Operational Procedure

# Laboratory Accreditation for Importation of Grapevine, Soil and Plant Diagnostic Material from High-Risk Areas

# (CA-12)

## Operational Procedure, version 3.0

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| Document Control | |
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Table 1: Revision register

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| 2.0 | 28/07/2016 | Major Revision // RE / GSC |
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# 1. Purpose

Imported plant and soil diagnostic samples pose a potential risk of introducing declared pests or disease, therefore those arriving in South Australia from high-risk areas must be certified as meeting the entry provisions of the Plant Quarantine Standard South Australia ("PQS") and handled in a Department of Primary Industries and Regions (PIRSA) Biosecurity CA-12 Accredited Laboratory.

The purpose of this Procedure is to describe the:

- the standards and procedures required for a CA-12 accredited laboratory or business importing grapevine, plant, or soil material for diagnostic or research purposes from interstate; and
- responsibilities and practices of accredited business and their personnel.

# 2. Scope

This procedure covers the importation, security, receival, storage, handling and disposal of regulated grapevine, plant, soil, and plant related material for diagnostic or research purposes prior to devitalisation or destruction by a business accredited under this Operational Procedure ("OP") in South Australia. This procedure is applicable to:

- Grapevine material and vineyard soils;
- Plant diagnostic samples;
- Soil diagnostic samples; and
- Any other plant or plant related product regulated under the Act

where these are covered by an entry requirement under the PQS.

CA-12 Accreditation includes Importer Registration and allows for approved alternate laboratory documentation or a CA-12 Diagnostic Samples Declaration form to be used instead of normal Plant Health Certification **except** for grapevine material or vineyard soil in the case it is coming from a Phylloxera Infested Zone ("PIZ") or Phylloxera Interim Buffer Zone ("PIBZ") and cannot be disinfested prior to leaving the PIZ in the destination state.

# 3. References

Table 1: Reference list

| Item | Source |
|---|---|
| *Plant Health Act 2009* | https://www.legislation.sa.gov.au/_legislation-documents/lz/c/a/plant-health-act-2009/current/2009.2.auth.pdf |
| Plant Quarantine Standard South Australia ("PQS") | https://pir.sa.gov.au/__data/assets/pdf_file/0003/464565/Plant_Quarantine_Standard_South_Australia_version_17.5.pdf |

# 4. Definitions

Table 2: Definition of terms and phrases

| Phrase | Definition |
|---|---|
| **Act** | The *Plant Health Act 2009*. |
| **Accredited Business** | A Business that complies with the conditions outlined in Section 5 of the Standard relating to an Import Verification Compliance Agreement (IVCA) with Biosecurity SA or an Interstate Certification Assurance (ICA) or Compliance Arrangement (CA) with the Department in the exporting State or Territory. |
| **Accredited Laboratory** | A laboratory accredited by Biosecurity SA under CA-12 Laboratory Accreditation to receive, process and dispose of imported diagnostic quarantine material. |
| **Accrediting Authority** | Department of Primary Industries and Regions. |
| **Accredited Laboratory** | A laboratory or other facility meeting the requirements of CA-12 accredited by the Accrediting Authority to receive regulated material for diagnostic, research or testing purposes under this procedure. |
| **Adverse Incident** | An incident involving a breach of CA-12 or DAFF Approved Arrangement procedures. |
| **Approved Arrangement** | Approved arrangements, previously known as Quarantine Approved Premises and Compliance Agreements, are voluntary arrangements entered into with the Commonwealth Department of Agriculture, Fisheries and Forestry ("DAFF"). |
| **Alternate Documentation** | Documentation which has been approved by PIRSA for use by an accredited business in place of normal certification. |
| **Authorised Person** | For the purposes of this procedure, a person who has been trained in the handling of diagnostic material and is nominated as the Certification Controller, Backup Certification Controller or Responsible Person on the accredited entities Application for Accreditation form. |
| **Authorised Signatory** | An officer of a CA accredited Business whose name and specimen signature are provided as an authorised signatory with the Business's Application for Accreditation. |
| **Business** | The legal entity(s) responsible for the operation of the facility and arrangement detailed in the Application for Accreditation and accredited under the Act. |

Table 2: Definition of terms and phrases

| Phrase | Definition |
|---|---|
| **Biosecurity SA** | Means a division of the Department of Primary Industries and Regions ("PIRSA") |
| **Compliance Plan** | A plan detailing the laboratory procedures required to meet CA-12 or DAFF Approved Arrangement requirements including the security, unique identification of samples and handling of Adverse Incidents including a Local Quarantine Emergency Plan. |
| **Certification** | A Plant Health Certificate or a Plant Health Assurance Certificate, which verifies that a consignment meets the requirements of an Interstate Certification Assurance Procedure or an interstate quarantine entry requirement. |
| **Certification Controller** | An officer responsible for preparing all the requirements to attain certification for the Business and responsible for ongoing compliance of the Business with the PHAC issued. |
| **Consignment** | A discrete quantity of diagnostic samples transported to a single laboratory or research institution at one (1) time covered by a single approved laboratory form or other certification. |
| **DAFF** | Commonwealth Department of Agriculture Food and Fisheries |
| **Declared Pest** | A pest or disease organism or pathogen declared under Section 4 of the *Plant Health Act 2009* as published in the South Australian Government Gazette and available on the PIRSA website www.pir.sa.gov.au/pqs. |
| **Department** | Department of Primary Industries and Regions. |
| **Destruction** | Any process with removes the risk of any regulated pest, disease or other pathogen remaining alive or able to transmit a disease or any other pathogenic condition to another organism. |
| **Direct Inspection** | means, unless otherwise clearly stated, an inspection of arriving machinery/equipment or for produce 2% of or 600 items/pieces from a consignment, by inspector or business under accreditation procedures to verify the pest free status or condition of the consignment. |
| **Disease** | means any plant pest / disease declared under section 4 of the *Plant Health Act 2009.* |
| **Facility** | The approved location where produce is received, handled, and disposed of and where operations covered by the CA arrangement are conducted. |
| **Grapes** | Means whole grape berries and stalks but not leaves or other parts of grapevines. |
| **Grapevines** | means plant material of any *Vitis* species (including *Vitis vinifera*, wine grape and table grape varieties, ornamental vines and American rootstock species), and is in the form of whole grapevines or part thereof, cuttings, rootlings (including grafted rootlings), potted vines or other propagules and excluding grapevine tissue cultures and grapes and grape-related material. |
| **Grapevine tissue cultures** | Means plant material of the genus *Vitis,* produced solely in accordance with Section 8 – Appendix 2 of the PQS. |
| **Inspector** | means an inspector appointed under Section 41 of the Act or an inspector appointed under equivalent legislation interstate. |

Table 2: Definition of terms and phrases

| Phrase | Definition |
|---|---|
| **Local Quarantine Emergency Plan** | A plan covering the requirements for activation in the event of a release or accident involving risk material. A copy of the plan shall be submitted with the "Application for Accreditation". |
| **PHAC** | Plant Health Assurance Certificate issued under the Act. |
| **PEZ** | A whole state or part thereof, recognised as not being infested with grape phylloxera (*Daktulosphaira vitifoliae*) |
| **PRZ** | An area of unknown grape phylloxera *(Daktulosphaira vitifoliae)* status. |
| **PIZ** | An area in which at least one vineyard known to be infested with grape phylloxera or known to have been infested with grape phylloxera *(Daktulosphaira vitifoliae)* exists. |
| **PIBZ** | A zone of 5 km radius around a new detection of grape phylloxera *(Daktulosphaira vitifoliae)* in Australia, as officially notified by the Chief Plant Health Manager in the jurisdiction in which the detection has been made, as an interim measure pending declaration of a new or amended PIZ in that jurisdiction. |
| **PIRSA** | Department of Primary Industries and Regions. |
| **Securely packed** | Securely packaged and transported in such a way to prevent spillage and to ensure easy tracking through dispatch, receival and disposal. |
| **Plant related product** | Any soil, potting mix, packaging, agricultural machinery or equipment or any other material or item declared by the Minister under Section 4 of the *Plant Health Act 2009* to be a plant related product. |
| **Plant Quarantine Standard South Australia ("PQS")** | Document established under Section 59 of the *Plant Health Act 2009* which provides the entry requirements for fruit, vegetables, plants and plant related products into South Australia. |
| **Risk material** | Any part of a grapevine, plant, plant product or soil imported under this arrangement which is potentially affected by a pest or disease or regulated under the PQS. |
| **Vineyard soil** | means earth, not limited to topsoil, from within 100 metres of an existing live commercial vine or a location where a vine was previously planted within the past 2 (two) years. |

# 5. Responsibilities

These position titles have been used to reflect the responsibilities of staff under the OP. In some businesses, one person may carry out the responsibilities of more than one position. These positions may not be present in all organisations. Staff responsible for these process control activities are called "Responsible Persons".

