



Audit questionnaire: approved source of tissue cultures free of media

Section 1: General information

Purpose of this questionnaire Obtain information from applicants to determine their compliance with the department's requirements for facilities to export tissue cultures free of media to Australia.

Facilities will be asked to provide copies of specific records during the desk audit process and may be asked to provide additional information where required to further support an assessment.

Before completing this questionnaire Ensure you understand our:

- Current import conditions for all genera intended for export to Australia as detailed in BICON.
- Requirements for facilities to export tissue cultures free of media to Australia (the *requirements*).

This questionnaire can be either completed

Electronically

Download the document to your computer and save any changes.

Manually

Use black or blue pen

Mark boxes with a tick or a cross

To submit this questionnaire Forward your completed form and supporting documents to Imports@aff.gov.au.

More information Phone: 1800 900 090 (within Australia)
+61 3 8318 6700 (outside Australia)

Email: Imports@aff.gov.au

Web: agriculture.gov.au

Section 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*

1.a Location and contact Information

Name (legal entity name)

Facility address

Street address _____

Town/city _____ Country _____ Postcode _____

Details of ownership

Contact person 1:

Given name(s): _____ Family name: _____

Job title: _____

Email address: _____

Phone number: _____

Contact person 1:

Given name(s): _____ Family name: _____

Job title: _____

Email address: _____

Phone number: _____

Person authorised to sign this form

Given name(s) _____ Family name _____

Job title/position in company _____

Work phone _____ Mobile phone _____

Email _____ Fax _____

1.b Facility site map and processing of plant material through the facility

Please provide a copy of the facility site map (diagram) including a description of how plant material is processed/moved through the facility (this could be supplemented with a processing flowchart)

Completed:

No Please do not submit this form

Yes Go to question 1.c

If the facility site map is attached separate to this questionnaire, please add the name of the document or reference number here:

1.c Photos of the facility and production process

Please provide photos of the facility covering the key production areas and processes.

Completed:

No Please do not submit this form

Yes Go to question 2.a

If photographs are attached as separate to this questionnaire, please add the name of the document or reference number here:

2 Awareness of the required import conditions

2.a Please review the current import conditions published on BICON to ensure you are familiar with Australia's requirements for the species you intend to export to Australia, this includes whether it is permitted and what testing requirements might be required.

Confirm that you have reviewed the current import conditions that apply:

No Please do not submit this form

Yes Go to question 2.b

2.b Please provide complete list of scientific names (genus and species) and common names of all plants stored and cultured at the facility. This can be attached as a separate document to your application.

Completed:

No Please do not submit this form

Yes Go to question 3.a

If attached as separate document(s), please add the name of the document or reference number here.

3 Existing accreditation(s)

3.a Where applicable, please provide evidence of relevant accreditation the facility currently holds. This may include, but is not limited to, export certifications from a National Plant Protection Organisation (NPPO), relevant international organisations or certifications in accordance with an international standard(s) (e.g. ISO accreditation).

If accreditations are being provided, certificates or other evidence can be attached as a separate document to you application.

If attached as separate document(s), please add the name of the document or reference number here.

4 Personnel

4.a Please provide a personnel organisation overview or chart for your facility, including the responsibilities delegated to each of the key personnel and a brief summary of staff experience.

Completed:

No Please do not submit this form

Yes Go to question 4.b

If attached as separate document(s), please add the name of the document or reference number here.

4.b The facility must maintain a training schedule to ensure all staff are appropriately trained to undertake activities in relation to their role in the production process. Please provide an overview of how the facility manages training requirements. This can include standard operating procedures (SOPs), or procedural documents.

Completed:

No Please do not submit this form

Yes Go to question 5.a

If attached as separate document(s), please add the name of the document or reference number here.

Section 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

5.a Procedures must be in place to control access into (and across) the facility in order to eliminate or minimise risk of contamination. *See section 5.a of the requirements.*

This should include SOPs, but may also include contracts/agreements with third-party security providers.

If attached as separate document(s), please add the name of the document or reference number here.

6 Building and equipment integrity

6.a Building(s) and equipment used for storage, handling and production must be designed and constructed to minimise the risk of contamination or cross-contamination and allow for adequate cleaning. *See section 6.a of the requirements.*

Please provide details of how this achieved.

6.b There must be a procedure in place for regular monitoring of the structural and biosecurity integrity of the facility. *See section 6.b of the requirements.*

Please provide details of how this is achieved. This may include SOPs outlining facility maintenance regimes which includes frequency of maintenance. Evidence of these activities must be provided, this may include records of activities undertaken.

If attached as separate document(s), please add the name of the document or reference number here.

