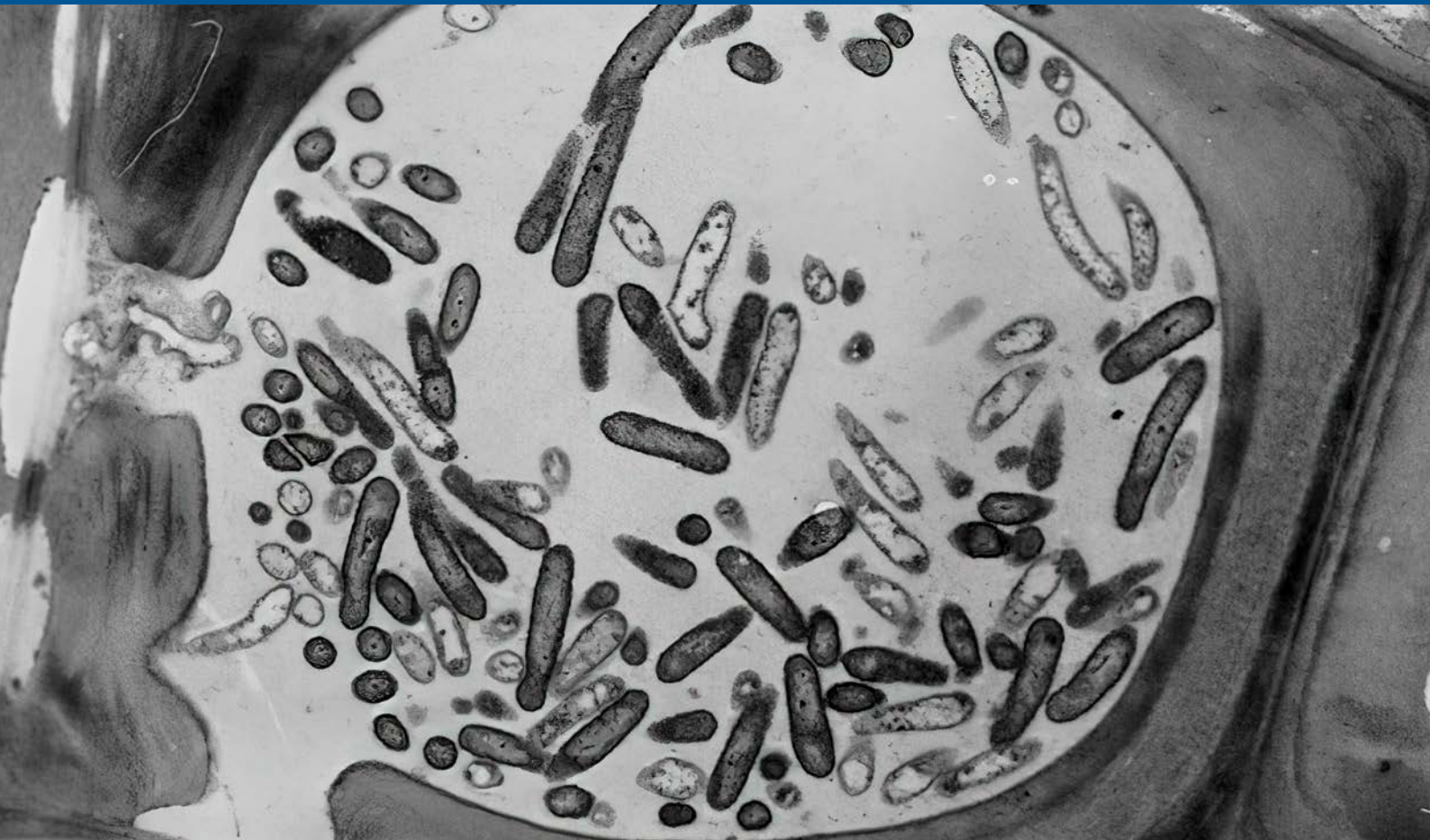




Australian Government
Inspector-General of Biosecurity

Effectiveness of preventive biosecurity arrangements to mitigate the risk of entry into Australia of the serious plant pest *Xylella fastidiosa*

REVIEW REPORT NO. 2021-22/03



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Executive summary

This Inspector-General of Biosecurity review examined current biosecurity measures that the Department of Agriculture, Water and the Environment applies to prevent the entry into Australia of bacterial plant-pathogens of the *Xylella* genus (*Xylella* spp.), including *Xylella fastidiosa* and its subspecies and genetic strains and *Xylella taiwanensis*.

Xylella spp. are Australia's No. 1 national priority plant pest. They cause a variety of major plant diseases, including Pierce's disease of grapevine, citrus variegated chlorosis, olive quick decline syndrome and several leaf scorch diseases in fruit trees. Introductions of *Xylella* spp. into new areas in other parts of the world have had huge and ongoing economic, social and environmental impacts. Australia has remained free of *Xylella* spp.

Xylella spp. are one of the most dangerous plant bacteria anywhere in the world because:

- there is no treatment or cure for plants infected with *Xylella* spp., and there is no known way of eliminating the bacterial plant pathogen under field conditions
- *Xylella* spp. can invade new areas, countries, and continents through human-mediated long-distance dispersal of infected plant materials and possibly infected insect vectors
- the pathogen can colonise a wide range of host plant species, including over 600 herbaceous and woody plants, cultivated crops and weeds in many plant families and genera
- the list of host plants continues to increase as the pathogen invades new territory
- *Xylella* spp. is transmitted through plant material taken from infected plants used for propagation and grafting
- *Xylella* spp. is transmitted by common, sap-feeding insect vectors
- disease caused by *Xylella* spp. can be transmitted and spread undetected via asymptomatic host plants
- the *Xylella* spp. pathosystem has a complex biology, making it difficult to predict its behaviour and impact in a new environment
- *Xylella* spp. infection leads to plant death in susceptible hosts
- the management of diseases caused by *Xylella* spp., including the replacement of dead and dying plants, costs agricultural industries millions of dollars a year.

To manage the risk of *Xylella* spp. diseases, the department's biosecurity policy position has long been to prevent *Xylella* spp. from entering Australia with nursery stock. It introduced and has updated import conditions for plant host species in the nursery

stock group of commodities. Nursery stock includes all live plants and plant materials (vegetative propagative material and tissue cultures), other than fruit or seed, to be used for propagation and planting. Nursery stock is considered high-risk, as it is used in fields, gardens and greenhouses, where the probability of disease transmission is greatest.

In the 1970s the department introduced regulation targeted at grapevine nursery stock, peach and nectarine only. In 2009, the list of plant host species increased to 188 and included 36 ornamental or alternative plant hosts of *Xylella* spp.

In 2015 the department introduced *Xylella* spp. emergency measures. These expanded the list of regulated plant species to over 20,000 (confirmed and potential) hosts because host plant species are regulated at the plant family level rather than species level under the emergency measures. The department chose this cautionary approach because the number of internationally confirmed plant hosts was growing rapidly.

According to the emergency measures, regulated plant species of nursery stock must meet offshore phytosanitary certification requirements in respect to freedom from *Xylella* spp. infection (offshore molecular testing for *Xylella* spp. or country freedom certification). Offshore certification requirements depend on whether *Xylella* spp. is present in the country or region of origin and the type of plant material (i.e., vegetative propagative material or tissue cultures). An import is directed to undergo post-entry quarantine (PEQ) growth and screening if certification does not meet Australian standards. Most nursery stock imports arrive with the required phytosanitary certificate. Once they arrive onshore, they must then meet further import conditions. Under those other import conditions, most nursery stock consignments can be released from the department's biosecurity control following document assessment and inspection. There are exceptions from the emergency measure's offshore certification and molecular testing requirements. They do not apply for some certified bulbs imported from the Netherlands and for agriculturally important crops for which import conditions mandate PEQ growth and screening at the department's PEQ facility at Mickleham.

The objective of this review was to provide an assurance assessment of the robustness of the department's biosecurity measures designed to prevent the entry and establishment of pathogens of the *Xylella* genus in Australia. Specifically, it aimed to assess the:

1. adequacy of preventative biosecurity measures for pathogens in the genus *Xylella*, including monitoring of international pest prevalence and risk pathways (likely entry routes)
2. agility of preventative biosecurity measures and operational controls
3. balance of focus of pest-specific risk assessment and operational pathway threat and vulnerability assessment
4. scientific and technological capabilities to provide rapid specialist support to frontline biosecurity officers.

This review makes 14 recommendations to significantly improve the effectiveness and efficiency of *Xylella* spp. prevention measures in the nursery stock pathway. The report broadly assesses elements of the department's prevention measures to be marginal or unsatisfactory. A substantial body of work needs to be completed to establish contemporary policy, regulatory and operational arrangements to provide a high level of assurance that biosecurity risk mitigation is effective for Australia's highest ranked exotic plant pest. An assessment framework was used to assess the department's roles in mitigating the risk to Australia posed by *Xylella* spp. The preventative biosecurity arrangements for *Xylella* spp. are rated poorly: 3 areas rated unsatisfactory, 9 rated marginal and only 1 rated optimal.