As a minimum, an accredited business must nominate one Certification Controller on the "Application for Accreditation" and preferably, one person to act as Backup Certification Controller.

Staff handling material under this OP must be trained by the accredited business and be listed as Responsible Persons on the Application for Accreditation form.

The **Certification Controller** is responsible for:

- Representing the laboratory or accredited business during audits and any other matters relating to this OP;
- Ensuring the laboratory or accredited business has current CA-12 accreditation and is in possession of a valid Certificate of Accreditation and endorsed Application for Accreditation issued by PIRSA;
- Ensuring staff responsible for handling material received under this OP are trained and aware of their responsibilities;
- Ensuring all Standard Operating Procedures, Compliance Plan and other records are maintained and available to all staff;
- Ensuring all staff comply with their responsibilities and duties under this OP;
- Ensuring actions taken in the event of an adverse incident are in accordance with the entities Compliance Plan which has been approved by a PIRSA Biosecurity inspector;
- Ensuring all clients intending to send material to their facility are sent the appropriate documentation for completion and return with the diagnostic samples;
- Ensuring all records specified in this OP are kept and maintained.
- The Backup Certification Controller assumes these responsibilities in the absence of the Certification Controller.

This role also performs the responsibilities of a Responsible Person.

**Responsible Persons** are required to:

- Ensure the person or organisation dispatching the sample to SA is aware:
    a. Samples must be handled and packaged in accordance with this OP, and
    b. A Diagnostic form or equivalent must be used and included; and
    c. If the sample is grapevine material or vineyard soil, ensure all documentation under Section 6.9 – 6.12 accompanies the samples into SA.
- Receive and verify the samples meet the requirements of this OP once they arrive in SA;
- Inspect each consignment of risk material on arrival to ensure the packaging has not been damaged or compromised during transit;
- Ensure all risk material received under this procedure is accompanied with valid documentation stating the origin and nature of diagnostic sample(s);
- Verify the documentation accurately describes the content and origin of the consignment;
- Unpack and check samples into the accredited businesses sample system;
- Ensure risk material received from interstate is handled, stored and disposed of in accordance with this CA;
- Ensure all records are kept and maintained in accordance with this Procedure;
- Ensure samples are maintained under secure conditions at all times from receival through to disposal;
- Immediately advise the Certification Controller of any non-conformances or adverse incidents;
- Apply corrective action in regard to consignments which do not meet the requirements of this procedure;
- Ensuring any adverse incidents are handled in accordance with this procedure and all details are recorded on the Adverse Incident Report.

## 5.1 Staff working under supervision

Staff not listed on the training register may handle diagnostic material under this procedure but must be under the direct supervision of a person nominated as a responsible person at all times while handling risk material under this OP.

# 6. Requirements

A business accredited under this arrangement must ensure all samples received at the accredited facility meet the requirements stipulated by this procedure before releasing them for diagnostic or research use by:

- Ensuring every consignment is accompanied with a completed copy of the Diagnostic Sample Declaration form or equivalent completed in full by the person dispatching the samples;
- Ensuring the packaging requirements of this OP have been met, packages are intact on arrival and have not leaked while in transit;
- Ensuring packages are labelled in accordance with this OP;
- Ensuring the number of samples stated on the declaration or laboratory form reconciles with the number received;

- Ensuring corrective action is taken in the event a sample or consignment does not meet the conditions of this OP;
- Ensuring all samples are received, verified, stored, handled, recorded and disposed of in accordance with this OP;
- Ensuring all packages are dispatched or couriered in such a way as to ensure they are fully traceable from origin to destination;
- Notifying PIRSA immediately in the event of an adverse incident;
- Maintaining all files and records required under this OP for audit purposes;
- Ensuring the Certification Controller or Backup Certification Controller are available for any audits;
- Submitting annual returns prior to the due date; and
- Paying all PIRSA charges and fees associated with CA-12 in accordance with PIRSA trading terms.

## 6.1 Compliance plan

Prior to commencing operation under this CA, the accredited business must supply PIRSA Biosecurity with a copy of their documented procedures for ensuring compliance with this OP.

This document must detail the procedures for secure receipt, handling, unique identification, storage and disposal of diagnostic samples from interstate sources as well as any inter or intrastate movements of samples between labs post-entry to SA.

This document must describe the procedures the accredited business would take in the case of an adverse incident (see **Attachment 6**). The document must be readily available to all staff undertaking duties under this OP.

This document must be made available for audit purposes and a new copy provided to PIRSA when amendments are made.

## 6.2 Adverse Incidents

Adverse incidents may occur at any stage from dispatch through to destruction of the sample after testing. These may result from:

- Accidental spillage;
- Accidental release into the environment;
- Breach of the conditions imposed by this CA or any other stipulated conditions;
- Equipment failure;
- Inadequate containment facilities;
- Improper handling, packaging or labelling of risk material;
- Untrained staff handling risk material.

As well as a Compliance Plan (**Section 6.1**), laboratory facilities should already have safety manuals and standard operating procedures appropriate for the activities undertaken at that facility.

The containment of any quarantine hazard that may be associated with any adverse incident that occurs is the priority of these procedures.

## 6.3 Facility plan

The accredited business or laboratory must supply a scale diagram of the facility with their Application for Accreditation. This diagram must include:

- Locations where risk material is stored;
- Work areas where risk material imported under this CA is analysed;
- Disposal areas for risk material; and
- Entry and Exits points

## 6.4 Training register

The names and specimen signatures of persons trained as responsible persons to handle diagnostic material under this CA, along with the date training was completed must be recorded on the training register or equivalent (**Attachment 2**).

Staff listed on the training register must be nominated as Responsible Persons on the accredited entities endorsed Application for Accreditation form.

## 6.5 Diagnostic sample declaration or equivalent

An accredited business must ensure a copy of the Diagnostic Sample Declaration form (**Attachment 7**) and packaging and labelling requirements in **Section 6.16** are provided to and completed by the person or organisation collecting non-grapevine material or vineyard soil interstate. This must accompany the samples into SA.

Alternatively, an equivalent form (such as the Accredited Facilities own lab sample form) may be used if it contains the information described below and has been approved in writing by PIRSA.

If using an equivalent form, a copy must be supplied to PIRSA prior to Accreditation being granted and whenever any modifications are made to the design.

As a minimum this form must contain:

- The name of the business or person who has consigned the sample(s);
- Telephone contact details of the business/person interstate responsible for the samples;
- Address of the person or interstate organisation completing the document;
- The number of samples included in the consignment;
- A description of the sample packaging (plastic bag, container etc.);
- The type of sample the consignment contains;
- A description of the material being collected (soil, leaf material, roots etc.);
- The street address or addresses the samples were collected from;
- The date samples were collected;

- The name of the Accredited Laboratory receiving the samples in SA;
- Whether or not the sample has been disinfested using an SA approved method prior to being dispatched; and
- A section where the person can sign and date the form as being true and correct.

A copy of this completed form must accompany the consignment into South Australia and be retained for audit purposes.

## 6.6 Commonwealth Department of Food and Fisheries Approved Arrangements

If an accredited laboratory holds a DAFF Approved Arrangement, proof of this must be supplied to PIRSA Biosecurity prior to accreditation being granted.

CA-12 Accreditation is still required in this situation. PIRSA will conduct two compliance audits in the first year dropping to one in subsequent years if no non-conformances are found at audit.

## 6.7 Grapevine material or vineyard soil from a PRZ, PIZ or PIBZ (disinfestation prior entry to SA)

**Section 6.7** covers the importation of grapevine material or soil from a PRZ, PIZ or PIBZ where the samples can be disinfested prior to dispatch to an accredited CA-12 laboratory **prior** to entering SA.