6.c Sterilisation equipment must allow for monitoring of processing parameters. This includes how the facility ensure equipment is validated to ensure it can meet temperature requirements, and how the treatment is deemed to have met parameters. *See section 6.c of the requirements.*

Please provide details of how this is achieved. This must include SOPs on monitoring processes for sterilisation equipment. Evidence of these activities must be provided, this may include records of activities undertaken.

If attached as separate document(s), please add the name of the document or reference number here.

7 Site use

7.a Are animals kept on site at the facility?

No Go to question 8.a

Yes Please provide information below

Section 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 health status of the material can be maintained.

8 Traceability of mother stock

8.a The facility must have processes in place for the documentation and traceability of mother stock plants. *See section 8.a of the requirements.*

Please provide details of how this is achieved. This should include SOPs outlining the handling and management of mother material at the facility. Evidence of these activities must be provided, this may include records of activities undertaken.

If attached as separate document(s), please add the name of the document or reference number here.

9 Secure storage of mother stock plants

9.a There must be measures in place for the storage of mother stock plants to prevent infestation and transmission of pathogens. *See section 9.a of the requirements.*

Please provide details of how this achieved.

9.b Where mother stock plants are maintained externally to the main tissue culture facility (i.e. outside greenhouse), the facility must have maintenance practices in place to maintain a buffer zone. *See section 9.b of the requirements.*

Please provide details of how this achieved.

9.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. *See section 9.c of the requirements*

Please provide details of how this achieved.

9.d There must be appropriate segregation of incoming plant material from plant material on-site. *See section 9.d of the requirements*

Please provide details of how this achieved.

Section 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 outputs

10 Facility measures

10.a Physical barriers must be in place to exclude insects (e.g. barriers, screens, double doors, pressurised entrances). *See section 10.a of the requirements*

Please provide details of how this achieved.

10.b The facility must have an active pest management program in place to monitor and detect insects. *See section 10.b of the requirements*

Please provide details of how this achieved. This should include SOPs outlining pest and disease management utilised at the facility.

If attached as separate documents, please add the name of the document or reference number here.

11 Records of activities

11.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. *See section 11.a of the requirements*

Please provide details of how this achieved.

11.b Record keeping activities must be in place to log all pest detections at all points in the production process, including on mother stock. *See section 11.b of the requirements*

Please provide activity records including outcomes in the event of pest and disease detections.

If attached as separate document(s), please add the name of the document or reference number here.

12 Disease screening activities

12.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. *See section 12.a of the requirements*

Please provide details of how this achieved. Evidence of these activities must be provided, this may include records of activities undertaken.

If attached as separate document(s), please add the name of the document or reference number here.

12.b Antibiotics, fungicides and biocides used in the production process must be listed in support of the facilities application. This can be attached as a separate document to your application.

Completed:

No Please do not submit this form

Yes Go to question 13.a

If attached as separate document(s), please add the name of the document or reference number here.

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.

Section 6: Hygiene and sanitation

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

13 Water

13.a Does the facility use potable water?

No Please provide information below on how water is sourced at the facility (i.e. river, rain, well) and steps are taken for sanitation (i.e. treatments)

Yes Go to question 14.a

14 General hygiene and sanitation of the facility

14.a There must be a process in place to ensure appropriate disinfection of tools and equipment used when handling plant material, or in between handling lines from different mother stock plants, or when transferring between areas of the facility to prevent cross-contamination. *See section 14.a of the requirements*

Please provide details of how this achieved. This should include SOPs outlining hygiene management practices utilised at the facility.

If attached as separate document(s), please add the name of the document or reference number here.

14.b There must be established processes for managing waste material at the facility, including infested or diseased plants and debris. *See section 14.b of the requirements*

Please provide details of how this achieved. This may include SOPs outlining waste management practices utilised at the facility.

If attached as separate document(s), please add the name of the document or reference number here.

14.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). *See section 14.c of the requirements*

Please provide details of how this achieved.

If attached as separate document(s), please add the name of the document or reference number here.

14.d There must be an established schedule for cleaning of the facility and plant areas to maintain a tidy and sanitised working environment. *See section 14.d of the requirements*

Please provide details of how this achieved. This may include SOPs outlining cleaning practices utilised at the facility.

If attached as separate document(s), please add the name of the document or reference number here.

14.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). *See section 14.e of the requirements*

Please provide details of how this achieved. This must include SOPs outlining the tissue culturing process utilised at the facility.

If attached as separate document(s), please add the name of the document or reference number here.

Section 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 product, and a full traceability system in place to track goods through the production and export pathway.

15 Handling

15.a All plant material handled at the facility, either mother stock plants or tissue cultures, must be stored in a manner that allows for identification. *See section 15.a of the requirements*

Please provide details of how this achieved.

If attached as separate document(s), please add the name of the document or reference number here.