This review has not assured the Inspector-General that optimal preventative biosecurity arrangements are in place for Australia's top plant biosecurity pest (a bacterial pathogen). Substantial improvement is needed in the setting and delivery of measures to prevent the entry of *Xylella* spp. into Australia. In summarising the diverse observations, findings and recommendations of the report, the Inspector-General makes the following comments:

- In the absence of a completed formal pest risk analysis (PRA) covering *Xylella* spp. risk to Australia, the department has not demonstrated the level of expert knowledge about the *Xylella* spp. pathosystem (including symptomatic and asymptomatic hosts, distribution, and most common distribution mechanisms, and detectability) that could be expected for Australia's listed No. 1 plant pest.
- There is a critical gap in international knowledge about *Xylella* spp. transmission via tissue cultures. This could cause a significant rethinking of the benefits (or not) of the expanded use of tissue culture to trade host plants of *Xylella* spp. globally.
- The fact that *Xylella* spp. infection is asymptomatic in many plant hosts necessitates onshore monitoring of imported plant hosts for *Xylella* spp. infection. Minimal use of molecular testing to verify the health status of plant imports means that the department has very limited knowledge about the level of *Xylella* spp. approaching the Australian border or about its potential leakage.
- The department's handling of the offshore arrangements for *tissue cultures without media* is unsatisfactory. If tissue culture is a pathway for *Xylella* spp., then the department is not effectively mitigating that pathway risk and has no measures in place to test or provide assurance that processes are reliably in place or working.
- The department's PEQ facility at Mickleham is world-class. It effectively handles a relatively small quantity of high-risk *Xylella* spp. plant hosts entering Australia. However, this facility needs to be better utilised in several ways.
- The department's handling of *Xylella* spp. host plants is significantly impeded by the absence of an overall policy framework for nursery stock, and any other relevant pathways, and persistence of a range of hangover arrangements that applied before the *Biosecurity Act 2015* and the 2015 emergency measures for *Xylella* spp.
- The ongoing historical failure of the department's management to instil a strong information management culture has led to poor utilisation of the corporate document management system and biosecurity databases, adding significant inefficiency and inconsistency to day-to-day management of the nursery stock pathway.
- As the Australian regulator and main organisation with active experience with *Xylella* spp., including targeted surveillance and diagnostics, the department should take a stronger lead on preventative (including peri-border) biosecurity, including by establishing the department's PEQ facility at Mickleham as a *Xylella* spp. hub or centre of excellence.

The recommendations in this report will provide a solid basis for a sound, systemic approach to preventative biosecurity measures for *Xylella* spp. The improvements to be made by the department should also provide exemplar approaches that will enable consistent improvements in preventative biosecurity for other high-ranking plant pests and diseases.

1. Recommendations

Recommendation 1

The department should complete the *Xylella* spp. pest risk analysis by the end of 2022 to support streamlined, agile and regulation-based responses under the *Biosecurity Act 2015* and adequately inform biosecurity industry participants and other key stakeholders.

Recommendation 2

The department should develop a policy framework for nursery stock. The framework would clarify the components of a risk management program for nursery stock (offshore and onshore) and the intended outcomes (e.g., resources and other inputs, activities and products and services delivered), as well as the contextual factors affecting its operations and actual outcomes and replace the risk grouping terminology that is currently used.

Recommendation 3

The department should strengthen the biosecurity control achieved through mandatory phytosanitary certification for nursery stock by undertaking random on-arrival sampling and molecular testing for *Xylella* spp., similar to, or consistent with, the compliance-based intervention scheme.

Recommendation 4

The department should re-examine the regulations of tissue cultures of *Xylella* spp. host plants for consistency with the regulation of other host plants. The re-examination should be underpinned by a sound analysis of the *Xylella* spp. risk associated with tissue cultures that will be conducted as part of completing the pest risk analysis.

Recommendation 5

The department should overhaul the regulation of overseas facilities supplying tissue culture free of media. The regulatory regime should focus on the essential factors requiring regulation at the stage of facilities approval. Approvals and reviews should be undertaken in a timely, contemporary manner and complement the regulatory requirements of the import permit process.

Recommendation 6

The department should establish the Mickleham post-entry quarantine facility – the only Australian laboratory conducting routine regulatory testing for *Xylella* spp. – as the lead national reference laboratory for *Xylella* spp.; this laboratory and other department diagnostic laboratories should urgently be equipped with a modern laboratory information system (LIMS).

Recommendation 7

The department should consider replacing the process management system (PMS) quality control approach for nursery stock with the standardised regulatory approach to approved arrangements under the *Biosecurity Act 2015* to achieve a more consistent, efficient and equitable regulatory regime for nursery stock.

Recommendation 8

The department should urgently design and implement a nursery stock pathway surveillance and molecular diagnostics program that includes major nursery stock sites closely linked to imports, nearby host plants of *Xylella* spp. and potential insect vectors present in the local environment.

Recommendation 9

The department should roll out a best-practice approach to assurance and verification across all biosecurity divisions, with the schedule of work and reports being routinely on the agenda of the Biosecurity and Compliance Board.

Recommendation 10

The department should maintain adequate focus on improving the quality and timeliness of evidence-based decision-making (day-to-day, tactical, strategic) through routine access and analysis of available data and information. This needs to be supported by markedly improved information and data management systems.

Recommendation 11

The department should ensure an ongoing focus on its frontline workforce management arrangements, optimising the balance of staff flexibility and ongoing availability of subject matter expertise to enable optimal biosecurity risk mitigation.

Recommendation 12

The department should review information on its website relevant for importers of nursery stock and other stakeholders in *Xylella* spp. risk mitigation to ensure ease of access, cohesiveness and accuracy. Information should be consolidated to clarify approval and audit processes and improve overall communication.

Recommendation 13

As part of at-border and post-biosecurity preparedness for a potential response to a detection of *Xylella* spp., the department should complete a collaborative desktop exercise simulating an incident response covering the first 7–10 days after initial post-biosecurity detection.

Recommendation 14

The department should complete a comprehensive overhaul of the preventative system for *Xylella* spp. host material to achieve the necessary regulatory clarity, clear focus on the best-available risk mitigation measures (onshore and offshore), simplicity and consistency of pathway options and accountability of relevant industry parties for effective risk mitigation actions.



Rob Delane

Inspector-General of Biosecurity

14 June 2022

2. Assessment summary

Table 1 Inspector-General of Biosecurity assessment ratings

Measures in place	Assessment rating ¹	Recommendation no
1. Threat assessment of known and likely offshore sources of <i>Xylella</i> spp., including: <ol style="list-style-type: none"> a. primary <i>Xylella</i>-infected risk regions and hosts b. most likely future risk regions. 	Unsatisfactory	1, 4
2. Identification and assessment of major current and likely risk pathways, including the traveller pathway, mail pathway, airfreight pathway, commercial pathway, and other pathways.	Marginal	3, 14
3. Appropriate infrastructure and operational capability in place, including: <ol style="list-style-type: none"> a. Mickleham quarantine facility. 	Optimal	6
4. Coordinated, agile management arrangements with efficient cooperation, including: <ol style="list-style-type: none"> a. inter-division management arrangements. 	Marginal	8, 14
5. Funding arrangements enable the department to respond appropriately and consider: <ol style="list-style-type: none"> a. resourcing – quantity, targeted application, and flexibility b. other resourcing issues. 	Marginal	14
6. Adequate ongoing monitoring and adjustment of intervention measures deployed for major pathways.	Unsatisfactory	3, 4, 5, 8,14
7. Regulatory powers and capability to apply regulation, including: <ol style="list-style-type: none"> a. appropriate regulations and processes b. frontline staff equipped to apply regulations c. Relevant approved arrangements audited, and compliance/enforcement actions taken. 	Marginal	2, 7, 11, 14

3. Introduction

Measures in place	Assessment rating ¹	Recommendation no
8. Appropriate technical support at all key sites	Marginal	3
9. Appropriate <i>Xylella</i> spp.-related data and management information, including: <ul style="list-style-type: none"> a. practical data capture systems b. timely, accurate management reports. 	Marginal	14
10. Adequate public information about the biosecurity risk of <i>Xylella</i> spp. targeted at: <ul style="list-style-type: none"> a. plant importing business b. relevant import sector business/ personnel cohorts c. travellers. 	Marginal	10, 12
11. Appropriate partnership with industry pre-border and at-border, including with: <ul style="list-style-type: none"> a. agribusiness sector b. import transport and logistics sector. 	Marginal	5, 13
12. Appropriate collaboration with: <ul style="list-style-type: none"> a. state and territory governments b. industry. 	Marginal	13
13. Plans for sustainable <i>Xylella</i> spp. measures with appropriate threat and vulnerability assessments, audits, and verifications.	Unsatisfactory	5, 9, 13, 14

1. The Inspector-General of Biosecurity applied 3 assessment ratings: 'optimal', 'marginal' and 'unsatisfactory'. The overall assessment rating for each measure, if not otherwise specified, integrates the ratings for sub-items.

3. Introduction

The Inspector-General of Biosecurity scheduled a review of the *Effectiveness of preventative biosecurity arrangements to mitigate the risk of entry into Australia of the serious plant pest Xylella fastidiosa* as a priority topic for completion in 2021–22 (IGB, 2022a).

The vision expressed in the *National Xylella action plan 2019–2029* is that Australia remains free of *Xylella fastidiosa*, including its subspecies and genetic strains (DA, 2019a). To support this vision, there needs to be a high level of assurance that preventative measures are effective.

3.1 Overview

About the *Xylella* genus

Bacterial pathogens of the *Xylella* genus (collectively, *Xylella* spp.) are among the most significant plant disease threats worldwide. Originating in the Americas, they have invaded new regions, countries and continents through human-mediated long-distance dispersal of infected plants. Introduction with infected insect vectors is less likely though considered possible.

Xylella spp. became of prominent concern in Australia following an outbreak of Pierce's disease of grapevines (caused by a *Xylella fastidiosa* subspecies) in southern California in the late 1990s. In that case, introduction of a highly effective insect vector to a region with endemic *Xylella* spp. led to alarming rates of infection, rapid spread and what was called the 'California vineyard collapse'.

