
biosecurity integrity	Where inputs and finished products are not contaminated with biosecurity risk material at any point during the primary production, manufacturing and handling phases (including during preparations for export).
biosecurity risk material	Any material with the potential to introduce a weed, pest or disease. Examples of biosecurity risk material includes, but is not limited to: • animals e.g. rodents, birds and insects • animal parts and animal products e.g. feathers, faeces • plants and plant parts including seeds • soil
biosecurity specifications	These are the specifications set by the facility to ensure biosecurity risks are managed in accordance with Australia's import conditions. See section 3 for a description of these requirements.
calibration	A demonstrated comparison of a measurement device against a more accurate traceable reference or standard device.
contamination	The undesired introduction of biosecurity risk material, into or onto inputs or finished products.
cross-contamination	Contamination of an input or finished product with another input or finished product.
finished product	A finished container of tissue cultures which have been removed from agar and repackaged for export.
facility	An overseas establishment that manufactures, stores, handles, transports or exports nursery stock to Australia.
inputs	Any materials required for the manufacture of the finished product.
motherstock	Plant material maintained for the purpose of producing tissue culture plants for export
potable water	Water that is processed and treated to meet standards for human consumption.
quality management system	A document or a series of documents that describe the policies and objectives as well as the processes to achieve those policies and objectives.
tissue culture	A form of micropropagation used to produce clones of the motherstock in an aseptic environment.

2 General requirements

Desired outcome: the facility has a documented structure, trained personnel with knowledge of Australia's import requirements, and established reporting lines to ensure that all processes are managed in way that effectively identifies and responds to biosecurity risk. Relevant accreditations should be in place where needed to support the conductance of activities in a manner which is consistent with international standards.

1. *Details of the applicant*
    a. The facility must provide the following details:
        i. Physical address / location
        ii. Details of ownership of the facility
        iii. A minimum of two points of contact including full name, position held and email address
    b. Diagram of the facility (site map) including a description of how plant material is processed/moves through the facility.
    c. Photos of the facility and production process must be supplied.
2. *Awareness of the required import conditions*
    a. The applicant must demonstrate their knowledge of Australia's import conditions.
    b. A complete list of scientific names and common names of all plants stored and cultured at the facility must be provided.
3. *Existing accreditations*
    a. Where applicable, the facility should provide evidence of existing accreditations for their facility and/or the testing laboratory. This may include but is not limited to certifications from:
        i. The export countries NPPO
        ii. Another country that they export to
        iii. Relevant international organisations or international standards (e.g. ISO accreditations)
4. *Personnel*
    a. The facility must provide a personnel organisation chart and a brief outline of delegation of responsibilities for key personnel.
    b. The facility must maintain a training schedule to ensure that all staff are appropriately trained to undertake activities in relation to their role in the production process.
    c. The facility should provide a brief summary of staff experience.

3 Integrity and security

Desired outcome: the facility is constructed and managed to ensure that it is fit-for-purpose, and the biosecurity integrity of inputs and finished products can be maintained.

5. *Site security*
    a. Procedures must be in place to control access into (and across) the facility in order to eliminate or minimise the risk of contamination:
        i. There must be a system for screening and/or supervision of external parties during site visits (e.g. subcontracted activities which are undertaken at the site)
        ii. The perimeter of the facility must be secured in a manner which prevents the entry of wild animals and unauthorised personnel or vehicles onto the site
        iii. Applicant should provide an outline of how internal access into key areas of the production facility is secured e.g. into the culture room
6. *Building and equipment integrity*
    a. Building(s) and equipment used for storage, handling and production must be designed and constructed to:
        i. eliminate or minimise the risk of contamination and cross-contamination
        ii. allow for adequate cleaning and maintenance
    b. There must be a procedure in place for regular monitoring of structural and biosecurity integrity of the facility. This should include:
        i. Monitoring to ensure all areas within the facility are free from structural issues that impact biosecurity integrity and allow entry of pests and diseases
        ii. Appropriate barriers over windows and ingress points to prevent the introduction of contamination (e.g. pests, pathogens, vectors)

    c. Sterilisation equipment must allow for monitoring of processing parameters;
        i. Temperature monitoring equipment must be validated to be of a sufficient type, resolution and accuracy to provide certainty that products have been appropriately sanitised.
        ii. The facility must maintain a procedure which determines whether a treatment/sterilisation cycle is successful and what process should be undertaken when a treatment fails.

d. Monitoring equipment must be serviced at periodic intervals during processing to ensure acceptable accuracy and reliability. Calibration and serving activities must be supported by a documented procedure.

    i. The calibration interval should be determined based on recommendations from the equipment manufacturer, the results of previous calibrations and other factors such as frequency of use and the operating environment. Calibration intervals should be no longer than 12 months

    ii. Calibration activities must be documented with results recorded

7. *Site use*

    a. There must be no animals kept on-site at the facility.

4 Sourcing and management of mother stock material

Desired outcome: the facility has procedures in place to ensure that clean, disease-free mother stock prior to initiation and the health status of the material can be maintained.