See **Section 6.8** for cases where disinfestation prior to entry is likely to affect the accuracy or effectiveness of the diagnostic testing or research.

If disinfestation can take place before samples are dispatched to SA, one or more of the methods listed below must be used before samples are securely packed prior to moving out of a PRZ, PIZ or PIBZ:

i. Freezing and then being held at -18ºC for 24 hours and packed with an ice pack for transport.
ii. Freezing and transfer under liquid nitrogen at – 196°C
iii. Freeze drying
iv. Oven drying at 45°C for a minimum of 120 minutes **Note:** Probes must be used with large samples to ensure middle of sample has reached the required temperature for the required time. Bulky samples must be spread out on trays prior to placing in oven to increase surface area exposed to the heat
v. Hot water treatment at 54°C ± 1°C for 5 minutes, or 50°C ± 1°C for 30 minutes
vi. Fixative – devitalisation using formalin / acetic acid, glutaraldehyde, or 70% ethanol
vii. Gamma irradiation at 50 grays in an approved facility
viii. For juice samples either
    - Filter, centrifuge or cold settle to ensure remaining particles are less than 50 microns in size; or
    - Freezing and then being held at -18°C for 24 hours and packed with an ice pack for transport; and
    - Sealed in an unbreakable container.

## 6.8 Grapevine material or vineyard soil from a PRZ, PIZ or PIBZ (where disinfestation is not possible prior to entry to SA)

Where disinfestation in accordance with **Section 6.7** has been proven to compromise a specific diagnostic test or the intended research use, diagnostic samples must not be sent to SA unless:

- Prior, written approval from the Chief Plant Health Inspector, in the form of a Plant Health Import Certificate or delegate which sets out the specific conditions and requirements for that importation has been issued; and
- The samples have been securely packaged in accordance with **Section 6.16**

## 6.9 Interstate permits for grapevine material or vineyard soil from a PRZ, PIZ or PIBZ

A permit must be issued by the Chief Plant Health Officer (Victoria) or by the Principal Director Biosecurity, or Director Compliance Operations (NSW) or their delegates prior to any samples leaving a PRZ, PIZ or PIBZ.

This is not a requirement under the SA PQS, this is an internal requirement of both Victoria and New South Wales before any grapevine or soil material leaves a PRZ, PIZ or PIBZ within their state boundaries. Penalties may apply if a permit is not obtained.

## 6.10 Grapevine material from a PEZ

Consignments from a PEZ must be accompanied by a copy of the CA-12 Diagnostic sample Declaration Form or equivalent. No other certification is required.

## 6.11 Soil from a vineyard or within a PEZ

Soil samples collected from a vineyard within a PEZ, or within 100 metres of any commercial grapevine or where grapevines have previously been planted within the last 2 years, must be accompanied by either the completed Diagnostic Sample Declaration (**Attachment 7)** or equivalent issued by the accredited business and securely packaged in accordance with **Section 6.16** prior to dispatch.

## 6.12 Soil samples collected 100 metres or more from a vineyard or live grapevine outside of a PRZ, PIZ or PIBZ

Soil diagnostic samples collected more than 100 metres from a vineyard or grapevine within a PEZ must be accompanied by a Biosecurity SA Soil Declaration of Source Form (available from the PIRSA website) and require no other documentation, provided they are not being collected in an area considered high risk for another declared pest or disease under Condition 20 of the PQS or by any other condition.

## 6.13 Areas considered high risk for soil movement

Areas considered high risk for soil movement under the PQS are:

- Vineyards (vineyard soil being soil within 100 metres of an existing live commercial vine or soil where a vine had been previously planted in the past 2 years), PIZ's, PIBZ's, and PRZ's (Condition 7 of the PQS);
- Areas described in Condition 2 of the PQS affected by Red Imported Fire Ant *(Solonopsis invicta)*;
- Land infested with or linked to a Potato Cyst Nematode *(Globodera pallida and G. rostochiensis)* (Condition 18 of the PQS);
- Areas or properties infected with *Fusarium oxysporum* Race 3 of tomato plants (Condition 21 of the PQS);
- Areas or properties infested with Green Snail *(Helix aperta)* (Condition 23 of the PQS);
- A PSTV'd (Potato spindle tuber viroid) infested or linked property used for growing potatoes (Condition 18A of the PQS); and
- Any property not covered by an Area Freedom Certificate for Tomato Potato Psyllid and CLSo (Condition 17 of the PQS).

If there is any doubt over whether there are, or have been, grapevines within 100 metres of the sample collection point, within the previous 2 years, it must be assumed that there have been grape vines present and the requirements of **Section 6.11** must apply.

## 6.14 Regulated plant material other than grapevine samples

All plant material regulated and covered by an entry condition in the PQS must be handled in accordance with this OP.

On receival of any plant diagnostic material, refer to Section 4 of the PQS "Index of Conditions of Entry / Regulated Movement" to verify the requirements for the plant material being imported under CA-12 before releasing the samples for work in the laboratory or institution.

## 6.15 Machinery or equipment used for sample collection interstate and being brought back into SA

Any machinery or equipment, including hand tools, used for sample collection and being brought back into SA after use interstate must be clean and free of any soil or plant material before entering or re-entering SA.

A PIRSA Machinery Declaration (**Appendix 9** of the PQS, which also applies to equipment) must be completed for any machinery or equipment used in the collection of samples interstate outside of a high-risk area as defined in **Section 6.13**.

Additional requirements apply for machinery or equipment used in a high-risk area and these are outlined in Condition 27 of the PQS.

## 6.16 Packaging and labelling

All risk material must be packed securely by the dispatching person or organisation interstate.

Samples must:

- Be double bagged and sealed to prevent leakage;
- Be placed inside a hard, durable container to prevent damage during transport; and
- Have a label affixed containing a brief description of the contents or a unique identification code.

The label on the outside packaging or courier bag must:

- State that the package contains Quarantine Material and contain a brief description of the contents;
- Show the accreditation number of the business receiving the samples in SA;
- Show the delivery address of the Accredited Facility the samples are being couriered to in SA; and
- The full contact details including telephone number of the person or organisation who dispatched the sample.

The label must be attached to the outermost layer of the package in a manner that prevents it from being dislodged or damaged during transit.

All lettering must be a minimum of 5 mm in height and be clearly legible.

The sample(s) shall then be transported to the Accredited Facility by courier or via personal carriage. Diagnostic material must be sent via a system which allows tracking from dispatch through to receival.

These packaging and labelling requirements must be provided to the sender along with a Diagnostic Sample Declaration Form (**Attachment 7)** or equivalent.

## 6.17 Receival and verification of samples

Accredited businesses must document and maintain agreed procedures for the secure receival and verification of diagnostic material imported under this procedure.

A Record of Receipt and verification information must be maintained using either an electronic or manual system. This record must be available at audits and include:

- Date of Receipt;
- Name and address of consigner;
- Treatment applied before dispatch (if applicable);
- Sample identification code or number;
- A description of the sample (plant, grapevine or soil material);
- Origin/region source address of sample;
- Quantity (number, volume or weight) of the samples;

- Name of the Responsible Person entering the record; and
- Signature.

## 6.18 Signage of areas

All areas used for the handling, storage and disposal of Diagnostic material imported under this CA must be clearly marked.

Signs must have a yellow background with black lettering.

### 6.18.1 External structures

All laboratories where risk material is handled or stored must display a sign with the wording **"Biosecurity Area"**.

Signs on external structures must be a minimum of 600 mm x 400 mm with the lettering a minimum of 25 mm in height. They must be weatherproof and resistant to the elements.

### 6.18.2 Internal structures

All cabinets, cool-rooms, doors, cages and storage areas where risk material is stored, handled, treated or inspected must display a **"Biosecurity Area"** sign unless the entire laboratory is accredited and secured using locks or swipe cards.

Signs within structures must be a minimum 295mm x 210mm with lettering a minimum of 8 mm in height.