15.b The facility must have a documented procedure for handling of all plant material, both mother stock plants and tissue cultures. *See section 15.b of the requirements*

Please provide details of how this achieved. This must include SOPs outlining the tissue culturing process utilised at the facility.

If attached as separate document(s), please add the name of the document or reference number here.

16 Traceability

16.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.

This can be articulated on the site map provided with the application, or written below.

17.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. *See section 15.b and 15.c of the requirements*

Please provide details of how this achieved. This may include SOPs outlining traceability process utilised at the facility.

If attached as separate document(s), please add the name of the document or reference number here.

Section 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

17.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).

If accreditations are being provided, certificates or other evidence can be attached as a separate document to you application.

If attached as separate document(s), please add the name of the document or reference number here.

18 Pathogen testing

18.a Please provide a complete list of disease screening activities undertaken on mother plants, including protocols. *See section 18.a of the requirements*

If attached as separate document(s), please add the name of the document or reference number here.

18.b Please provide evidence of the above disease screening activities by way of a laboratory report which includes outcomes of screening activities. *See section 18.b of the requirements*

If attached as separate document(s), please add the name of the document or reference number here.

Section 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 approval of the facility.

19 Packaging and export

19.a The facility must have procedures in place to ensure that all tissue cultures packaged for export are compliant with import conditions. *See section 19.a of the requirements*

Please provide details of how this achieved. This may include checklists, SOPs and/or evidence of assurance processes for finished export ready tissue cultures

If attached as separate document(s), please add the name of the document or reference number here.

19.b Please provide pictures of the finished export ready product, including pictures of individual vessels and export packaging.

Completed:

No Please do not submit this form

Yes Go to question 20.a

If attached as separate document(s), please add the name of the document or reference number here.

20 Assurance that import conditions have been met

20.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. *See section 20.a of the requirements*

Please provide details of how this achieved.

If attached as separate document(s), please add the name of the document or reference number here.

Section 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

21.a The facility must have and maintain a documented quality management system. *See section 21.a of the requirements*

Please provide details of how this achieved. At a minimum this must include an appendix of the quality management systems document outlining each procedure contained and an explanation for each section of the document. The department may request sections be provided in support of your application.

If attached as separate document(s), please add the name of the document or reference number here.

21.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. *See section 21.b of the requirements*

Please provide details of how this achieved.

If attached as separate document(s), please add the name of the document or reference number here.

22 Record keeping

22.a The facility must have a record keeping system in place which includes the retention of documentation for a minimum period of time. *See section 22.a of the requirements*

Please provide details of how this achieved. This should include SOPs outlining recording keeping processes utilised at the facility.

If attached as separate document(s), please add the name of the document or reference number here.

Section 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

23.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.

Please provide details of how this achieved.

If attached as separate document(s), please add the name of the document or reference number here.

24 External auditing

24.a The facility must be audited or inspected by its NPPO to ensure all systems and processes sufficiently meet Australia's requirements. *See section 24.a-24.c of the requirements*

Please provide details of how this achieved.

If attached as separate document(s), please add the name of the document or reference number here.

Section 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.

Have you attached documentation from the NPPO confirming their endorsement of your facility in compliance with the requirements and that an inspection/audit has been completed by a NPPO officer? *See NPPO endorsement of the requirements (page 20)*

Completed:

No Please do not submit this form

Yes Go to Section 13: Declaration

Section 13: Declaration

To be completed by the person named in section B of this form.

I declare that the information I have provided is true and correct. I understand that giving false or misleading information is a serious offence.

If I become aware that the information I have provided is incomplete or incorrect, I will notify the Department of Agriculture, Fisheries and Forestry as soon as practicable.

I have read and understood the [privacy notice](#) and [Privacy Policy](#).

Signature (type or sign your name) _____

Date (dd/mm/yyyy) _____

Full name _____

Privacy notice

‘Personal information’ means information or an opinion about an identified, or reasonably identifiable, individual. ‘Personal information’ that is collected under or in accordance with the *Biosecurity Act 2015* is also ‘protected information’ under the Act.

The Department of Agriculture, Fisheries and Forestry collects your ‘protected information’, including personal information in relation to this form, as required under the Biosecurity Act for the purposes of determining import conditions for your animal feed and related purposes. If you fail to provide some or all of the relevant personal information requested in this form, the department may be unable to process the import permit application that relates to this form. Information collected by the department will only be used or disclosed as authorised under the Biosecurity Act and under other relevant laws, particularly the *Privacy Act 1988*. Your personal information will be used and stored in accordance with the Australian Privacy Principles.

The department may disclose your personal information to other Australian Government agencies, persons or organisations. It will not usually be disclosed overseas. In every case it will only be disclosed if authorised by the Biosecurity Act.

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