8. *Traceability of the mother stock*
    a. The facility must document the following information for each mother stock plant used to initiate cultures:
        i. Scientific name (genus and species)
        ii. Geographic location where the stock originates from
        iii. Evidence that testing has been undertaken on the mother stock plants to ensure they are free from pathogens of quarantine concern to Australia prior to initiating these into tissue cultures
        iv. Date of first initiation into the culture program
        v. Unique identifier or reference for the plant
9. *Secure storage of mother plants*
    a. There must be measures in place to prevent the entry of insects/vectors into areas containing mother stock plants to minimise the risk of infection by vector-transmitted pathogens of concern.
    b. Where mother stock is maintained in outside greenhouses, a buffer zone must be maintained around facilities and a program to remove weeds and non-crop material must be in place.
    c. The facility must have established arrangements to ensure that the mother stock is maintained in a location which protects it from infection or contamination.
    d. There must be appropriate segregation of incoming plant material from plant material on-site.
    e. There should be procedures in place to ensure segregation of mother stock which has been screened for production of tissue cultures destined for the Australian market from those used for other destination markets.

5 Pest and disease management

Desired outcome: the facility has appropriate procedures and supporting systems in place to monitor and control pests to prevent contamination and infestation of inputs and finished products.

10. Facility measures

a. Physical barriers must be in-place to exclude insects (e.g. barriers, screens, double doors, pressurised entrances).

b. The facility must have an active pest management program in place to monitor and detect insects. This must include:

i. Information on the type of traps utilised

ii. Location of the traps in the facility

iii. Thresholds applied to trap finds which would trigger a change in management responses (i.e. seasonal changes, increase in surveillance)

iv. Procedures to manage detections, including identification and application of insecticides.

c. Applicants should outline what controls (i.e. chemicals, biological, physical) are applied to maintain clean plant material (preventative and responsive treatment programs within greenhouses and tissue culture laboratories etc).

11. Record of activities

a. There must be evidence provided on the frequency of monitoring of plants for pests and diseases (i.e. daily, weekly) using established methods and corrective actions.

b. Record keeping activities must be in place to log all pest detections at all points in the production process, including on mother stock. In addition, all detections should include reference to the outcome of the detection.

12. Disease screening activities

a. Procedures must be in place to ensure disease screening of both mother plants and tissue cultures to ensure they are free from pathogen contamination.

b. A list of all antibiotics, fungicides and biocides used in the production process must be provided in support of the facilities application.

Note: No antibiotics, fungicides, or biocides are to be used in containers in which the tissue cultures are to be established and exported in as this can mask the presence of pathogens on-arrival in Australia.

6 Hygiene and sanitation

Desired outcome: the facility has appropriate hygiene and sanitation practices in place to ensure that the biosecurity integrity of inputs and finished products is not compromised.

13. Water

a. Only potable water should be used at all points in the production process, this includes water used in the care of mother plants.

14. General hygiene and sanitation of the facility

a. There must be a process in place to ensure appropriate disinfection of tools and equipment used when handling plant material, or in between handing lines from different mother stock plants, or when transferring between areas of the facility to prevent cross-contamination.

b. There must be established processes for managing waste material at the facility, including infested or diseased plants and debris.

c. There must be established protocols for staff moving between different areas of the facility and handling plant material to prevent cross-contamination (e.g. hand washing, gloves, coverall aprons, foot baths).

d. There must be an established schedule for cleaning of the facility and plant areas to maintain a tidy and sanitised working environment.

e. There must be an established protocol for ensuring that plants generated from the tissue culturing process remain aseptic and free from contamination (e.g. use in a laminar flow, appropriate sterilisation of growing media, plant containers used to grow or contain plants and work surfaces to prevent contamination.).

7 Handling and traceability

Desired outcome: the facility has systems and procedures in place to prevent contamination and cross-contamination during handling of inputs and finished products, and a full traceability system in place to track goods through the production and export pathway.

15. Handling

a. Plant material and finished products must be stored in a manner that:
   i. Allows for their identification
   ii. Is dedicated for export to Australia.

b. There must be a documented procedure for handling plant material (mother stock and tissue cultures):
   i. Separation between receival and dispatch areas of the facility
   ii. Screening of incoming plant material to ensure they are free from pests, diseases or other contamination of biosecurity concern
   iii. Where applicable under Australian import conditions, evidence of disease screening to ensure cultures have been initiated from clean mother stock.

16. Traceability

a. The facility must provide information on the flow of goods through the production process to ensure it promotes best practice for maintaining clean production pathways.

b. The facility must keep records of the origin of the inputs, batch/lot and distribution records of finished products to facilitate full-traceback, trace forward or recall activities.

c. The facility should utilise a system which records, monitors and tracks all tissue cultures and mother stock material and their location through the facility.

8 Testing requirements (where applicable)

Desired outcome: the facility has procedures in place to ensure that Australia's testing requirements for biosecurity pathogens can be met.

17. Testing laboratory endorsement

a. The laboratory may demonstrate competence to produce technically valid results (e.g. accreditations to internationally recognised standards such as ISO 17025, Good Laboratory Practices or equivalent).