Australia's Plant Health Committee has listed *Xylella fastidiosa* and its subspecies and genetic strains as No. 1 on the top 42 list of national priority plant pests (NPPPs). The NPPP list, nationally endorsed for the first time in 2016 and reendorsed in 2019 following a review, prioritises and focuses national efforts and prevention measures on unwanted pests and diseases that pose the greatest risks to Australia's economy, agricultural industries, environment and way of life. It is published on the department's website (DA, 2019b).

Economic and environmental impacts

Xylella spp. are of significant biosecurity concern to Australia:

- Internationally, diseases caused by *Xylella* spp. inflict damages on agricultural industries totalling millions of dollars annually.

- There is no treatment and cure for diseases caused by *Xylella* spp. *Xylella* spp. are the causal, frequently lethal, agent for major plant diseases such as Pierce's disease of grape, citrus variegated chlorosis of citrus species, almond leaf scorch, pear leaf scorch and olive quick decline syndrome, among others.
- *Xylella* spp. infect a very broad range of plant hosts. They can infect and multiply in hundreds of cultivated and uncultivated plants (agricultural, ornamental and native).
- *Xylella* bacteria are transmitted to new host plants by common, abundant and polyphagous insect vectors.
- Diseases caused by *Xylella* spp. pose an increasing risk to agricultural industries, as evidenced by the expanding global geographic and host range.
- Many plants infected with *Xylella* spp. show no disease symptoms and can therefore constitute a pathogen reservoir in the environment. Because of the lack of symptoms, areas can be declared, inaccurately, as free from *Xylella* spp., unless plants collected during extensive surveillance activities are specifically tested for infection. It can also lead to undetected dispersal via exports of asymptomatic plants.
- Where host plants do show disease symptoms, the symptoms can be unspecific and easily mistaken for water stress and physiological disorders. Visual screening alone cannot reliably detect infection and the disease can be dispersed undetected.

In 2021 the Australian Bureau of Agricultural and Resource Economics and Sciences (ABARES) estimated the impacts of *Xylella* spp. entering and establishing in Australia (Hafi et al., 2021). Direct economic cost to susceptible horticultural crops and flow-on impacts on dependent sectors were considered. The study assessed that the most likely event would be an incursion of a single subspecies. It estimated that the direct cost to the cropping industry of a single subspecies entering and establishing would be between \$1.2 billion and \$8.9 billion in 2017–18 dollars over 50 years at a 3% discount rate. When the less likely event of multiple subspecies entering and establishing was considered, the direct impact increased to up to \$11.1 billion.

Departmental responses to *Xylella* spp. risk

The department manages the risk from *Xylella* spp. through regulating plant species in the nursery stock group of commodities. Regulation was firstly introduced in the 1970s (Table 2). The department defines 'nursery stock' as 'any propagative plant material, other than seeds, imported for growing purposes' (DAWE, 2021a). Nursery stock can be imported in 2 main plant forms:

- vegetative propagative material (non-tissue cultures)
- micropropagation material (tissue cultures).

Forms of vegetative propagative materials are listed on the department's website (DAWE, 2021b) and include:

- Bare-rooted plants
- Budwood
- Bulbils
- Bulbs
- Corms
- Cuttings
- Grafting wood
- Pips
- Rhizomes
- Roots
- Seedlings
- Slips
- Stems
- Tubers

The department defines ‘tissue cultures’ as:

Plant tissue culture, or micro-propagation, is a plant form that is prepared under aseptic conditions, reducing the risk of pests and pathogens. ...

Tissue culture can be imported into Australia in agar or another sterile nutrient medium, or free of media ... (DAWE, 2021b)

In November 2015, in response to the increasing global spread, the department introduced [emergency measures](#) for nursery stock to manage the biosecurity risk presented by pathogens in the genus *Xylella* (DAWE, 2021c).

The emergency measures for nursery stock were updated in 2016, 2019, 2020 and 2021 (Table 2). They are in addition to other import conditions in place to manage a wide range of plant pests and diseases, not just *Xylella* spp., in nursery stock. The department introduced additional emergency import conditions for seeds of *Carya* spp. for sowing in 2022.

Over time, the number of host plants subject to the department’s measures for *Xylella* spp. has grown to well over 20,000 agricultural and ornamental plant species belonging to over 100 plant families.

In addition to regulating plant host species at the plant family level, the emergency measures specify a requirement for offshore phytosanitary certification (offshore molecular testing for *Xylella* spp. or country freedom certification) to show freedom from *Xylella* spp. infection. Certification requirements depend on the presence of *Xylella* spp. in the country or region of origin and the type of plant material – that is, whether it is vegetative propagative material (non-tissue culture) or tissue cultures. Some exceptions are relevant (DAWE, 2021a). Quarantine growth and screening measures apply if certification requirements do not meet Australian standards.

In August 2018, the department announced the commencement of a formal pest risk analysis (PRA) for bacterial pathogens in the genus *Xylella* to:

- assess the risks presented by *Xylella fastidiosa* and its subspecies, including the more recently identified species *Xylella taiwanensis*
- evaluate the emergency measures introduced in 2015
- consider ongoing phytosanitary measures and ensure any ongoing phytosanitary measures are technically justified
- meet Australia’s international obligations under the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

At the time, the department was expected to release a draft report for a 60-day public consultation period in early 2019 (DAWR, 2018a).

The Inspector-General notes that the PRA initiated in 2018 was still listed as a short-term, high-priority action in the [National Xylella Action Plan 2019–2029](#) with a possible, yet unspecified, delivery date in 2022:

Action 1.1 Conduct a pest risk assessment and maintain appropriate regulation at the Australian border to minimise the risk of introduction into Australia. (DA, 2019a)

A PRA is an important tool to assess the changing global distribution and hosts of this pathogen and to identify the most effective risk management measures available to prevent entry to Australia. The department has not provided a cogent explanation for the significant delay in progression of the *Xylella* spp. PRA.

Table 2 summarises, in descending order, the decisions and initiatives the department has taken, national developments, and the timeline of the global spread of *Xylella* spp.

Table 2 Summary of decisions by the department, national developments and global response to *Xylella* spp.

Date, descending	Event	Source
2022, May	<p>Emergency import conditions for <i>Carya</i> spp. seeds for sowing</p> <p>The department introduced emergency measures to manage the risk of entry of <i>Xylella fastidiosa</i> within imported <i>Carya</i> spp. seed for propagation and planting.</p> <ul style="list-style-type: none"> The department notified the additional measures for <i>Carya</i> spp. seed imported from any country. <i>Carya</i> spp. seed must be grown and disease screened for a minimum of 12 months at the Australian Government post-entry quarantine (PEQ) facility at Mickleham, Victoria. The plants must be tested and found free from <i>Xylella</i> species before release from biosecurity control. 	DAWE, 2022a
2021, November	<p>Amended emergency import conditions for nursery stock</p> <p>Notification of amended emergency measure for <i>Xylella</i> spp.</p> <ul style="list-style-type: none"> The host range was expanded to include the plant family Hypericaceae. The measures covered 106 regulated plant families. The department's website and biosecurity import conditions database system (BICON) were updated to advise of the additional plant family. Trading partners were notified on 1 November 2021 by World Trade Organization (WTO) Application of Sanitary and Phytosanitary Measures (SPS) notification, reference G/SPS/N/AUS/376/Add.4. 	DAWE, 2021c
2021, June	<p>Amended emergency import conditions for nursery stock</p> <p>Notification of amended emergency measure for <i>Xylella</i> spp.:</p> <ul style="list-style-type: none"> The host range was expanded to include 7 more plant families: Araucariaceae, Argophyllaceae, Athyriaceae, Corynocarpaceae, Dennstaedtiaceae, Haloragaceae and Violaceae. The measures covered 105 regulated plant families and over 20,000 actual and potential host plant species, not all of which are currently imported into Australia. The department's website and BICON were updated to advise of additional plant families. Trading partners were notified on 5 May 2021 by WTO SPS notification, reference G/SPS/N/AUS/376/Add.3. 	DAWE, 2021c
2021, June	<p>European Union: The European Food Safety Authority (EFSA) published the <i>Update of the Xylella spp. host plant database – systematic literature search up to 31 December 2020</i>:</p> <ul style="list-style-type: none"> EFSA announced it would issue an updated database twice per year to support the risk management of <i>Xylella</i> spp. The review reported over 600 host plant species in more than 280 plant genera and more than 80 plant families. 	EFSA et al., 2021

