



Australian Government
Department of Agriculture,
Fisheries and Forestry

Laboratory Authorisation Program for *Xylella* testing

Program for authorising laboratories conducting *Xylella* testing on
host nursery stock imported into Australia



June 2026

Version 1

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Department of Agriculture, Fisheries and Forestry
GPO Box 858 Canberra ACT 2601
Telephone 1800 900 090
Web agriculture.gov.au

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We acknowledge the continuous connection of First Nations Traditional Owners and Custodians to the lands, seas and waters of Australia. We recognise their care for and cultivation of Country. We pay respect to Elders past and present, and recognise their knowledge and contribution to the productivity, innovation and sustainability of Australia's agriculture, fisheries and forestry industries.

Cover image

Xylella fastidiosa, © 2001 University of California Berkeley, Electron Microscopy Laboratory, emlab.berkeley.edu/EML/images/SEM-Gallery1/pages/XyellaBacteria.htm.

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Purpose

The Laboratory Authorisation Program for *Xylella* spp. testing (hereafter referred to as ‘the Program’) applies to plant diagnostic laboratories seeking to register as an authorised provider to detect and report on the presence/absence of *Xylella* spp. in nursery stock exported to Australia. Authorised laboratories will be listed in the Department of Agriculture, Fisheries and Forestry’s (the department) [list of authorised *Xylella* testing laboratories](#).

To become an authorised laboratory for *Xylella* spp. testing, the laboratory must meet minimum departmental standards to achieve Australia’s appropriate level of protection. This authorisation program has been established to manage the application, assessment, and on-going status of laboratory providers conducting *Xylella* spp. testing in support of export certification of host nursery stock to Australia.

The Program is used to determine the suitability of laboratory providers to:

- apply Australia’s mandatory diagnostic testing protocols
- ensure minimum sample sizes for mother plants are used in line with Australian requirements
- ensure test results are appropriately interpreted in line with Australian requirements to support ‘positive’ or ‘negative’ test declarations
- that quality management principles are applied through the diagnostic testing and clearance chain

The Program sets out the following:

- application requirements to become a *Xylella* spp. authorised testing laboratory
- requirements to maintain registration
- non-compliance processes
- information sharing governance
- decision-making processes

Program requirements may be subject to change, at the department’s discretion. The department will advise registered testing laboratories of any relevant changes to the Program and the status of their registration in writing.

More information regarding Australia’s mandatory *Xylella* test protocols, sampling procedures, and import measures can be found [here](#).

Enquiries or notifications can be directed to Imports@aff.gov.au

1 Policy Statement

1.1 Scope

1.1.1 The Program applies to testing laboratories:

- a) located outside Australia, and
- b) registered or applying to be registered under the Program.

1.2 Registration Policy

- 1.2.1 Australia maintains strict biosecurity measures to prevent the introduction of the bacterial pathogen, *Xylella*, through imported host nursery stock. These measures include offshore diagnostic testing on plant material produced and exported from a country/region that is assessed by Australia as high-risk for *Xylella*.
- 1.2.2 Testing laboratories approved under the Program are published in on the department’s webpage [here](#).
- 1.2.3 To be approved, the testing laboratory must comply with all requirements specified under this Program.
- 1.2.4 Prior to application, the applicant must obtain support from their in-country National Plant Protection Organisation (NPPO) and attach written evidence of this support to the application.
- 1.2.5 The department will provide the applicant with an outcome of registration as per Table 1.

Table 1 Registration outcomes

Registration outcomes	Standard	Registration outcome
Registered	<ul style="list-style-type: none">• All registration requirements met, and• Sufficient evidence provided to give assurance that the testing laboratory complies with all the requirements under the <i>Xylella</i> Laboratory Authorisation Program, and• Sufficient evidence provided to give assurance that the testing laboratory can detect <i>Xylella</i> spp. if present within plant samples.	Approved
Not registered	<ul style="list-style-type: none">• One or more registration requirements not met, or• Insufficient evidence provided to give assurance that the testing laboratory complies with all the requirements under the <i>Xylella</i> Laboratory Authorisation Program, or	Not approved

- Insufficient evidence provided to give assurance that the testing laboratory can detect *Xylella* spp. if present within plant samples.