## 6.19 Laboratory Area

The laboratory area must meet the following criteria:

- The laboratory area must be in a clearly delineated and separate lockable or otherwise secured room;
- All buildings and structures must be maintained in a state of good repair;
- Access to material imported under this CA must be strictly limited to staff nominated on the endorsed Application for Accreditation form;
- Risk material imported under this CA must be kept clearly identified and separate from all other material. If other materials are to be analysed in the same area, then all material is to be treated as risk material;
- All equipment used in the analysis of risk material must be sanitised immediately afterwards by a method approved by PIRSA Biosecurity;
- All protective clothing (including gloves) used in the analysis of risk material must be disposed of in line with **Section 6.22** or sanitised through high temperature laundering or in another manner approved by PIRSA;
- Laboratory areas must be kept clean at all times; and
- Any waste material, including packaging associated with imported diagnostic material must be cleaned up immediately and disposed of in accordance with this CA.

## 6.20 Storage of Imported Diagnostic Material

All material imported under this CA must be held within a secure storage area until completion of analysis.

The storage area must be large enough to contain the largest consignments expected and must be clearly marked with the wording “Quarantine Area – Restricted Access”.

The storage area must be kept securely locked when unattended and after-hours access must be limited to persons nominated on the endorsed Application for Accreditation form and Training Register **(Attachment 2)**.

## 6.21 Destructive analysis

Please contact PIRSA if you would like approval for any destructive analysis technique. PIRSA may request documentary evidence proving that the technique is destructive and mitigates the risk of any material containing any viable declared pest or disease material capable of infecting another organism.

Once sample material has been subjected to an approved destructive analysis technique, samples are no longer required to be handled under this procedure as any risk has been mitigated. Details must be recorded on the Diagnostic Material Disposal form (**Attachment 5**).

## 6.22 Disposal of diagnostic material

Diagnostic material, including any solid residues or packaging must be destroyed or disinfested using one of the following methods.

The following methods are suitable for the destruction of all diagnostic material.

### 6.22.1 Autoclaving

Diagnostic material can be disposed of by autoclaving it at 121°C for 30 minutes.

### 6.22.2 Deep burial

Diagnostic material can be disposed at a DAFF deep burial facility (QAP) or a PIRSA Biosecurity approved facility. Prior to using deep burial for soil disposal, the accredited business must obtain proof that the facility is accredited for deep burial and have this documentation available for auditing purposes.

A record of disposal must also be obtained to provide auditable proof of deep burial.

### 6.22.3 Formalin Saturation (excluding Grapevine Material and Vineyard Soil)

Samples can be saturated with a solution of 1% formalin for 8 hours.

#### 6.22.4 Heat Treatment

Diagnostic material can be disinfested or destroyed by dry heat treatment. The temperature must be held at 121°C for 2 hours.

#### 6.22.5 Incineration

Diagnostic material can be disposed of at a DAWR or PIRSA Biosecurity approved incineration facility.

#### 6.22.6 Irradiation (excluding Grapevine Material and Vineyard Soil)

Diagnostic material can be irradiated at 5 megarads at a facility approved for this purpose.

All liquid effluent shall be disposed of through the sewerage or other systems approved by Accrediting Authority.

## 6.23 Grapevine Material and Vineyard Soil

Grapevine material, vineyard soil and associated plant material can be disinfested or disposed of by:

- Freezing and then being held at -18°C for a minimum of 24 hours;
- Freeze drying;
- Oven drying at 45°C for a minimum of 120 minutes (using probes for large samples to ensure the entire sample has reached the target temperature and spreading samples out on trays prior to placement in oven);
- Hot water treatment at 54°C ± 1°C for 5 minutes, or 50°C ± 1°C for 30 minutes;
- Devitalisation using formalin/acetic acid, glutaraldehyde or 70% ethanol;
- Gamma irradiation at 50 grays in an approved facility; or
- Autoclaving at 121°C for 30 minutes

## 6.24 Disposal records

Disposal and treatment records must be retained for all material destroyed.

Details of the destruction must be recorded on the accredited facilities Diagnostic Material Disposal form (**Attachment 5** or PIRSA approved equivalent documentation or system).

This document or system must include the following information:

- Sample identification number or code;
- A description of the tests performed on the sample;
- Destruction method;
- Date the samples were destroyed; and
- Signature of Responsible Person to verify the sample has been destroyed and disposed of.

Prior to disposal, material must be kept sealed and stored in a secure part of the accredited facility and be clearly marked as “Quarantine Material”.

## 6.25 Inter and Intra laboratory movement within SA

Any movements of risk material between accredited businesses or laboratories within SA must follow the same requirements as if they were being imported from interstate.

This includes maintaining records to enable any samples of risk material to be completely traceable back to their interstate origin, and which accredited laboratories or businesses have handled them previously.

All movements, through to destruction, must be recorded on the record of receipt or equivalent document or electronic system.

# 7. Procedure

## 7.1 Receival of samples from interstate

Before releasing samples received from interstate, a nominated Responsible Person must conduct the following verifications before samples can be released for use at the facility.

A copy of the latest PQS and this OP must be available as a reference to ensure all samples received meet SA entry conditions.

An up-to-date copy of the PQS is available at http://www.pir.sa.gov.au/planthealth. This is always the most current version of South Australia's entry conditions and is considered the master copy. It should be checked regularly for any updates and any printed copies regarded as a backup in case the web version cannot be easily accessed.

## 7.2 Quarantine direction orders

Before physically inspecting consignments, the responsible person must verify whether a consignment is subject to any Quarantine Direction Order(s) ("QDO") and rectify any non-conformance(s) before samples can be inspected and released.

Until a responsible person has verified samples are not subject to a QDO the consignment is regarded as being quarantined under Section 43 of the Act.

Should samples arrive under a QDO the directions issued on the order must be strictly followed. Fines apply for disobeying a QDO and not following the directions can also be grounds for cancellation or suspension of CA-12 accreditation and could result in prosecution.

If a samples arrive under a QDO the Responsible Person must, before releasing the samples, ensure the requirements of the QDO are fully met. If there are any doubts or concerns, call PIRSA for advice.

The following steps must be taken when resolving a QDO:

- Complete the bottom section of the QDO form and sign in the required space to attest the requirements have been fully met;
- Enter the details of the QDO and remedial action in the **Adverse Incident Report (Section 6.2)** and advise PIRSA as soon as practicable. Please note that if PIRSA are not advised within 24 hours, costs incurred in follow-up activity can be recovered;
- File the completed QDO form with the relevant documentation (any Plant Health Certification, Declarations or laboratory documentation) for record keeping; and
- Fax a copy of the QDO to PIRSA on 08 8207 7844 or scan and email to PIRSA.PlantHealthMarketAccess@sa.gov.au;

## 7.3 Ensure the package is labelled correctly

- Ensure all required labelling as specified in **Section 6.16** is on the packaging;
- Inspect each package to ensure it has not been damaged or has leaked during transit;
- Verify samples have been double bagged and sealed;
- Check to ensure that all documentation relating to the samples is present on or inside the package; and
- Immediately enter the details on the Accredited Facilities Record of Receipt (**Attachment 3**) or equivalent system (such as a Laboratory Information Management System "LIMS").

If the package has leaked, or any information is missing, the samples must be quarantined until the matter is resolved. If there has been any leakage of the package during transport or at the facility, contact PIRSA on 08 8207 7814 for further instruction.

## 7.4 Verify presence of regulated plant or plant related material

Verify whether the container or package contains any Plant or Plant Related Product listed in PQS Index and therefore requires a valid Certificate, Declaration, Laboratory sample documentation or other proof of origin.

## 7.5 Verify the authenticity and validity of any documentation

Verify consignment is accompanied by the correct documentation. All documentation must be filled in accurately and completely. Specific requirements for the diagnostic or research samples handled under this OP are described below.

### 7.5.1 Grapevine plant material or vineyard soil from a PEZ

Samples can be accompanied with either:

- The accredited laboratory's PIRSA approved sample form which has been completed in full and signed by the person or business interstate who collected and dispatched the sample; or
- A completed copy of the PIRSA CA-12 Diagnostic Sample Declaration Form (**Attachment 8**)

### 7.5.2 Grapevine material or soil (disinfested prior to entry) from a PRZ, PIBZ or PIZ

- The accredited laboratory's PIRSA approved sample form which has been completed in full and signed by the person or business interstate who collected and dispatched the sample; or
- A completed copy of the PIRSA CA-12 Diagnostic Sample Declaration Form (**Attachment 7**)

Documentation must also clearly state the disinfestation process used before the samples were dispatched to SA.