Date, descending	Event	Source
2021, May	<p>National Xylella Action Plan 2019–2029</p> <p>The first national annual forum was held to support the implementation of the National <i>Xylella</i> Action Plan 2019–2029. Participants included Australian governments, research and development corporations, and peak industry bodies.</p>	DA, 2019a
2021, April	<p>Research: 3rd European conference on <i>Xylella fastidiosa</i></p> <p>The conference presented the latest findings, data and knowledge on <i>Xylella fastidiosa</i> as a pathosystem since it was first detected in Europe in 2013. Participants included 900 people from over 60 countries, including Australia.</p>	EFSA et al., 2021
2020, August	<p>Amended emergency import conditions for nursery stock</p> <p>Notification of amended emergency measure for <i>Xylella</i> spp.:</p> <ul style="list-style-type: none"> • The host range was expanded to include 9 additional plant families: Cannaceae, Gesneriaceae, Linaceae, Polemoniaceae, Resedaceae, Scrophulariaceae, Simmondsiaceae, Strelitziaceae and Tamaricaceae. • The measures covered 98 regulated plant families. • The department’s website and BICON were updated accordingly. • Trading partners were notified on 24 July 2020 by WTO SPS notification, reference G/SPS/N/AUS/376/Add.2. 	DAWE, 2021c
2020, August	<p>European Union: On 14 August 2020, following the latest scientific evidence made available by EFSA and experience in the different European Union (EU) outbreak areas, the Commission adopted new measures against <i>Xylella fastidiosa</i> (Commission Implementing Regulation (EU) 2020/1201) repealing current Decision (EU) 2015/789).</p>	DG Sante, n.d., a
2020, February	<p>United Kingdom: The United Kingdom Department for Environment, Food and Rural Affairs published a draft rapid pest risk analysis for <i>Xylella fastidiosa</i>.</p>	DEFRA, 2020
2019, September	<p>Updated import conditions for garlic to manage diversion risk</p> <p>Import conditions for fresh garlic bulbs for human consumption were changed following a high-profile case and sentencing of a grower for smuggling garlic into Australia for planting. From 1 September 2019, all importers of fresh garlic bulbs must have a valid import permit before the goods are imported into Australia.</p>	DAWE, 2021c
2019, August	<p>National Priority Plant Pest list</p> <p><i>Xylella fastidiosa</i> remained Australia’s No. 1 National Priority Plant Pest (NPPP) following a review of the 2016 NPPP list by Australia’s national Plant Health Committee.</p>	DAWE, 2020a

Date, descending	Event	Source
2019, July	<p>National Xylella Action Plan 2019–2029</p> <p>The national Plant Health Committee endorsed the National <i>Xylella</i> Action Plan 2019–2029.</p> <p>The plan aims to provide a national approach to enhance Australia’s capacity to prevent the introduction of <i>Xylella</i> spp. and prepare for a response if the pathogen is detected in Australia. It sets out actions to achieve this outcome.</p> <p>Finalisation of the pest risk analysis, which the department recognised as a priority in 2016 and commenced in 2018, is listed as a high-priority, short-term action. This is to be completed within 3 years (July 2022).</p>	DA, 2019a
2019, July	<p>Amended emergency import conditions for nursery stock</p> <p>Notification of amended emergency measure for <i>Xylella</i> spp.:</p> <ul style="list-style-type: none"> • Israel was added as a high-risk country. • Trading partners were notified on 18 July 2019 by WTO SPS notification, reference G/SPS/N/AUS/376/Add.1. 	DAWE, 2021a
2019, June	<p>Israel: Authorities informed the European Plant Protection Organization (EPPO) secretariat of the first record of <i>Xylella fastidiosa</i> subspecies <i>fastidiosa</i> on its territory. Symptomatic almond trees were discovered and destroyed. The pest status of <i>Xylella fastidiosa</i> in Israel was officially declared as present in one area only, under containment.</p>	EPPO, 2022a
2019, May	<p>European Union: The EFSA published an update to its 2015 pest risk analysis (EFSA Panel on Plant Health, 2015): <i>Update of the scientific opinion on the risks to plant health posed by Xylella fastidiosa in the EU territory.</i></p>	EFSA Panel on Plant Health et al., 2019
2019, January	<p>Portugal: Portuguese authorities notified the European Commission of the first outbreak of <i>Xylella fastidiosa</i> subspecies <i>multiplex</i> in Porto. Results confirmed the presence of the pest on host plants typical for the Mediterranean area, such as asparagus, lavender, olive, <i>Quercus suber</i>, rosemary, <i>Artemisia arborescens</i>, <i>Coprosma repens</i>, <i>Vinca major</i>, <i>Myrtus communis</i> and <i>Ulex minor</i>.</p>	DG Sante, n.d., b
2018, December	<p>Italy: Authorities notified the European Commission of the first outbreak of <i>Xylella fastidiosa</i> subspecies <i>multiplex</i> in Tuscany. The main host plants detected are typical for the Mediterranean area and include <i>Spartium junceum</i>, <i>Polygala myrtifolia</i>, almond, rosemary, lavender, common myrtle and figs.</p>	DG Sante, n.d., b
2018, September	<p>European Union: The EFSA published the <i>Update of the Xylella spp. host plant database.</i></p>	EFSA Panel on Plant Health, 2018
2018, August	<p>Commencement of pest risk analysis</p> <p>On 2 August 2018 the department issued a biosecurity advice notice on its website announcing the commencement of a pest risk analysis covering <i>Xylella fastidiosa</i> and its subspecies.</p> <p>The department expected to release a draft report for a 60-day public consultation period in early 2019.</p>	DAWR, 2018a
2018, June	<p>European Union: The EFSA Panel on Plant Health published an update to its 2015 pest risk analysis (EFSA Panel on Plant Health, 2015): <i>Updated pest categorisation of Xylella fastidiosa.</i></p>	EFSA Panel on Plant Health, 2018

Date, descending	Event	Source
2018, February	<p><i>Xylella fastidiosa</i> priority actions workshop</p> <p>The department convened a workshop to consider the priority actions identified at the International Symposium on <i>Xylella fastidiosa</i>, held in Brisbane in May 2017, to plan implementation of a national approach to further enhance Australia's capacity to prevent <i>Xylella</i> spp. entering the country and to prepare for a response. The workshop was attended by industry representatives and Australian state/territory and New Zealand biosecurity agencies.</p>	PBRI, 2018
2017, June	<p>Spain: Authorities notified the European Commission of the presence of <i>Xylella fastidiosa</i> subsp. <i>multiplex</i> on the mainland in Alicante, Autonomous Region of Valencia. Almonds were the main host plants infected, together with other plants typical of the Mediterranean area such as rosemary, myrtle-leaf milkwort, <i>Helichrysum italicum</i> and others. No infections have been detected so far on olive trees.</p>	DG Sante, n.d., b
2017, May	<p>International Symposium on <i>Xylella fastidiosa</i>, Brisbane</p> <p>The department held a symposium to inform on the science underpinning the preparedness for, and management of, this pest of worldwide significance and facilitate engagement opportunities among over 100 national and international experts and delegates and affected Australian industries.</p>	DAWR, 2017a
2016, October	<p>Spain: Authorities notified the European Commission of the first outbreak of <i>Xylella fastidiosa</i> subspecies <i>fastidiosa</i> in Mallorca. Since then, various outbreaks have been detected in the Balears, leading to the detection of subspecies:</p> <ul style="list-style-type: none"> • <i>Xylella fastidiosa</i> subspecies <i>multiplex</i> (Mallorca and Menorca) • <i>Xylella fastidiosa</i> subspecies <i>pauca</i> (Ibiza). 	DG Sante, n.d., b
2016, June	<p>National <i>Xylella</i> Preparedness Workshop, Melbourne</p> <p>The department funded a workshop, coordinated by Plant Health Australia, focusing on post-border preparedness to raise awareness of the pathogen among industry participants.</p>	PHA, 2016
2016, June	<p>National Priority Plant Pest list</p> <p><i>Xylella fastidiosa</i> was listed as Australia's No. 1 NPPP. For the first time, a nationally agreed top 42 NPPP list was endorsed by the national Plant Health Committee to strategically focus risk management and decision-making on the greatest risks.</p>	DA, 2019b

Date, descending	Event	Source
2016, May	<p data-bbox="384 237 679 264">Import conditions review</p> <p data-bbox="384 277 1038 398">The department reviewed the import conditions for nursery stock to provide an overview of the changes and the impact of the emergency measures to manage the risk associated with <i>Xylella</i> spp. The review:</p> <ul data-bbox="384 412 1038 981" style="list-style-type: none"> <li data-bbox="384 412 1038 501">• identified that the emergency measures impacted 86 BICON cases and 260 import permits, which were updated with revised conditions <li data-bbox="384 510 1038 600">• acknowledged that a pest risk analysis was the next step to evaluate the emergency measures and device the final import conditions required to regulate <i>Xylella</i> spp. <li data-bbox="384 609 1038 757">• stated that the responsibility to verify and confirm country freedom and establish offshore approved arrangements for growing and testing material from high-risk countries or regions resides with the National Plant Protection Organisation of the exporting country <li data-bbox="384 766 1038 913">• concluded that additional pathogen testing and extended post-entry quarantine duration may increase the cost of importing nursery stock from high-risk countries or regions, which could reduce overall volumes of some ornamental plants and trees <li data-bbox="384 922 1038 981">• identified the potential for increased noncompliance (e.g. misdeclarations) due to strengthened conditions. 	DAWR, 2016c
2016, April	<p data-bbox="384 994 1038 1084">Germany: <i>Xylella fastidiosa</i> was detected on oleander in a nursery glasshouse. An area freedom declaration was made in 2018.</p>	JKI, 2018
2016, January	<p data-bbox="384 1097 1038 1164">Emergency import conditions for nursery stock from low-risk countries or regions¹</p> <p data-bbox="384 1178 1038 1388">After emergency measures for nursery stock from high-risk countries or regions were introduced in November 2015, additional emergency measures were notified for host species from countries or regions other than those considered high-risk by 19 January 2016. These are low-risk countries where <i>Xylella</i> spp. are unknown to be present. The additional measures were:</p> <ul data-bbox="384 1402 1038 1491" style="list-style-type: none"> <li data-bbox="384 1402 1038 1469">• publication of a webpage to support the introduction of emergency measures for <i>Xylella</i> spp. <li data-bbox="384 1478 1038 1491">• country freedom certification requirements. 	DAWE, 2021c

¹ When referring to the department's *Xylella* spp. emergency measures, the term 'low-risk countries' covers countries or regions where *Xylella* spp. is not known to be present.