Testing laboratories approved under the Program will be assigned a status on the [list of authorised *Xylella* testing laboratories](#) as per Table 2.

Table 2 Registration status categories

Registration status categories	Standard
Approved	A testing laboratory registered with the department under the <i>Xylella</i> Laboratory Authorisation Program that has met the minimum registration requirements for conducting the <i>Xylella</i> testing for nursery stock exports to Australia.
Under review	Indicators of non-compliance have been identified and biosecurity risk must be managed while a review into the testing laboratory takes place.
Suspended	A testing laboratory has failed to comply with requirements under its registration, or Australia's import requirements, and biosecurity risk must be managed.
Withdrawn	A registered testing laboratory that has voluntarily withdrawn from the <i>Xylella</i> Laboratory Authorisation Program or failed to renew registration.

1.3 Compliance policy

1.3.1 The department will conduct compliance management activities against the requirements in the Program.

1.3.2 The department will conduct compliance management activities during:

- registration assessment
- reinstatement following a period of suspension or withdrawal
- the under-review process
- routine, random or targeted compliance monitoring.

1.3.3 The department may initiate compliance management activities:

- when indicators of non-compliance or non-compliances are identified
- based on information provided by overseas regulatory agencies
- for any other reason relevant to managing Australia's biosecurity, as determined by the department.

1.3.4 Compliance management activities may be conducted:

- as onsite, virtual and/or via desktop activities

- b. in partnership with overseas regulatory agencies
 - c. via a suitable method as determined by the department.
- 1.3.5 Compliance management activities include the collection and analysis of information and data, through:
- a. asking questions
 - b. inspecting, authenticating, taking extracts from or making copies of documents
 - c. requiring the production of records
 - d. inspecting, examining or conducting tests
 - e. taking images or making recordings
 - f. examining or observing activities
 - g. accessing external information, intelligence and data sources – including commercial business data sets and specialist sources such as aerial or satellite imagery
 - h. undertaking any other activity deemed reasonable by the department.
- 1.3.6 When undertaking compliance management activities, the department may consider any relevant information and/or documentation collected by:
- a. the testing laboratory
 - b. other regulatory mechanisms operating within Australia
 - c. the relevant overseas regulatory agency
 - d. any other source of information deemed to be relevant to the compliance management activities in relation to a testing laboratory's registration status.
- 1.3.7 If non-compliance is identified, or indicators of non-compliance are identified, or the department is not satisfied that a testing laboratory is able to comply with Australia's testing requirements, the department may impose compliance management actions. These actions can include:
- a. directing tested consignments, including goods in transit, for further risk management onshore (e.g. post-entry quarantine and diagnostic testing)
 - b. introducing additional monitoring, verification and/or data collection activities
 - c. placing the testing laboratory under review
 - d. suspending the testing laboratory
 - e. any other reasonable action to gain assurance the testing laboratory is compliant with the Program.

1.3.8 Testing laboratories will be notified, by the department in writing, if compliance management activities result in a change to their registration status, and the grounds for this change in status. The exporting country NPPO will also be notified of any such actions.

Under review

1.3.9 A testing laboratory may be assigned a registration status of ‘under review’ if they are suspected of non-compliance due to:

- a. indicators of falsified or fraudulent documents (including testing records)
- b. failing to provide documentation or evidence in a timely manner as requested by the department
- c. any other indicators of non-compliance.

1.3.10 If a testing laboratory has been assigned a registration status of under review:

- a. The testing laboratory will be listed as ‘under review’ on the department's list of authorised *Xylella* testing laboratories, and
- b. The department will undertake a review, comprising of compliance management activities, to determine compliance with the Program.

1.3.11 The department will write to the testing laboratory within 21 calendar days from the date of the registration status changing to under review, providing information on the review process.

1.3.12 At the conclusion of the review process, the registration status of the testing laboratory will be updated on the list of authorised *Xylella* testing laboratories. These registration statuses are as per Table 3.