A permit must be issued by the interstate quarantine authority prior to samples leaving a PRZ, PIBZ or PIZ.

### 7.5.3 Grapevine material or soil (which could not be disinfested prior to entry) from a PRZ, PIBZ or PIZ

- A Plant Health Import Certificate ("PHIC") signed by the Chief Plant Health Inspector or delegate clearly stating the measures which must be taken regarding the collection, packaging and handling of the samples once they arrive in SA; and
- A Plant Health Certificate issued by an inspector interstate certifying the samples have been collected and packaged in accordance with the PHIC and the street address or addresses the samples were collected

A permit must also be issued by the interstate quarantine authority prior to samples leaving a PRZ, PIBZ or PIZ.

### 7.5.4 Soil from a PEZ or more than 100 metres of a vineyard or location where commercial grapevines were previously planted within the last 2 years

- The accredited laboratory's PIRSA approved sample form which has been completed in full and signed by the person or business interstate who collected and dispatched the sample; or
- A completed copy of the PIRSA CA-12 Diagnostic Sample Declaration Form (**Attachment 7**)

### 7.5.5 Soil or plant material from a high risk area

Any soil collected from within one of the high-risk areas defined in **Section 6.13** other than grapevine material or soil which are covered in **Sections 6.7 – 6.12** require:

- The accredited laboratory's PIRSA approved sample form which has been completed in full and signed by the person or business interstate who collected and dispatched the sample; or
- A completed copy of the PIRSA CA-12 Diagnostic Sample Declaration Form (**Attachment 7**)

### 7.5.6 Plant material (excluding grapevine samples) from outside of a high risk area

Any plant material collected from outside of a high-risk area as defined in the PQS and the areas defined in **Section 6.13** of this OP require:

- The accredited laboratory's PIRSA approved sample form which has been completed in full and signed by the person or business interstate who collected and dispatched the sample; or

- A completed copy of the PIRSA CA-12 Diagnostic Sample Declaration Form (**Attachment 7**)

### 7.5.7 Soil from (excluding vineyard soil) outside of a high risk area

Any soil from outside of a high-risk area as defined in the PQS and the areas defined in Section 6.13 of this OP requires:

- The accredited laboratory's PIRSA approved sample form which has been completed in full and signed by the person or business interstate who collected and dispatched the sample; or
- A completed copy of the PIRSA CA-12 Diagnostic Sample Declaration Form (**Attachment 7**); or
- A completed Soil Declaration of source form (See **Attachment 10** of the PQS).

Soil from outside of a high-risk area accompanied by a Soil Declaration of source form does not require handling under this OP.

Any equipment (including hand tools and technical equipment) used in the collection of vineyard samples, including any vine material or soil from a **PEZ, PRZ, PIZ or PIBZ** must be accompanied by a Plant Health Certificate certifying it has been cleaned and sterilised in accordance with the PQS.

## 7.6 Sample inspection

Ensure all samples listed on the documentation accompanying the package are present in the package by comparing the number provided in the documentation with what is present in the package.

If there are any discrepancies, contact the person sending the samples to determine the cause, including cases where there is no sign of the package being damaged or opened during transit.

All sample packages must be inspected at the rates provided below to ensure all are labelled correctly and correlate with any declarations, PHIC's or PHC's.

Table 3: Sample inspection rates

| Number of packages | 2% inspection rate |
|---|---|
| 1-5 | 100 % of one (1) package, or equivalent |
| 6-10 | 100 % of two packages or equivalent |
| 11-150 | 100% of three packages, or equivalent to achieve 2% inspection rate |
| >150 | 100% of one (1) in 50 packages or equivalent |

## 7.7 Release of verified consignments

If the consignment has the correct documentation and the samples meet the conditions of the SA PQS, prior to releasing the consignment the Responsible Person must;

- Certify/verify on the reverse side of the accompanying verified Declaration, PHIC or PHC by;
    - stamping (or writing) “Inspected and Verified”,
    - stamping or writing the date, and
    - signing.

Samples can then be released for use in the laboratory and documentation must then be filed at the laboratory facility in date order for audit purposes.

A consignment that fails the verification process described under **Section 7** and its sub sections must be considered **non-conforming.**

## 7.8 Non-conforming consignments

Consignments will be regarded as non-conforming and unable to be released if:

- The accompanying certification is not a valid Declaration, Approved Laboratory form, PHC or PHAC;
- Certification cannot be obtained for the consignment or part consignment;
- The certification is incorrectly completed;
- The composition of the consignment differs from that stated in the certification;
- Any package in the consignment is unlabeled or incorrectly labelled;
- Pests are present or suspected; or
- The business or person which consigned the samples to SA is currently suspended from sending produce into South Australia.

If regulated pests or diseases are suspected or found to be present, the consignment must be held in a secure area physically segregated from other consignments and PIRSA informed immediately.

### 7.8.1 Control of non-conforming consignments

If the original documentation is not provided with the consignment at the time of receipt or if the errors or omissions the **Responsible Person** shall;

- Secure the non-conforming consignment in the facilities designated quarantine area and ensure that it is not tampered with, used or moved;
- Record the relevant details on the “**Sample Incident Record**” (**Attachment 4)** noting any irregularities with certification or consignments in the comment’s column; and
- Attempt to obtain the correct documentation by the end of the next working day to enable release of the samples.

### 7.8.2 Corrective action resolution

If correct documentation can be obtained by the end of the next working day the **Responsible Person;**

- Shall stamp, date and sign on the reverse side of the documentation and file in date order for audit purposes; and
- Consignment can be released for use in the laboratory;

If correct documentation cannot be obtained within 24 hours, the **Responsible Person** shall;

- Leave the consignment in the designated quarantine area and contact PIRSA to discuss options; and
- Record and update the relevant details on the **"Sample Incident Record (Attachment 4)"** and
- Notify PIRSA of the non-conforming consignment by the end of the working day.

Upon notification, PIRSA will confirm the non-conformity, determine appropriate action and issue further direction in writing.

In the event non-conforming consignments are found to have been released, the business must, at its expense, retrieve and quarantine the consignment for presentation to PIRSA. Such release can also incur penalty or prosecution.

PIRSA may also seek to recover costs incurred from any follow-up activity such as investigations or destruction of the affected samples.

## 7.9 Authenticated copies of documentation

An authenticated copy of documentation may be provided as a means of verifying the quarantine status of plant or plant related product in situations where the original declaration, certificate or PHIC is absent or lost.

The copy must be signed, dated and endorsed with "This is a true and correct copy of the original" at the top of the document by the inspector or person who issued the original documentation.

## 7.10 Use in the laboratory

Ensure only staff listed on the **Training Register (Attachment 2)** handle diagnostic material under the CA-12 OP. Other staff may handle and work with sample material, however they must be under the direct supervision of someone trained and listed on the Training Register**.**

If not in use, or staff are not present, the laboratory must be secured to prevent unauthorised individuals accessing the samples.

All work surfaces and equipment must be kept clean and any protective clothing laundered in accordance with **Section 6.19.**

## 7.11 Disposal of samples or sample material

Samples must be disposed of in clearly marked bins in accordance with **Section 6.22** the Diagnostic Material Disposal Form **(Attachment 5)** or PIRSA approved equivalent, updated.

## 7.12 Adverse Incident

In the event of an adverse incident, such as a spillage or uncontrolled release of sample material, see (**Section 6.2**) immediately contain the material if it is safe to do so in accordance with the laboratory **Compliance Plan** (see **Section 6.1**) and immediately inform the **Certification Controller.**

The **Certification Controller** must then inform PIRSA within 24 hours of the incident occurring.

The business will be required to complete and lodge an Adverse Incident Report with PIRSA.

# 8. Accreditation

PIRSA may accredit a business to implement a CA-12 arrangement provided that the business complies with the requirements of this CA-12 OP.

## 8.1 Application for accreditation

### 8.1.1 Certificate of accreditation

An accredited Business will receive a Certificate of Accreditation detailing the facility location, OP, scope (type of produce and chemical covered) and period of accreditation.

The Business must maintain a current Certificate of Accreditation and make this available on request by an Inspector.

A Business must not commence or continue certification of produce under the CA-12 arrangement unless it is in possession of a valid and current CA-12.