Date, descending	Event	Source
2015, November	<p>Emergency import conditions for nursery stock from high-risk countries or regions²</p> <p>The department introduced emergency measures to manage the risk of entry of <i>Xylella fastidiosa</i>, and its subspecies and strains, with nursery stock: rooted plants, cuttings, budwood, some bulbs and tubers, and tissue cultures intended for propagation and planting.</p> <p>Additional measures were notified for known host species from high-risk countries or regions:</p> <ul style="list-style-type: none"> • all countries in the Americas including the Caribbean • all countries in Europe • India • Iran • Lebanon • Taiwan • Turkey. <p>All other countries or regions were considered low-risk at the time. Measures for low-risk countries or regions were to be announced by 19 January 2016.</p> <p>Emergency measures targeted 89 plant families, covering approximately 20,000 confirmed and potential host plant species, and included more than the currently traded species.</p> <p>There were phytosanitary certification requirements regarding freedom from <i>Xylella</i> spp., to be confirmed by mandatory offshore molecular testing.</p> <p>Trading partners were notified on 9 November 2015 by WTO SPS notification, reference G/SPS/N/AUS/376. There were additional notifications on 15 December 2015 and 18 January 2016 via Australia's International Plant Protection Convention (IPPC) contact point.</p> <p>Notifications were also published in the department's new BICON system and the old, soon to be phased-out, ICON (Import Conditions) database.</p>	DAWE, 2021c
2015, July	<p>France: Authorities notified the European Commission of the first outbreak of <i>Xylella fastidiosa</i> subspecies <i>multiplex</i> in Corsica. Since then, the same subspecies has been also detected on the mainland, departments Var and Alpes-Maritimes. In one isolated outbreak in southern France, department Mentone, the presence of <i>Xylella fastidiosa</i> subsp. <i>pauca</i> was detected.</p>	DG Sante, n.d., b
2015, May	<p>European Union: On 18 May 2015, the Commission implemented measures to prevent the introduction into and the spread within the EU of <i>Xylella fastidiosa</i> (Wells et al.) (Commission Implementing Decision (EU) 2015/789).</p>	DG Sante, n.d., a
2015, January	<p>European Union: The EFSA Panel on Plant Health published scientific advice, including a comprehensive pest risk analysis: <i>Scientific opinion on the risk to plant health posed by Xylella fastidiosa in the EU territory, with the identification and evaluation of risk reduction options.</i></p>	EFSA Panel on Plant Health, 2015

² When referring to the department's *Xylella* spp. emergency measures, the term 'high-risk countries' covers countries or regions where (i) *Xylella* spp. has been officially confirmed to be present; (ii) there are unconfirmed historic records of *Xylella* spp. presence; or (iii) there have been trading bloc arrangements with other *Xylella* spp. positive regions and unregulated movement of nursery stock. Current high-risk countries/regions are listed on the department's website (DAWE, 2021c).

3. Introduction

Date, descending	Event	Source
2014	Iran: Reports were made of <i>Xylella fastidiosa</i> in vineyards and almond orchards in several provinces.	Amanifar et al., 2014
2014, February	Updated import conditions for olive nursery stock The department reviewed existing import conditions for olive nursery stock from all sources. It updated the country and host list to include 254 plant host species of <i>Xylella fastidiosa</i> .	DA, 2014
2013, November	European Union: The EFSA published scientific advice to assist decision-makers: <i>Statement of EFSA on host plants, entry and spread pathways and risk reduction options for Xylella fastidiosa Wells et al.</i>	EFSA, 2013
2013, October	Italy: Authorities notified the European Commission of the first outbreak of <i>Xylella fastidiosa</i> subspecies <i>pauca</i> in the south of Apulia (province of Lecce). There were reports of <i>Xylella fastidiosa</i> in olives and a range of other hosts. No infections had been confirmed in vineyards and citrus.	DG Sante, n.d., b; Saponari et al., 2013
2013, April	Review of policy for importation of grapevine propagative materials The department published the final <i>Review of policy: importation of grapevine Vitis species) propagative material into Australia</i> . Recommended risk management measures included mandatory on-arrival inspection and treatment as appropriate for the type of plant material, mandatory growth in government post-entry quarantine, and active pathogen testing, including molecular testing. Both vegetative propagative material and tissue cultures of <i>Vitis</i> spp. were associated with the quarantine pest <i>Xylella fastidiosa</i> . The review considered 'that certain pathogens (bacteria, phytoplasma, viroids and viruses) may not be excluded from the pathway and remain associated with micropropagated plantlets (tissue culture)'. The review considered 'that certain pathogens (bacteria, phytoplasma, viroids and viruses) may not be excluded from the pathway and remain associated with micropropagated plantlets (tissue culture)'.	DAFF, 2013
2013	Taiwan: There were reports of <i>Xylella fastidiosa</i> in commercial vineyards.	Su et al., 2013
2009	Updated import conditions to include additional nursery stock The department introduced measures to specifically manage the risks of introduction of <i>Xylella fastidiosa</i> in nursery stock: 188 host species, including 36 ornamental hosts from countries where the pathogen was known to be present at the time. Notification was published in the department's ICON import conditions database.	DAFF, 2009
2001, September	Australia: The project 'Analysis of the potential for the establishment of Pierce's disease in Australian grapevines', by the Victorian Department of Natural Resources and Environment, conducted a risk analysis for the Grape and Wine Research and Development Corporation. It identified ornamental plants that are symptomless carriers of the bacterium as potential risk pathways and highlighted the risk of entry via illegal imports of host plants by travellers and in mail consignments.	Merriman et al., 2001

Date, descending	Event	Source
2000	Research: <i>Xylella fastidiosa</i> became the first plant-pathogenic bacterium to have its genome sequenced. The work enhanced understanding of the origins of the pathogen and mechanisms of pathogenicity and virulence.	Simpson et al., 2000
1993	Taiwan: <i>Xylella</i> was reported as the cause of pear leaf scorch disease in Asian pear: <ul style="list-style-type: none"> • This was the first reported outbreak in Asia. • In 2016, a new species of <i>Xylella</i>, <i>X. taiwanensis</i>, was confirmed in Taiwan. 	Su et al., 2016
1980s and 90s	California, United States: The invasive glassy-winged sharpshooter arrives in the late 1980s or early 1990s in California from the south-eastern United States, possibly introduced with nursery stock. The introduction of the pest accelerated the spread and severity of outbreaks of Pierce's disease in grapevine, which had impacted grapevine production in California since the 1880s.	Purcell, 2013
1987	Brazil: Citrus variegated chlorosis was first noted in sweet oranges.	Hopkins and Purcell, 2002
1980s	Argentina: Citrus variegated chlorosis emerged as a new disease in sweet oranges.	Hopkins and Purcell, 2002
1973	Import conditions for some nursery stock For the first time, the department established import conditions for grapevine nursery stock, peach and nectarine to manage the risk of the new bacterial pathogen, <i>Xylella fastidiosa</i> .	Department consultation with the Inspector-General
1973, 1978	Research: Bacterial-like bodies were identified in, and isolated from, infected plants and associated with Pierce's disease of grapevine.	Hopkins and Mollenhauer, 1973; Davis et al., 1978
1884	United States: Pierce's disease was first noted in southern California.	

3.2 Review objectives

The Inspector-General's objective for this review was to provide an assurance assessment of the robustness of the department's biosecurity measures designed to prevent the entry and establishment of pathogens of the *Xylella* genus in Australia. Specifically, the review assessed the:

1. adequacy of preventative biosecurity measures for pathogens in the genus *Xylella*, including monitoring of international pest prevalence and risk pathways (likely entry routes)
2. agility of preventative biosecurity measures and operational controls
3. balance of focus of pest-specific risk assessment and operational pathway threat and vulnerability assessment
4. scientific and technological capabilities to provide rapid specialist support to frontline biosecurity officers.

4. Review approach

4.1 Authority of the Inspector-General of Biosecurity

The Inspector-General of Biosecurity is an independent statutory role under the *Biosecurity Act 2015* appointed by the federal Agriculture Minister to conduct general reviews of the performance of functions and the exercise of powers by the Director of Biosecurity and senior biosecurity officials. The Secretary of the Department of Agriculture, Water, and the Environment is the Director of Biosecurity.

The Inspector-General is independent of the Minister and the Director of Biosecurity but may consider the Minister's request for a review and seek immediate action from the Director of Biosecurity, senior biosecurity officials and the Minister to protect and enhance the integrity of Australia's biosecurity system.

For a review, the Inspector-General requests data and information from department officials, both in writing and verbally. The Inspector-General must publish a report on each review they conduct under the *Biosecurity Act 2015*.

The Inspector-General's scope does not extend to Australia's national biosecurity policies, international trade issues and market access opportunities.

4.2 Scope

The aim of the review was to make an assurance assessment of the robustness of biosecurity measures preventing the entry and establishment of pathogens of the *Xylella* genus in Australia. The Inspector-General required the department to demonstrate, through documented evidence (information and data) and discussions, that the review should make a positive assessment. Any recommendations for improvement would be made as part of the assurance assessment.

This review examined:

- the adequacy of the department's biosecurity risk mitigation strategies and action/operational plans for importation of live plant species, including nursery stock, cut flowers and foliage, and other biosecurity risk materials as appropriate
- the authority for decision-making and processes to mitigate biosecurity risks at the border

- the adequacy of current quantum, makeup and agility of the department's biosecurity risk management resources to address rapidly expanding demands to maintain Australia's biosecurity risk exposure at an appropriately low level
- pre-border and at-border intelligence activities to keep diseases caused by *Xylella* spp. out of Australia
- assurance and verification activities (endpoint/leakage surveys) and outcomes to ascertain 'residual risk' for major entry pathways
- sampling and testing regimes for susceptible products and hitchhiking insect vectors to inform decision-making at policy and operational levels
- data and information technology management systems used for recording observations and outcomes, and their performance in decision-making
- frontline operational facilities and inspection processes and post-entry quarantine.