Table 3 Review results

Review findings	Standard	Registration Status
Review satisfactory	Sufficient evidence provided to give assurance that the testing laboratory complies with <i>Xylella</i> Laboratory Authorisation Program requirements, and Sufficient evidence provided to give assurance that the testing laboratory can detect <i>Xylella</i> spp. within plant samples.	Approved
Review unsatisfactory	Insufficient evidence provided to give assurance that the testing laboratory complies with <i>Xylella</i> Laboratory Authorisation Program requirements, or Insufficient evidence provided to give assurance that the testing laboratory can detect <i>Xylella</i> spp. within plant samples.	Suspended

Suspension

- 1.3.14 A testing laboratory may be assigned a registration status of 'suspended' for:
- failure to comply with Program requirements and/or Australia's import requirements
 - identification of *Xylella* spp. in a consignment exported to Australia and certified as being tested by the testing laboratory and found free from all species of *Xylella*.
 - providing falsified or misleading information to the department
 - failure to provide documentation or evidence within specified timeframes, as requested by the department
 - refusal or failure to participate in compliance management activities, as and when requested by the department.
- 1.3.15 If a testing laboratory has been assigned a registration status of suspended the testing laboratory will be listed as 'suspended' on the department's list of authorised *Xylella* testing laboratories.
- 1.3.16 Adverse regulatory actions taken by overseas regulatory agencies may be recognised by the department and result in a testing laboratory being listed as 'suspended'.
- 1.3.17 A testing laboratory will remain suspended until they complete the reinstatement process.

Withdrawal

- 1.3.18 A testing laboratory can withdraw from the Program voluntarily if they cease to operate or no longer wish to participate in the Program.
- 1.3.19 To withdraw, the testing laboratory must notify the department in writing, with a date for when the withdrawal will take effect.
- 1.3.20 If the department approves the withdrawal, the testing laboratory will be listed as 'withdrawn' on the department's list of authorised *Xylella* testing laboratories.
- 1.3.21 A testing laboratory will remain withdrawn until they complete the registration process and meet the department's requirements for approval.

Withdrawal when suspended

If the testing laboratory withdraws from the Program while suspended, the List of authorised *Xylella* testing laboratories status will remain as suspended.

Reinstatement

- 1.3.23 Testing laboratories that are suspended and wish to regain their status of 'approved' must complete reinstatement process.

1.3.24 The department will write to the testing laboratory within 21 calendar days from the date the reinstatement request was received, providing information on the reinstatement process.

Reinstatement process
<p>The reinstatement process may include:</p> <ul style="list-style-type: none"> • completion of a full registration process • close out corrective action measures • participation in one or more compliance management activities • conducting internal investigations • participating in a reinstatement interview or demonstration • participating in a reinstatement audit • providing evidence of compliance through photos, videos or documentation.

1.3.25 The department will provide the testing laboratory with the outcome of the reinstatement process. The result will be one of the results as per Table 4.

Table 4 Reinstatement results

Reinstatement result	Standard	Registration Status
Reinstated	<ul style="list-style-type: none"> • Sufficient evidence provided to give assurance that the testing laboratory complies with <i>Xylella</i> Laboratory Authorisation Program requirements, and • Sufficient evidence provided to give assurance that the testing laboratory can detect <i>Xylella</i> spp. within plant samples. 	Approved
Refuse to reinstate	<ul style="list-style-type: none"> • Insufficient evidence provided to give assurance that the testing laboratory complies with <i>Xylella</i> Laboratory Authorisation Program requirements, or • Insufficient evidence provided to give assurance that the testing laboratory can detect <i>Xylella</i> spp. within plant samples. 	Suspended

Decision review process

1.3.26 A testing laboratory can request the department review a decision made in relation to the following:

- a. rejection of a registration or application
- b. suspension
- c. the result of a reinstatement process.

1.3.27 Once a testing laboratory has been notified of a decision relating to a registration, suspension or reinstatement decision, the testing laboratory may apply to the department in writing for a review of decision within 30 days from the date of being notified.