## 8.2 Audit process

### 8.2.1 Initial audit

Prior to accrediting a Business, an Inspector carries out an initial audit of the Business to verify the CA-12 system is in place and capable of operating in accordance with the requirements of the OP, and the system is effective in ensuring compliance with all specified requirements.

On completion of a successful initial audit, applicants will be granted accreditation and posted or provided with a Certificate of Accreditation.

### 8.2.2 Compliance audits

Compliance audits are conducted to verify that the CA-12 system continues to operate in accordance with the requirements of the OP.

Compliance audits are, wherever practical, conducted when the CA-12 system is operating.

A compliance audit is conducted within four weeks of the initial audit or receipt of the first samples received and cleared under this arrangement.

On completion of a successful compliance audit, annual accreditation is granted to cover the current season, up to a maximum of twelve months from the date of initial accreditation, and a new Certificate of Accreditation issued.

A compliance audit is conducted between six and nine months after the date of accreditation for an CA-12 arrangement that operates for more than six months of the year.

### 8.2.3 Random audits

Random audits are conducted on a selected number of accredited Businesses each year. Random audits may take the form of a full compliance audit, or audits of limited scope to sample treatment mixtures, certified produce, CA-12 system records or CA-12 system documentation.

Unscheduled compliance audits may be conducted at any time to investigate reported or suspected non-conformances.

## 8.3 Non-conformance and sanctions

### 8.3.1 Non-conformances

The above audits are intended to evaluate the business against the Requirements (**Section 6**) and Procedures (**Section 7**) to ascertain the business is effectively implementing the requirements of CA-12 accreditation.

If the auditor detects failure to meet one or more requirements needed for accreditation, the auditor must raise a non-conformance report (NCR). If the NCR report indicates the integrity of the accreditation has been significantly compromised, the NCR may provide grounds for suspension or cancellation of the accreditation of the business.

### 8.3.2 Types of non-conformances

Non-conformities are categorised as minor, major or critical.

A minor non-conformance is one which does not compromise the effectiveness of the operational or assurance procedures but which varies sufficiently or is omitted from the documented procedure so as to be regarded as irregular. One example would be an occasional failure by the business to keep accurate records.

A major non-conformance is one, which compromises the integrity of the system and is likely to increase the risk of a breakdown in procedures. One example would be inadequate verification of samples and record keeping procedures.

A critical non-conformance relates to the failure by the business to carry out operational and documentation procedures that are crucial to the effectiveness of the system. Examples include deliberate and/or repeated failures to collect and verify certification accompanying consignments or to knowingly clear or release non-conforming samples, or knowingly release samples infested with a regulated pest.

### 8.3.3 Actions following detection of non-conformances

**Minor non-conformances**

Repeated minor non-conformances of a similar nature may result in the issue of a major non-conformity at subsequent audit.

**Major non-conformances**

Detection of a major non-conformity will result in a follow up audit and may lead to temporary suspension of the CA-12 until the problem is investigated and rectified. If the problem is not rectified the non-conformity may be termed critical. The issue of a major non-conformity may lead to an investigation and possible prosecution of the Business for being in breach of legislation.

**Critical non-conformances**

The confirmation of a critical non-conformity may result in very intensive auditing of the CA-12, or suspension or cancellation of accreditation, or the instigation of other verification arrangements as determined by PIRSA. It may lead to an investigation and possible prosecution where a breach of the legislation can be confirmed.

Physical or verbal abuse or aggressive behaviour towards an Inspector, or otherwise hindering the audit process is an offence under the Act and may also incur a critical non-conformance and / or result in immediate cancellation of the CA-12.

### 8.3.4 Suspensions and cancellations

PIRSA may suspend or cancel an accreditation of a business if it found that the business has:

- Failed to rectify an NCR;
- Provided false or misleading information during audits;
- Failed to meet accreditation requirements to handle material under this CA-12; or
- Failed to pay fees owed to the Department

See Section 24 of the Act for a complete list of grounds for cancellation. Businesses may also voluntarily surrender their accreditation. All outstanding fees owed to the Department must be settled.

### 8.3.5 Charging policy and prosecutions

The Department will charge fees (set by the Department) to the business for all audits and investigations carried out by its staff and/or contractors. Businesses are required to settle their account in a timely manner (within 14 days of notice – See Section 21 of the Act). The Department is entitled to recover fees and fines through prosecution. See Section 25 of the Act for offences related to accreditations.

## 8.4 Re-accreditation

Accredited Businesses are required to re-apply for accreditation each year the business seeks to operate under the CA-12 arrangement. Businesses seeking re-accreditation must lodge a renewal application prior to accreditation lapsing, or if accreditation has lapsed, prior to commencing further receival, verification and use of diagnostic material under the CA-12 arrangement.

A compliance audit is conducted each year within twelve weeks of the Business commencing treatment of produce following re-accreditation.

Re-accreditations after suspension or cancellation will also be preceded by audits.

An accredited Business will receive a Certificate of Accreditation for an CA-12 detailing the scope of the arrangement including;

- the facility location;
- the Operational Procedure;
- any restrictions on the accreditation such as the type of diagnostic material covered;
- the period of accreditation.

The Business must maintain a current Certificate of Accreditation ("COA") and make this available on request by an Inspector.

A Business may not commence or continue receiving diagnostic material under the CA-12 arrangement unless it is in possession of a valid and current COA for the diagnostic material covered by this OP.

## 8.5 CA-12 system documentation

The Business shall maintain the following documentation:

- a copy of the Business's current endorsed Application for Accreditation;
- a current copy of this Operational Procedure;
- a current Certificate of Accreditation for an Interstate Certification Assurance Arrangement.

CA-12 system documentation must be made available on request by PIRSA.

## 8.6 CA-12 system Records

A laboratory or business accredited for CA-12 must maintain sufficient records to ensure backward and forward traceability for any diagnostic samples it has received and subsequently disposed of.

System records can be stored either in hard copy or electronically must be easily accessible and available at audits.

The forms included in the appendices should be used, however if a similar document or system already exists for capturing this information, this can be used instead provided it captures all of the required information and approved by PIRSA Biosecurity.

All records must be easily accessible and available for auditing purposes.

All records and documents must be retained for 12 months and be made available to a PIRSA inspector upon request.

The following documentation must be maintained

- Record of Receipt;
- Diagnostic Material Disposal Form;

- Training Register;
- Adverse Incident Report Form;
- Endorsed Application for Accreditation Form;
- Certificate of Accreditation;
- A copy of the CA-12 Compliance Arrangement Operational Procedure;
- The Compliance Plan and Local Quarantine Emergency Plan;
- Declarations / Certification received; and
- Current DAFF Approved Arrangement documentation – if applicable.

# 9. Attachments

Table 8: List of appendices

| Appendix | Title |
|---|---|
| Attachment 1 | Application for Accreditation Form |
| Attachment 2 | Training Register |
| Attachment 3 | Record of Receipt |
| Attachment 4 | Sample Incident Record |
| Attachment 5 | Diagnostic Material Disposal Form |
| Attachment 6 | Adverse Incident Report Form |
| Attachment 7 | Diagnostic Sample Declaration Form |

The above list of Appendices form part of the CA-12 Operational Procedure and must be read and used in conjunction with all sections as listed above. The format of any of the appendices may be subject to change by PIRSA at any time.

This CA-12 OP, and accurate up to date associated information and subsequent updated versions and associated documentation (Act, PQS etc.) may be accessed on the PIRSA website at www.pir.sa.gov.au/ica or www.pir.sa.gov.au/planthealth

Additional clarification or advice is available from PIRSA on (08) 8207 7814.