4.3 Out of scope

This review did not examine:

- the effectiveness of the department's controls to manage residual (post-border) biosecurity risks associated with *Xylella* spp. and *Xylella*-susceptible agricultural and native species
- policy and activities that are the responsibility of stakeholders other than the department, including state/territory agencies/governments, individuals, and biosecurity industry participants
- commercial considerations other than generic commercial drivers that may increase the risk of entry of *Xylella* spp. into Australia.

4.4 Process

The Inspector-General conducted the review as follows:

- In preparation for the review, a workplan and preliminary information and data request was drafted and provided to senior executives. The Inspector-General discussed the drafts with senior executives and considered their feedback.
- The department identified key contacts for the review and nominated key personnel to be interviewed by the Inspector-General and the review team in the early stages of the review.
- The draft workplan and draft data request was also discussed with relevant biosecurity staff to ensure shared understanding of the purpose, scope, process and accountabilities for the review.
- Consultation meetings were held with staff in relevant areas in the department. Before the meetings, interviewees were provided with the workplan and preliminary information and data request.
- Where the review of information and the initial consultation meetings led to further questions, these were followed up in secondary information and data requests via email and/or additional meetings.
- A limited number of targeted site visits (due to COVID-19 travel restrictions) were made to meet operational staff and business personnel. These provided further insights into preventative biosecurity measures for *Xylella* spp.

5. *Xylella fastidiosa*

In common usage, the name *Xylella fastidiosa* can mean a species of the pathogen as well as multiple bacterial pathogens of the *Xylella* genus. This report refers collectively to all species, subspecies and genetic strains of the pathogen as *Xylella* spp.

Xylella spp. are a serious worldwide threat to agriculture, the environment and the economy. They are ranked No. 1 on Australia's priority list of 42 unwanted plant pests and diseases (DA, 2019b). The national Plant Health Committee initially made this significant policy assessment in June 2016 and reviewed and updated it in 2019.

The science underpinning the review is briefly summarised in the following sections. For more comprehensive reviews of the science, the Inspector-General refers the reader to those of the European Food Safety Authority (EFSA) (EFSA, 2021, 2013), EFSA Panel on Plant Health et al. (2019, 2018), and EFSA Panel on Plant Health (2015).

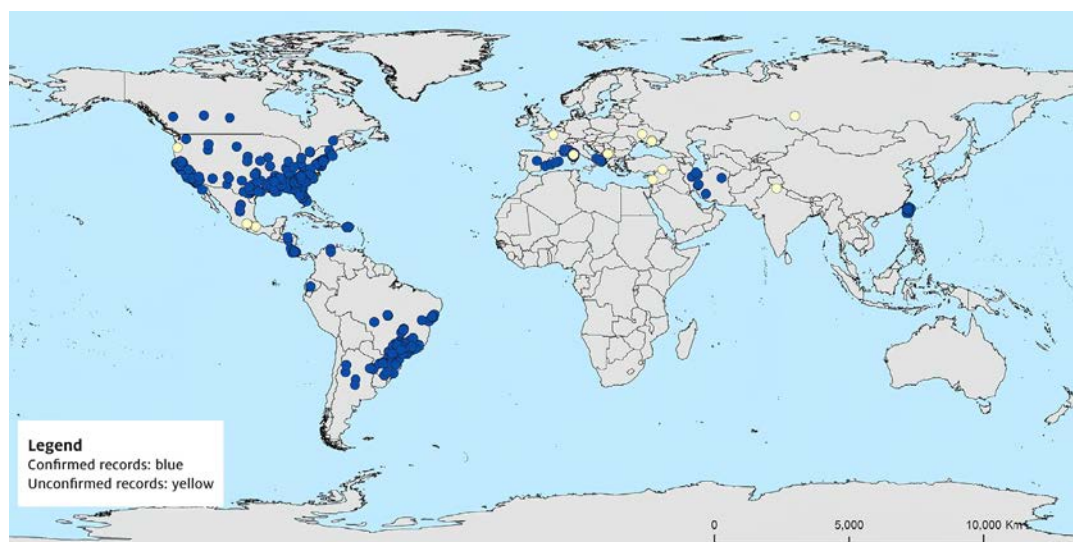
5.1 Biology

Xylella fastidiosa, including its subspecies (e.g. *fastidiosa*, *multiplex* and *pauca*) and genetic strains, and *Xylella taiwanensis* are bacterial pathogens of the *Xylella* genus that cause major plant diseases. Depending on the host species and the bacterium subspecies, diseases include Pierce's disease of grapevine, citrus variegated chlorosis, olive quick decline syndrome, phony peach disease, plum leaf scald, alfalfa dwarf, and several leaf scorchs recorded on almond, elm, oak, oleander, mulberry, and maple. The host range of *Xylella* spp. is diverse and extensive, and many hosts remain asymptomatic following infection.

Xylella spp. are spread by vegetative propagation of infected plant materials and by common sap-sucking insect vectors such as spittlebugs and sharpshooters. *Xylella* spp. can invade new territories and hosts through the long-distance transport of infected, potentially asymptomatic, plants and plant materials destined for planting. However, the arrival of *Xylella* spp. with infectious vectors has not been ruled out (EFSA Panel on Plant Health, 2015). Figure 1 shows the worldwide distribution of *Xylella* spp. in 2018 (EFSA, 2018).

Because *Xylella* spp. infections can be asymptomatic in many host species, *Xylella* spp. can go undetected for many years and may be inadvertently spread to other regions through trade in host plants. This characteristic of *Xylella* spp. also means that the pathogen may be significantly more widespread than has been officially reported.

A pest risk analysis (PRA) for European Union (EU) countries by the EFSA Panel on Plant Health rated the probability of entry of X. fastidiosa from countries where X. fastidiosa is reported is very high with plants for planting and moderate with infectious insect vectors carried with plant commodities or travelling as stowaways (EFSA Panel on Plant Health, 2015).

Figure 1 Global distribution of *Xylella* spp. in 2018

Source: EFSA, 2018.

Pathogenic mechanism and symptomatology

Xylella spp. colonise the water-conducting network (the xylem) of host plants. They then grow and multiply in the xylem as well as in the foregut of insect vectors feeding on xylem sap (Figure 2). The main pathogenic mechanism of *Xylella* spp. is the clogging of xylem vessels due to excessive colonisation in susceptible plant species such as grapevine, citrus and olive. This impairs water uptake (Chatterjee et al., 2008). In susceptible hosts, the pathogen can move more easily within the xylem. This allows it to reach large population numbers. Large pathogen loads that are spread out within the host increase the chance for vectors to acquire and transmit *Xylella* spp. and perpetuate the infection (EFSA Panel on Plant Health, 2015; Purcell, 2013).

Figure 2 Pathogen–host–vector complex: diseased host plant (*Nerium oleander*), bacterial colonisation of an insect's foregut, and an insect vector (*Homalodisca vitripennis*)

Source: Almeida and Nunney (2015).

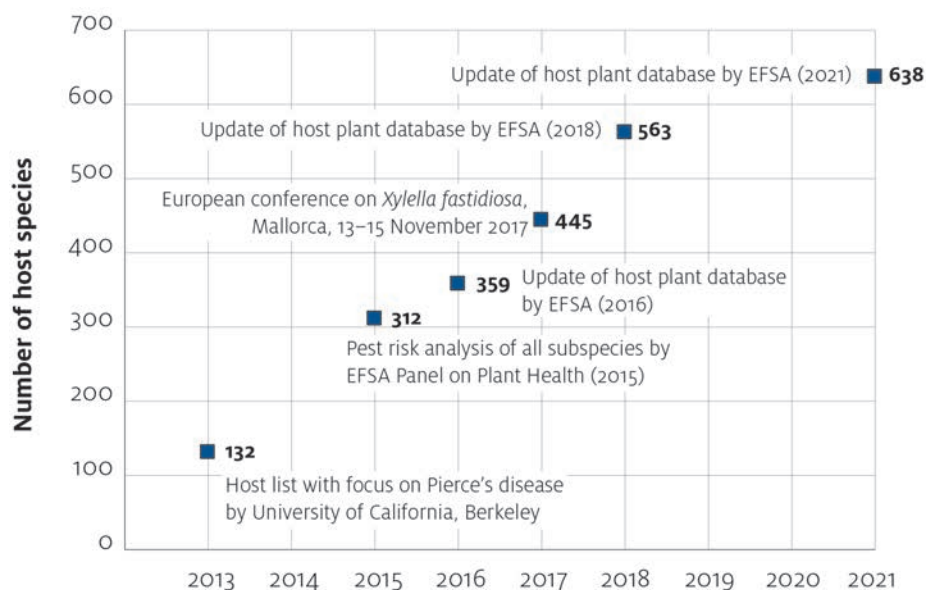
Detailed descriptions of symptoms for different host plant species are given by the European Plant Protection Organization (EPPO) (2022b), EFSA (2020) and the International Plant Protection Convention (IPPC) (2018). Briefly, the symptoms and impact of an infection are broad and depend on the susceptibility of the host plant. Plants may be asymptomatic or symptoms may be like those associated with water stress or physiological disorders. During early infection, for plants that show symptoms, initially the non-specific symptoms are signs of water stress. Later on, more severe symptoms develop – for example, leaf scorch, chlorosis, stunted growth and the premature fall of leaves and fruit. The latent period from infection to disease expression can exceed one year (Saponari et al., 2017). Symptoms are more pronounced in plants stressed by high or low temperatures or by drought. Disease development culminates in quick decline and death in susceptible hosts.