2 Program Requirements

2.1 Registration requirements

- 2.1.1 To be considered for registration under the Program, a testing laboratory must submit an application to the department. A copy of the application form can be found [here](#).
- 2.1.2 The application must be **completed in English and supporting documentation must be provided in English**. If the original documentation is not written in English, both the original version and an English translated version (certified translation) must be provided.
- 2.1.3 If requested by the department, the testing laboratory must participate in compliance management activities as part of the registration application.
- 2.1.4 Testing laboratories with multiple branches/locations that operate independently and manage their own staff, equipment, workload management, records and systems, must submit a separate application for each branch/location.
- 2.1.5 Testing laboratories registering multiple branches/locations must provide additional information on company structure and operations, if requested by the department.
- 2.1.6 Testing laboratories with multiple branches/locations that operate under a central office to manage all staff, equipment, workload management, testing records and testing certification, must only submit one application.
- 2.1.7 The testing laboratory must meet all registration requirements to the satisfaction of the department.
- 2.1.8 The testing laboratory must provide information relating to their application that is accurate, true, and not misleading.

Registration outcome notification

The department will notify applicants of the outcome of their application as per Table 1. The outcome will be:

- ‘Registered’ for testing laboratories that have met all registration requirements, or
- ‘Not registered’ for testing laboratories that have not met all registration requirements.

2.2 Testing laboratory requirements

Entity Identifier

Testing laboratories that are deemed suitable for the *Xylella* Laboratory Authorisation Program registration will be issued an Entity Identifier (AEI).

- 2.2.1 For the mandated *Xylella* diagnostic tests, the testing laboratory must have:
- suitable equipment for the diagnostic tests and number of tests performed
 - knowledge and understanding of diagnostic requirements and mandatory protocols
 - suitably trained laboratory technicians.
- 2.2.2 The testing laboratory must perform diagnostic tests in accordance with:
- Australian import conditions
 - Australia's mandatory *Xylella* diagnostic test protocols and results thresholds
 - the sample sizes for testing as relevant to the mandated *Xylella* diagnostic tests.
- 2.2.3 For every test performed under the Program, the testing laboratory must certify the test results on a formal laboratory test report.
- 2.2.4 If requested by the department, the testing laboratory must participate in compliance management activity.
- 2.2.5 The testing laboratory must provide information to the department that is accurate, true, and not misleading.
- 2.2.6 For onsite or virtual compliance management activities, the registered testing laboratory must ensure:
- specific staff are present, as requested by the department
 - an English-speaking individual is present to facilitate communication.
- 2.2.7 For virtual compliance management activities, the registered testing laboratory must facilitate the use of any technology deemed appropriate by the department.
- 2.2.8 For onsite compliance management activities, the testing laboratory must provide access to the facility, equipment and testing documentation at the time and date requested and must provide a safe working environment.
- 2.2.9 If requested by the department, the testing laboratory must provide the following information to the department:
- individual testing information including testing records, data and/or certificates

- b. registration information
 - c. equipment calibration records
 - d. evidence of diagnostic equipment
 - e. any other documentation requested by the department.
- 2.2.10 Unless another timeframe is specified by the department, the registered testing laboratory must provide all information requested within 21 calendar days.
- 2.2.11 The testing laboratory must maintain all testing records and reports listed in clause 2.2.9. The loss or destruction of testing records removes traceability to export-ready plants produced from tested mother plants. This will result in exported consignments having to undertake retesting to support export certification to Australia.
- 2.2.12 Any documents or records provided to the department must be in English. If the original documentation is not written in English, both the original version and an English translated version must be provided.
- 2.2.13 The testing laboratory must inform the department in writing of any significant changes to the company as soon as practicable. This includes changes in:
- a. ownership
 - b. facilities location
 - c. contact details
 - d. operating procedures
 - e. business closure
 - f. national or international regulatory agency registration, where relevant
 - g. any other significant changes to the business or operations.
- 2.2.14 The testing laboratory must provide the full name and contact details of any person with the authority to communicate with the department on the registered testing laboratory's behalf.