18. Pathogen testing

a. Testing protocols must be provided for all screening activities undertaken on mother plants.

b. The facility must provide a copies of laboratory test reports issued by the testing laboratory for diagnostics undertaken on plants – attesting to tests being undertaken and results obtained.

Note: For plant species which are regulated as being hosts of *Xylella* spp. which have been produced or sourced from a country regulated by the department for the presence of this pathogen, mother stock must be subject to the following PCR protocols prior to initiation into cultures (information on Australia's requirements for Xylella testing can be found here):

the rimM gene sequence real-time PCR test of Harper *et al*. (2010)

AND

the conventional PCR of Minsavage *et al*. (1994) or an equivalent PCR that detects *Xylella taiwanensis* (previously *Xylella fastidiosa* subspecies).

9 Release of finished products

Desired outcome: the facility has procedures in place to ensure that finished products leaving the facility meet biosecurity conditions and complies with the approval of the facility.

19. Packaging and export

a. There must be procedures in place to ensure plants are packaged and transported in a manner which complies with Australian import conditions:
   i. packaging used is clean and new
   ii. labelled with the full botanical name (genus and species)
   iii. enclosed and sealed containers
   iv. packaged in a manner which does not compromise the integrity of the containers
   v. containers must not be overcrowded to ensure that product can be easily inspected upon arrival in Australia
   vi. containers must be transparent to allow for inspection on -arrival.

b. The facility must provide pictures of the finished export ready product, including pictures of individual vessels and export packaging.

Note: Each sealed box/carton of vessels for export to Australia must not exceed 20kg.

20. Assurance that import conditions have been met

a. The facility must have a procedure in place to ensure that all import conditions have been met before release of the product from the facility for export to Australia.

10 Quality management system

Desired outcome: the facility has a quality management system in place that ensures all activities contribute to managing the biosecurity risk of the product and are consistently defined, implemented and maintained at all levels.

21. Quality management system

a. The facility must have and maintain a documented quality management system. The system must include:

   i. A manual which lists all processes and activities that can affect the biosecurity integrity of the product

   ii. An organisational structure and clearly defined responsibilities for all roles involved in the production, handling and distribution of finished products

   iii. Processes for document control, internal auditing and management review

   iv. Staff training requirements including how staff will be verified as being competent in their roles and responsibilities

b. The quality management system must have a mechanism for notifying key stakeholders and the department of any changes that impact the ability of the facility to meet the requirements provided in this document and import permit conditions. This includes:

   i. Changes in ownership or management

   ii. Sourcing of motherstock

   iii. Tissue cultures exported which do not meet import requirements, including failure for appropriate testing being undertaken

22. Record keeping

a. A record keeping system must be in place which includes:

   i. Activities and processes relevant to this document must be recorded without delay after they have been performed

   ii. Records should be kept for a minimum of 2 years

   iii. Records must be made available to the department upon request

11 Audits

Desired outcome: the facility has a regular auditing schedule in place to quality check all aspects of the production process.

23. Internal auditing

a. The facility must conduct internal audits of its processes and personnel to ensure that best practices and systems are being applied, and to promote continued improvement.

24. External auditing

a. The facility must be audited or inspected by its NPPO to ensure all systems and processes sufficiently meet Australia's requirements.

b. Outcomes of this audit must be reported to the department.

c. The facility must keep and provide records of audits conducted by its NPPO upon request to demonstrate they have undergone the necessary NPPO oversight to maintain their eligibility to the export tissues free of media to Australia.

12 NPPO endorsement

Desired outcome: the facility has been inspected by the NPPO officer and a letter of endorsement has been provided to the department in support of the facility being approved.

a) The facility must be inspected by the NPPO to verify the following;

i) the production facility is fit-for-purpose, sanitary and well maintained

ii) tissue cultures are being produced under aseptic conditions

iii) the media used in the production of the plantlets is sterile and free from microbial suppressants and is poured into the container for solidification prior to tissue implantation

iv) plantlets for export will be inspected by officers of the NPPO prior to the removal of the plantlets from the media and that any diseased or contaminated plantlets found will be rejected from export to Australia

v) tissue cultures have been transferred out of the media under aseptic conditions into sterile transport containers in accordance with the additional declaration on the phytosanitary certificate

Note: The NPPO will be required to provide the following additional declaration on the accompanying Phytosanitary Certificate for each consignment stating that:

"Prior to the removal of the plant tissue from media, the tissue cultures were inspected and found to be free of contamination. The plant tissue was aseptically transferred under supervision to sterile containers which were then sealed and not subsequently re-opened."

b) A letter of endorsement from the NPPO must be provided to the department via email (imports@aff.gov.au with the subject line – (Plant T2) NPPO endorsement of *Facility name*) certifying the following:

i) the facility was inspected and meets the criteria listed in section 12 of the Requirements for facilities to export tissue cultures free of media to Australia

ii) the NPPO will undertake the required inspections and oversight for all exported consignments and provide the necessary endorsement and certification listed in the Requirements for facilities to export tissue cultures free of media to Australia

Note: The letter must include the name and position of the NPPO officer who conducted the inspection, date of the inspection and be presented on a government letterhead.