Plant species can harbour *Xylella* spp. but remain symptomless, while in others the infection can result in rapid decline and death (Martelli et al., 2016; Hopkins and Purcell, 2002). Where plants are asymptomatic, they can constitute low-level pathogen reservoirs in the environment. Visual screening cannot conclusively confirm infection, as symptoms are typically non-specific or plants remain asymptomatic. Highly sensitive molecular methods are therefore required to test accurately for *Xylella* spp. (IPPC, 2018). The Inspector-General notes that this rather cryptic nature of *Xylella* spp. is a significant challenge for preventative biosecurity as well as targeted surveillance and early diagnosis in nurseries and in the field.

Hosts

Xylella spp. have an extensive host range, including many herbaceous and woody plants, cultivated crops and weeds. A 2020 review of the scientific literature by EFSA et al. (2021) reported over 600 host plant species in more than 280 of plant genera and over 80 botanical families when all detection methods (e.g. molecular, microscopy, visual screening) were considered and included in the literature review (Figure 3). The department's research counts 106 host plant families. These families are regulated under Australia's emergency measures and cover over 20,000 confirmed and potential host plant species (not all of which are currently imported into Australia), illustrating the department's cautious approach to managing *Xylella* spp. (Table 2).

Figure 3 Increase in the number of *Xylella* spp. plant host species

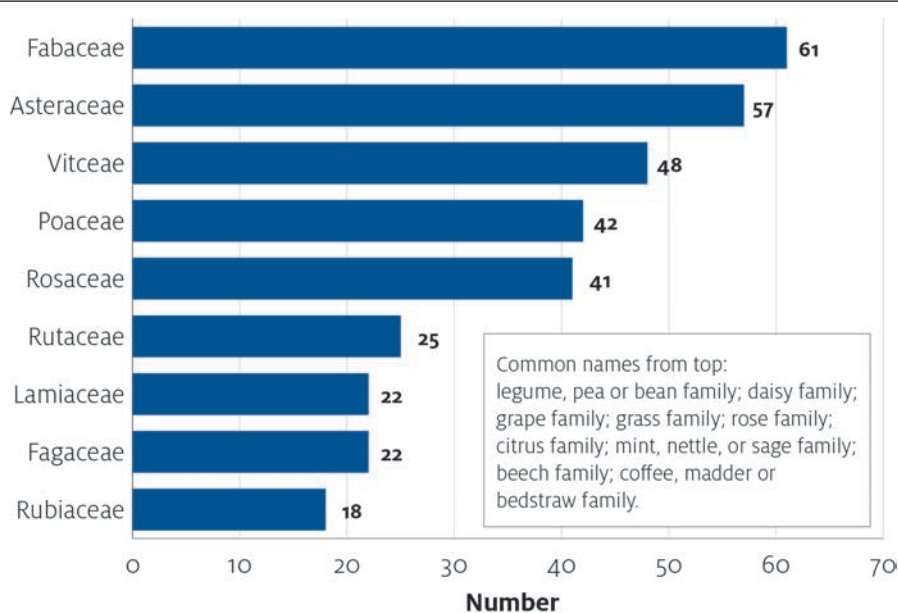


Source: After EFSA, 2018, 2021.

The number of plant hosts is expected to increase further as the pathogen invades new territories. Figure 4 shows the top 10 plant host families from an extensive literature search by the European Food Safety Authority (EFSA, 2020). Table 3 gives a high-level overview of plant hosts impacted by different *Xylella* species. The list includes Australian wattles (*Acacia* spp.) and westringias (*Westringia* spp.). The wide range of impacted plant genera and families imply that it is likely that more Australian native plants can be colonised by the pathogen (EFSA, 2020, 2018).

In many plant hosts, *Xylella* spp. infections are asymptomatic. In symptomatic hosts, disease symptoms are non-specific, at least during the early stages of infections, and resemble water stress and physiological disorders. The fact that *Xylella* spp. infections can spread asymptotically makes it highly cryptic and difficult to detect. It is therefore widely accepted that, to ensure *Xylella* spp. preparedness, the range of agricultural, horticultural and environmental hosts of *Xylella* spp. must be considered (e.g. DAWR, 2017a; EFSA Panel on Plant Health, 2015). The department's approach has been to regulate plant hosts of *Xylella* spp. at the family level and include both confirmed and potential host plant species, as mentioned above. Host plant species are abundant in Australia's diverse geographical regions and environments. Therefore, a well-informed, sharply targeted approach to *Xylella* spp. prevention, post-border verification and assurance, and response preparedness is needed.

Figure 4 Top 10 plant host families for *Xylella* spp. and number of known host species within each family



Source: From an extensive literature search by EFSA, 2020.

Table 3 Partial list of species in the *Xylella* genus by host plant

<i>X. fastidiosa</i> subsp. <i>fastidiosa</i>	<i>X. fastidiosa</i> subsp. <i>multiplex</i>	<i>X. fastidiosa</i> subsp. <i>pauca</i>	<i>X. fastidiosa</i> subsp. <i>sandyi</i>	<i>X. fastidiosa</i> subsp. <i>morus</i>	<i>Xylella taiwanensis</i>
Alfalfa	Almond	Almond	Coffee	Mulberry	Pear
Almond	Asparagus	Citrus	Daylily		
Coffee	Blueberry	Coffee	Magnolia		
Citrus	Crepe myrtle	Hibiscus	Oleander		
Grapevine	Elm	Oleander			
Lupin	Gingko	Olive			
Maple	Lavender	Peach			
Oleander	Maple	Wattle			
Rosemary	Oak	Westringia			
	Oleander				
	Olive				
	Peach				
	Pear				
	Plum				
	Sunflower				
	Wattle				
	Westringia				

Sources: EFSA Panel on Plant Health, 2018; Su et al., 2016; Hopkins and Purcell, 2002.

Genetic diversity of *Xylella* spp.

Xylella fastidiosa is primarily native to the Americas, although a distant relative is found in Taiwan (*Xylella taiwanensis*). Subspecies of *Xylella fastidiosa* historically evolved in relative geographical isolation. American representatives include the subspecies *fastidiosa*, *multiplex*, *pauca*, *morus*, and *sandyi* (Almeida and Nunney, 2015).

There is evidence of host–pathogen specificity (Sanderlin, 2017; Nunney et al., 2013). The mechanisms underlying the host–pathogen specificity and the resulting disease severity remain largely unknown (EFSA Panel on Plant Health, 2018). In contrast, there is no specialisation in respect to the insect vector (Almeida and Nunney, 2015). The finding of host–pathogen specificity implies that there are multiple, distinct diseases caused by *Xylella* spp. rather than just one.

The diversity within the *Xylella* genus is large and evolving. Genetic analyses (multilocus sequence typing) identified up to 81 different, genetically distinct sequence types worldwide in 2018 (EFSA Panel on Plant Health, 2018). Different subspecies of *Xylella fastidiosa* may be found in the same host – this allows for genetic hybridisation; hence new strains of the pathogen and diseases can evolve. The human-mediated introduction of exotic subspecies of *Xylella fastidiosa* into new regions has given rise to new genetic diversity, pathogenicity and virulence. The list of host plants has continued to expand concurrently (EFSA Panel on Plant Health et al., 2018; Almeida and Nunney, 2015).

Vectors

Potential vectors of *Xylella fastidiosa* are all sucking insects that are specialised xylem feeders – a hypothesis that, so far, still stands (Cornara et al., 2019; EFSA Panel on Plant Health, 2015; Hill and Purcell, 1997). A large group of candidate vectors are the ‘true hoppers’ (Hemiptera suborder Auchenorrhyncha), as they are commonly known. These are froghoppers and spittlebugs (superfamily Cercopoidea), cicadas (superfamily Cicadoidea), and sharpshooters (subfamily Cicadellidae Cicadellinae). These xylem sap-feeders are widespread and common in parts of the world currently not affected by *Xylella fastidiosa*, including Australia.

The bacterium is confined to the xylem, so insects that feed preferentially on the mesophyll or phloem, and only occasionally on xylem sap, are unable to transmit (Chatterjee et al., 2008; Purcell, 1980a). Adult insect vectors remain infectious for their entire life, but immature insects lose the *Xylella* bacteria through moulting and expulsion of foregut contents (EFSA Panel on Plant Health, 2015; Almeida et al., 2005).

There are 3 main steps in the vector-based transmission of *Xylella* spp. (Figure 2). First, the vector acquires the pathogen from the xylem of an infected plant. Second, the pathogen attaches to, and colonises, the surface of the insect’s foregut. Third, the vector inoculates the pathogen into the xylem of a susceptible host, generating a new infection.

Transmission efficiencies vary with the insect species, the host and the *Xylella fastidiosa* subspecies and strains (EFSA Panel on Plant Health, 2015; Redak et al., 2004). Interactions between these factors mean that a vector may be efficient in transmitting a strain of *Xylella* spp. among grapevines but very inefficient in transmitting the same strain among alfalfa plants, and vice versa (Daugherty et al., 2011).

Arguably, the best researched vector of *Xylella fastidiosa* is the glassy-winged sharpshooter (*Homalodisca vitripennis*) because of its prominent role in permanently changing the ecology, spread and severity of Pierce’s disease of grapevine in California (Hopkins and Purcell, 2002). The insect is native to the south-eastern United States (US). It was accidentally introduced into California in the 1990s, most likely as eggs on nursery stock. The insect is known for its high acquisition and transmission efficiency of *Xylella fastidiosa* and as highly invasive and a strong flyer.