3 Privacy Notice

- 3.1 Personal information is defined under the [Privacy Act 1988 \(Privacy Act\)](#) as information or an opinion about an identified individual, or an individual who is reasonably identifiable:
- a. whether the information or opinion is true or not
 - b. whether the information or opinion is recorded in a material form or not.
- 3.2 Protected information is defined under the [Biosecurity Act 2015 \(Biosecurity Act\)](#) as information of any of the following kinds obtained or generated by a person:
- a. sensitive information (within the meaning of the *Privacy Act 1988*)
 - b. information (including commercially sensitive information) the disclosure of which could reasonably be expected to find an action by a person (other than the Commonwealth) for breach of a duty of confidence
 - c. information the disclosure of which could reasonably be expected to prejudice the prevention, detection, investigation, prosecution or punishment of one or more offences
 - d. information the disclosure of which could reasonably be expected to prejudice the protection of public safety, human health or the environment
 - e. information the disclosure of which could reasonably be expected to prejudice the security, defence or international relations of Australia
 - f. information of a kind prescribed by regulations made for the purposes of this paragraph.
- 3.3 The department may disclose personal or protected information to overseas regulatory agencies (if applicable) including NPPOs as referred to in the International Plant Protection Convention and other persons or organisations where necessary for the purposes of administering the Program.
- 3.4 By agreeing to be registered under the Program you consent to the disclosure of any personal or protected information, collected as part of the Program, to overseas regulatory agencies. The department has not taken steps to ensure that overseas regulatory agencies do not breach relevant legislative requirements or the Australian Privacy Principles. This means that:
- a. the overseas regulatory agencies may not be accountable under the Privacy Act or the Biosecurity Act
 - b. you may not be able to seek redress under the Privacy Act or the Biosecurity Act
 - c. you may not be able to seek redress in the overseas jurisdiction
 - d. the overseas regulatory agencies may not be subject to any privacy obligations or to any principles similar to the Australian Privacy Principles.

4 Information sharing policy

- 4.1 The department may use personal information, as described under the Privacy Act, obtained from other Australian Government agencies or overseas regulatory agencies (if applicable) for the purpose of assessing and exercising compliance and enforcement functions in relation to the Program.
- 4.2 The department may use protected information, as described under the Biosecurity Act, obtained from other Australian Government agencies or overseas regulatory agencies (if applicable) for the purpose of assessing and exercising compliance and enforcement functions in relation to the Program.
- 4.3 In cases where the department may need to access and use either personal or protected information, it will be done so under the respective legislative framework.
- 4.4 The department may disclose personal information, as described under the Privacy Act, obtained from other Australian Government agencies or overseas regulatory agencies for the purpose of assessing and exercising registration, authorisation, compliance management and enforcement functions, in relation to the Program.
- 4.5 The department may use protected information, as described under the Biosecurity Act, obtained from other Australian Government agencies or overseas regulatory agencies for the purpose of assessing and exercising registration, authorisation, compliance management and enforcement functions, in relation to the Program.

5 Version History

Version	Date	Description
1.0	30 June 2026	Publication of document.

Glossary

Term	Definition
AEI	The Entity Identifier (formerly known as the AQIS Entity Identifier) is used to track and manage the offshore laboratory authorisation that supports the certification of consignments entering Australia.
Biosecurity Act	The Biosecurity Act 2015 (the Biosecurity Act) explains how we manage biosecurity threats to plant, animal and human health in Australia and its external territories.
Biosecurity risk	The likelihood of a disease or pest entering, establishing or spreading in Australia; and the potential for the disease or pest to cause harm to human, animal, plant, or environmental health, or economic consequences associated with the entry, establishment or spread of the disease or pest.
Consignment	Refers collectively to the goods that are being exported or imported, any packing materials used, and the mode of transport such as a shipping container.
The department	The National Plant Protection Organisation of Australia or their agent.
Import conditions	The department's conditions for the import of goods, including permit conditions and treatments.
In transit	Consignments or goods are classified as 'in transit' when they have left the country of origin but have not yet been cleared through the border in Australia.
Non-compliance	Non-compliance is a failure to meet the <i>Xylella</i> Laboratory Authorisation Program requirements.
Pest	Species, strain or biotype of a plant or animal, or a disease agent, that has the potential to cause, either directly or indirectly, harm to human, animal or plant health or the environment.
Privacy Act	The Privacy Act 1988 (the Privacy Act) provides the basis for nationally consistent regulation of privacy and the handling of personal information
Virtual	An online mechanism, such as Microsoft Teams, Zoom, Skype, email, or any other electronic means. Conducted online, as opposed to onsite or in person.