Government of South Australia
Department of Primary Industries and Regions

**ACCREDITATION / REGISTRATION APPLICATION**
**Plant Health Act 2009**
**ICA/CA Accreditation Sec 16 / Registration Sec 26**

**APPENDIX 1**
***ICA / CA / IR***

**APPLICATION for ACCREDITATION / REGISTRATION or ANNUAL RETURN (ICA / CA / IR)**

## Attachment 1 - APPLICATION for ACCREDITATION or ANNUAL RETURN (CA)

**Complete clearly and return to Biosecurity SA - Plant Health Operations, 33 Flemington St, Glenside SA, 5065.**
**Or email scanned completed copy to PIRSA.PlantHealthMarketAccess@sa.gov.au**
**(Please print. See Conditions / Application Instructions on pages 2 and 3 of this Application.**

**Type of application being made** (Tick or mark one): ☐ **Annual Return** ☐ **New** ☐ **Amendment**

NOTE; This application can only cover one Procedure (Arrangement) at one Facility

Has Business previously been registered for movement of produce? ☐ Yes ☐ No
If yes, provide Interstate Produce (IP) Number (& Facility number).

| S | | | | | - | | |
|---|---|---|---|---|---|---|---|

**Operational Procedure / Arrangement** (# Arrangement details must be included - see note on page 3)

| ICA/CA/IR Number | | Title of Arrangement Operational Procedure or Registration * |
|---|---|---|
| **CA** | **12** | **Accreditation for Importation of Grapevine, Soil and Plant Diagnostic Material from High-Risk Areas** |

**Applicant Details.**

**Type of Ownership of Business.** (Tick or mark one)

☐**Individual** ☐**Partnership** ☐**Incorporated Company** ☐**Cooperative Association** ☐**Trust** ☐**Government**

| | | | | | |
|---|---|---|---|---|---|
| **Individual Name:** | **Last Name** | | **First Name** | | |
| **Business Name:** | | | | | |
| **Postal Address Line 1:** | | | **Line 2:** | | |
| **Suburb:** | | | **State:** | **Postcode:** | |
| **Partner Names:** | **Last Name** | | **First Name** | | |
| (Provide additional partners on a separate sheet) | **Last Name** | | **First Name** | | |
| | **Last Name** | | **First Name** | | |
| **Other Trading Names:** | | | | | |
| **ABN / ACN Number:** | | | | | |

Have you, any Partner or Director of the Business or anyone in a Management role been convicted of an indictable offence or other offence involving dishonesty in the past five years ? **(answer by circling / marking appropriate box).** Yes / No

A Company must attach a copy of *Certification of Incorporation* with new applications.
A Co-operative Association must attach a copy of *Certificate or Registration* to new applications

*Certification* is attached ☐

**Facility / Accreditation Details**

| | | | |
|---|---|---|---|
| **Facility Address Line 1:** | | **Line 2:** | |
| **Suburb:** | | **State:** | **Postcode:** |
| **Accreditation Contact:** | **Last Name** | **First Name** | |
| **Position:** | | | |
| **Property Valuation No.:** | | **Section:** | **Hundred:** |
| **Contact Details:** | **Phone:** | **Mobile:** | |
| | **Fax:** | **Email:** | |
| **Postal Address** | | **Line 2:** | |
| **Postal Suburb** | | **State:** | **Postcode:** |

**Persons Permitted to Sign or Verify Plant Health Certification**

| Role | Last Name | Given Name(s) | Specimen Signature |
|---|---|---|---|
| Certification Controller / Responsible Person | | | |
| Backup Cert Controller / Responsible Person | | | |
| Authorised Signatory / Responsible Person | | | |
| Authorised Signatory / Responsible Person | | | |

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Products Certified / Imported:** | | | | | | | | | | | | | |
| (List all fruit & vegetable types, machinery, grapevines or nursery stock) | | | | | | | | | | | | | |
| **Seasonal Operator:** (tick or Y = Yes) | NO | | YES | | **If yes, indicate operating months** | | | | | | | | |
| **Importing Details** | | | | | | | | | | | | | |
| **Consignments per year** | | | **Nursery Membership Y= Yes / N= No** | | | | NGISA | | NIASA | | AGCAS | | |
| **States of Origin:** (tick or Y = Yes) | QLD | | VIC | | WA | | NSW | | NT | | TAS | | Overseas |

Government of South Australia
Department of Primary Industries and Regions

**ACCREDITATION / REGISTRATION APPLICATION**
**Plant Health Act 2009**
**ICA/CA Accreditation Sec 16 / Registration Sec 26**

**APPENDIX 1**
***ICA / CA / IR***

**APPLICATION for ACCREDITATION / REGISTRATION or ANNUAL RETURN (ICA / CA / IR)**

## Product / Certification Assurance Records and Methodology

The business must carry out the necessary responsibilities and duties, and maintain records strictly in accordance with the applicable Operational Procedure unless permission to use different records/methods is requested below and is granted and endorsed by the Department of Primary Industries and Regions

I hereby request to use the following alternative or additional records/methods detailed below.

| | |
|---|---|
| | Granted by PIRSA ☐ |
| | Inspector Initials / Stamp |

PIRSA STAMP

I / We the undersigned applicant(s) do hereby declare that the information provided herein is accurate to the best of my/our knowledge and belief and make this application on my behalf, or on behalf of the above-mentioned business as a representative appointed to do so.

| *Partner, Director / Approved Representative | Designation | Signature | Date |
|---|---|---|---|
| | | | / / |
| | | | / / |
| | | | / / |
| | | | / / |

**Note: Where applicants are members of a partnership, each partner must sign the application.**
**For corporations/associations a Director, Company Secretary or Manager with legal authority to sign for the company must sign.**
**Use the following checklist to ensure you have provided key information to enable the application to be processed.**

☐ You, All Partners or Director have signed above. ☐ All Responsible Persons have signed page 1. ☐ ABN is provided.
☐ Type of ownership indicated. ☐ Copy of Company Certification attached (new applicants).
Applicants must provide an Annual Return on the prescribed form each year they are accredited.
Incomplete applications will delay processing as they will need to be returned.
Please direct any queries regarding this application or the Accreditation/Registration to the Market Access Officer on 8207 7814.

## Office Use Only

**DESK AUDIT** ☐ **Passed** ☐ **Not Passed** because ……

Alternate record-keeping granted Yes ☐ No .....

…….. …….. ..... / ….. / …..

Name of Desk Auditor (please print) Signature of Officer Date

## Conditions of Accreditation S16 / Registration S26

PIRSA STAMP

For the purposes of this accreditation / registration the following conditions may apply:

- The applicant must operate in full accordance with the Act and for ICA/CA Arrangements with the applicable Operational Procedure, which includes maintenance and provision of prescribed records for regular audit.
- The applicant is responsible to ensure that staff undertaking responsibilities required of the accreditation are adequately trained to do so.
- The frequency and number of audits will be determined by the Minister and carried out by persons authorised by the Minister.
- All fees for audits and inspections will be set by the Minister and the costs borne by the accredited person or business.
- The applicant will receive a Certificate of Accreditation / Registration which must be prominently displayed at the Business Facility.
- Restrictions may be imposed on the type of product an importer may bring into South Australia.
- A copy of the relevant Operation Procedure or Act can be viewed or downloaded from – www.pir.sa.gov.au/ica

## Issue of Assurance Certificates / Registration of Importers / Verification of Product

The *Plant Health Act 2009* requires any person issuing a Plant Health Assurance Certificate (PHAC) to be accredited to do so. Penalties apply. (See section 25).

The *Plant Health Act 2009* requires any person bringing or introducing plant or plant related products into SA to be registered (section 26) and imported products require verification. It is an offence to import without being registered or to fail to have imported product verified. Penalties apply (see sections 7, 25 and 33).

Only an accredited person may issue an assurance certificate (PHAC) or verify imported products (i.e., verify that an assurance certificate or other document relating to a plant or plant related product under a corresponding law complies with the requirements of the corresponding law). It is an offence to issue a Plant Health Assurance Certificate or verify imported product without being accredited. Penalties apply (see sections 7, 25 and 33).

**ENSURE YOU ALSO READ PAGE 3**

**ACCREDITATION / REGISTRATION APPLICATION**
**Plant Health Act 2009**
**ICA/CA Accreditation Sec 16 / Registration Sec 26**

**APPENDIX 1**
***ICA / CA / IR***

**APPLICATION for ACCREDITATION / REGISTRATION or ANNUAL RETURN (ICA / CA / IR)**

## Application Notes

The form must be fully completed by an Applicant on their behalf or on behalf of a legal entity/business that they have authority to represent. Partnerships require all partners to sign.

Attach a separate page if there is insufficient space available for all required details. (Late fees apply for Annual Returns)

## Operational Procedure / Arrangement

**The ICA / CA / IR number and name you are seeking Accreditation/Registration for must be entered here. E.g., ICA23, CA01 etc. Applications without these details will be delayed or not processed.**
**(You may make application for both CA01/(IVCA) and IR01 by ticking the YES box)**

**Applicant Details**

- **Type of Ownership** shall be either – Individual, Partnership, Incorporated Company, Co-operative Association, Trust or other legal entity. (It may not be a Family Trust).
- **Name of the Legal Entity** either Individual, Business, Corporation, Association or Trust (if a Family Trust a trustee representing the Trust). Use attachment if insufficient room.
- **Address**; physical address of business is required
- **Partner Names**; all partners names must be provided.
- **Other Trading Name(s);** List any other trading names used. Use attachment if insufficient room**.**
- **ABN / ACN Number;** ABN is the Australian Business Number.
- **Convictions;** Need to answer whether you, or any Director of the business or anyone in a management role been convicted of an indictable offence or offence involving dishonesty in the past five years?
  This question must be answered. If it is not, the application will not be processed.

**Facility/ Accreditation Details**

- **Facility Address / Location;** Clearly indicate the location or physical address details where product will be prepared/verified that will enable a PIRSA officer to easily locate the premises. (Usually, the registered address of the business).
- **Contact:** Name and role of the principal contact to be used regarding the accreditation/Registration.
- **Property Valuation Number and Section and Hundred;** Must clearly indicate the Property Valuation Number, Section and Hundred of the property. These are available from the Council rate notice.
- **Postal Address;** A mailing address may be provided for posting of all correspondence.

**Persons Permitted to Sign or Verify Plant Health Certification**

- **Role;** The role of the person able to verify product on behalf of the accredited business.
- **Names;** The full name and specimen signature of each of these persons.

**Product Details**

- **Products Certified / Imported;** Indicate the imported product / equipment / machinery you expect to certify/verify using this procedure.
- **Seasonal Operator;** Indicate whether seasonal operation will apply and if so what months.
- **Consignments per year;** Importers to provide estimate number of consignments per year
- **Nursery Membership;** Nurseries to provide membership details
- **States of Origin;** Provide a yes for States that product is expected to come from.

## Product / Certification Assurance Records and Methodology

- Complete only if you wish to maintain records in alternate method to that specified in Procedure.

## Authorising / Signing

The Applicant (individual, all partners or company director/senior manager) must sign acknowledging they represent the business seeking accreditation and the information is accurate. It is an offence under section 51 of the Plant Health Act 2009 to make a false or misleading statement (whether by reason of the inclusion or omission of a particular) in an application made or information provided. Penalties apply.

Separate applications are required for each accreditation / registration. (i.e., ICA, CA, IVCA, Importer etc)

see www.pir.sa.gov.au/ica

Please direct queries regarding this Application, Accreditation or Registration to the Market Access Officer on 8207 7814.

Manager, Market Access & Systems
Department of Primary Industries & Regions

**Attachment 2 Training Register**

Name of Accredited Business ……..

| Position | Full Name | Signature of Employee acknowledging an understanding of the requirements of CA-12 Compliance Arrangement | Date Training Completed |
|---|---|---|---|
| Certification Controller | | | |
| Backup CC | | | |
| Responsible Person | | | |
| Responsible Person | | | |
| Responsible Person | | | |
| Responsible Person | | | |
| Responsible Person | | | |
| Responsible Person | | | |

Note: This form must be kept updated by the Certification Controller

To the best of my knowledge this form is correct and complete

Name: …… Signature: ……

Date: ……

**Attachment 3 - Record of Receipt – Arrival Verification**

Name of Accredited Laboratory: …… Record Number: ……..

| Date of Receipt | Name and address of consignor | Treatment applied in exporting State (If applicable) | Sample ID # | Sample type (Description of sample type) | Source address of Sample including State and Region | Number and weight / volume of imported samples | Name and Signature of Responsible Person verifying Samples/Documentation |
|---|---|---|---|---|---|---|---|
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Checked by:

…… …….

Certification Controller (please print name) Signature of Certification Controller……..

**Attachment 4 – Sample Incident Record**

**(Use to record details of samples arriving without required certification or incorrect certification)**

**Name of Business:** …….. **Sheet Number**……

| Receival Date | Certificate Number (If available) | Name of person or business that dispatched the sample | Originating State | Sample / Consignment Unique ID | Sample type | Qty | Comments / Results* |
|---|---|---|---|---|---|---|---|
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*** Column for noting omissions/discrepancies etc.**

**Attachment 5 – Diagnostic Material Disposal Form Name of Accredited Laboratory**: …… Record Number: ……..

| Sample ID# | Diagnostic tests carried out on samples | Date of destruction | Method of destruction and disposal of sample | Name and Signature off Responsible Person verifying sample has been destroyed/disposed of in accordance with section 6.16/6.17 |
|---|---|---|---|---|
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Checked by: …… …….

Certification Controller (please print name): …… Signature of Certification Controller…….

Accredited Business must enter a record for <u>each</u> consignment received for certification under ‘The Arrangement’.

**Attachment 6 - Adverse Incident Report Form**

| | | |
|---|---|---|
| Adverse Incident Report | Number: | |
| Time incident occurred: | Time reported: | |
| Date incident occurred: | Date reported: | |
| Informant: | | |
| Last name: | e-mail: | |
| First name: | Tel: | |
| Position: | Signature: | |
| Has Diagnostic material been released to the environment? | Yes | No |
| Has the release or spill been contained? | Yes | No |
| Did the incident result from human error? | Yes | No |
| Did the incident result from quarantine procedure failure? | Yes | No |
| Did the incident result from equipment/facility failure? | Yes | No |
| Describe the incident including locations, dates, times and personnel involved | | |
| | | |
| Adverse Incident Report | Number: | |
| Describe action(s) taken including locations, dates, times and personnel involved | | |
| | | |
| Describe any continuing action(s) including locations, dates, times and personnel involved | | |

| | | |
|---|---|---|
| | | |
| Date PIRSA Biosecurity - Plant Health informed | | |
| Were corrective actions required? | Yes | No |
| Recommended corrective actions | | |
| | | |
| Further follow up required? | | |
| | | |
| Signature ……Date: …… | | |

## Attachment 7 - CA-12 DIAGNOSTIC SAMPLE DECLARATION FORM

## FOR GRAPEVINE, PLANT AND SOIL SAMPLES GOING TO A CA-12 ACCREDITED BUSINESS IN SOUTH AUSTRALIA FOR DIAGNOSTIC TESTING OR RESEARCH

### Conditions 6, 7 & 20 – SA Plant Quarantine Standard (PQS).

***Important Notes***

Diagnostic Material must only be sent to CA-12 accredited facilities in South Australia using this Declaration. (For non-CA-12 laboratories refer to PQS)

If grapevine material and vineyard soil is not disinfested prior to it entering SA from a PRZ, PIZ or PIBZ it must be accompanied by a Plant Health Import Certificate signed by the Chief Plant Health Inspector and a Plant Health Certificate issued by an officer of the accrediting authority in the originating state. This Declaration cannot be used in that case.

When completing this Declaration, you must provide all required information to ensure your diagnostic material can be assessed and cleared for entry into South Australia.

Penalties up to $10,000 apply for providing false or misleading information
(Sec. 51, Plant Health Act 2009)

### Section 1. Consignor Details

Name of Business/person dispatching samples (full legal name)

……

Physical Address (Location samples were collected):

……

Date Samples Collected: ……

Samples are packaged/labelled in accordance with CA-12 requirements (Circle one) **YES** **NO**

Samples have been treated (circle) **- YES / NO.**

Treatment Details

……

### Section 2. Accredited Laboratory Receiving Diagnostic samples in SA

Name of Laboratory Receiving the samples in SA

**Address**

……

**Description of Diagnostic Samples (if insufficient space please attach list)**

| Description of Sample | Type of Packaging | Quantity # (of packages) |
|---|---|---|

---

### Section 3. Declaration

I the undersigned hereby declare that all of the information provided in this declaration is true and correct.

Signature: …… Date:……Name **(Print):**……

Email:……

***For further information on this declaration or the entry provisions for South Australia please contact PIRSA Biosecurity - Plant Health on (08) 82077820 or visit www.pir.sa.gov.au/legislation***