The glassy-winged sharpshooter has successfully colonised the Pacific region as a hitchhiker in aircraft and on boats transporting plants between islands: French Polynesia (1999), Hawaii (2005), Easter Island (2005) and the Cook Islands (2007). In the Pacific, a biocontrol agent, the egg parasitoid *Gonatocerus ashmeadi*, was successfully introduced to provide permanent and safe control of the glassy-winged sharpshooter (Rathé et al., 2014; Hoddle and Van Driesche, 2009). As *Xylella* spp. have invaded new territories, the number of confirmed vectors has continued to increase (Cornara et al., 2019; EFSA Panel on Plant Health, 2015).

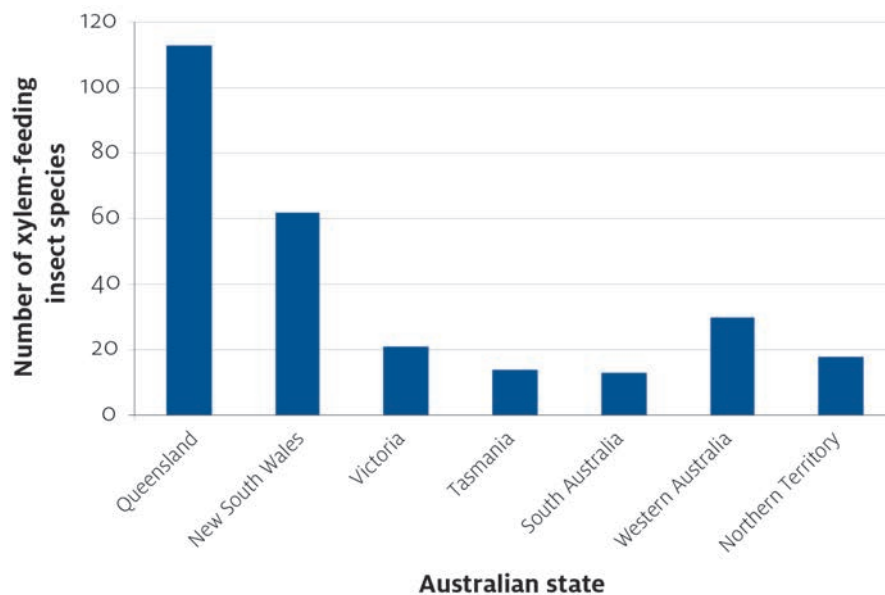
The most important driver of the *Xylella* spp. disease epidemics in Europe is the endemic meadow spittlebug *Philaneus spumarius*, which has only become an agricultural pest in Europe since the recent high-impact outbreaks of *Xylella fastidiosa* (Cornara et al., 2018; EFSA Panel on Plant Health, 2015). *Philaneus spumarius* plays no major role in the *Xylella* spp. disease epidemics in the US (Cornara et al., 2019; EFSA Panel on Plant Health, 2015).

Philaneus spumarius is abundant and highly polyphagous. It has been confirmed in most extra-tropical regions of the northern hemisphere as well as in New Zealand (CABI Invasive Species Compendium, 2021; EFSA Panel on Plant Health, 2015; Archibald et al. 1979). It was most likely to have been introduced into New Zealand from Europe, probably as overwintering eggs on dry plant material (Cornara et al., 2018; Hamilton and Morales, 1992). Transmission studies have shown that the overall transmission

dynamics of *Xylella fastidiosa* by the meadow spittlebug are similar to those of the glassy-winged sharpshooter (Cornara et al., 2018).

Native vectors play a role in epidemiology of *Xylella* spp. In Costa Rica, 2 widespread spittlebugs, *Carneocephala fulgida* and *Draeculacephala minerva*, are the vectors of the bacterium (DG Sante, 2016). Rathé et al. (2012) reviewed known Australian xylem sap-sucking insects that could potentially transmit *Xylella* spp. (Figure 5).

Figure 5 Number of known Australian native insects that are xylem-feeders and could potentially spread *Xylella* spp.



Source: Rathé et al., 2012.

Climate

Xylella spp. occur in a wide range of climate zones, including tropical, subtropical and temperate regions (EFSA Panel on Plant Health, 2015, 2019). These are also climates of the Australian continent (Peel et al., 2007). Climate is an important factor in the epidemiology of diseases caused by *Xylella* spp., as temperature and precipitation influence insect vector activity and the growth and survival of the pathogen.

Severe winter temperatures have restricted the spread of diseases caused by *Xylella* spp. into cold climate regions (e.g. high latitudes and altitudes). In the US, for example, Pierce's disease is more virulent in regions with mild winters and has not been reported from regions with very cold winters (Purcell, 2013). There are some reports that, when the pathogen is exposed to sub-zero winter temperatures, it can die and grapevines can recover from Pierce's disease (Purcell, 1977, 1980b). However, the effect of climate on epidemiology varies with the bacterium, insect vector and the host plant. These interactions are not yet sufficiently understood (EFSA Panel on Plant Health, 2015).

5.2 Overseas outbreaks

Each outbreak of disease caused by *Xylella* spp. has unique features. The features and consequences of 3 different outbreak types are described in the following sections. A lesson from these is that new host–pathogen combinations and invasive insects have caused alarming increases in the problems associated with *Xylella* spp. (e.g. EFSA Panel on Plant Health, 2018, 2015; Martelli et al., 2016; Su et al., 2016; Hopkins and Purcell, 2002).

Introduction into new territory

In 2013, reports on a new, severe olive disease emerged from the Salento Peninsula of Apulia in southern Italy. In the same year, *Xylella fastidiosa* was identified in olive trees as well as in almond and oleander showing leaf scorch symptoms. It was the first confirmed outdoor outbreak in any European Union (EU) country (Saponari et al., 2019). By May 2015, attempts to eradicate the disease had been officially replaced by a containment program. This involved establishment of a buffer zone, monitoring of the plant infection status, tree removal, and control of the insect vector, the endemic meadow spittlebug, *Philaenus spumarius* (Morelli et al., 2021).

In the worst affected southern part of Apulia, many trees were severely damaged or died of the new disease, olive quick decline syndrome. Centenarian trees showed the most severe symptoms (Martelli et al., 2016). By 2018, the infected area had increased from 8,000 hectares to 715,000 hectares and covered 36% of Apulia, with 21 million olive trees at risk. Extensive monocultures of 2 autochthonous, susceptible olive cultivars enabled the disease to spread more easily (Morelli et al., 2021).

Genetic analysis identified the *Xylella fastidiosa* subspecies *pauca*, strain ST53, in Apulian olives. This strain is closely related to a strain reported in Costa Rica, leading to the conclusion of a recent and single introduction (EFSA Panel on Plant Health, 2018). In 2018, a new outbreak was reported from Tuscany, central Italy.

The outbreak has led to the death of millions of trees and created ‘unprecedented turmoil for the local economy’ (Saponari et al., 2019). The true cost of damages is difficult to estimate, as *Xylella fastidiosa* has transformed landscapes of deep cultural and historical significance (IPPC, 2017).

Introduction of exotic strain of the pathogen

Citrus variegated chlorosis is a disease caused by the *Xylella fastidiosa* subspecies *pauca*. It emerged as a disease in southern South America in the 1980s and spread with the movement of infected nursery trees (Hopkins and Purcell, 2002). The subspecies is native to South America and present in both citrus and coffee, but to that point it had not been known to cause serious infection (Nunney et al., 2014). This raised the question of how the new disease evolved.

There is evidence that the human-mediated movement of an exotic *Xylella fastidiosa* strain, possibly of subspecies *multiplex*, from North America to South America and subsequent hybridisation has changed the epidemiology of the pathogen. In other words, genetic introgression from another *Xylella fastidiosa* strain created the genetic variation necessary for the pathogen to become highly virulent and invasive (Nunney et al., 2014).

Citrus variegated chlorosis appeared first in Argentina in the 1980s. In Brazil, the world’s largest producer of sweet oranges, the disease was first noted in only a few trees in 1987. By 1992, over 2 million trees were affected. A survey conducted in Brazil’s São Paulo state in 2013 established that approximately 56% of the 180 million trees were infected. There were large regional differences in infection rates due to climatic conditions (Coletta-Filho et al., 2013). Since 1987, over 100 million diseased citrus trees have been removed, and the cost of managing citrus variegated chlorosis is estimated at US\$120 million per year in Brazil alone (IPPC, 2017).

Introduction of exotic vector

The *Xylella fastidiosa* subspecies *fastidiosa* has been a major constraint to grapevine production in California for over 100 years. However, the accidental introduction of the

exotic and highly invasive glassy-winged sharpshooter (*Homalodisca vitripennis*) from the southwest of the US into southern California in the 1990s resulted in an enhanced vector–pathogen system and fundamentally changed the epidemiology of Pierce’s disease of grapevine (Hopkins and Purcell, 2002). The insect is a strong flyer and prolific feeder that can ingest and excrete over 100 times its body weight per day (Rathé et al., 2014).

By 2000, the spread and severity of Pierce’s disease had increased to what was called the ‘California vineyard apocalypse’. Today, an integrated management strategy is in place: infected vines are removed and replaced with less susceptible varieties, alternative plant hosts of *Xylella fastidiosa* are managed, and there is an area-wide control program for glassy-winged sharpshooter (DAWR, 2017a). The annual cost of Pierce’s disease is estimated at over US\$100 million, with over US\$50 million attributable to lost productivity, including vine replacements (Tumber et al., 2014).

Finding: Pathogens of the *Xylella* genus can be present in asymptomatic hosts for many years before disease emergence. The time lag between infection and appearance of disease symptoms makes it difficult to detect, contain and eradicate the pathogen. Levels of virulence depend on the specifics of the pathogen–host–vector environment complex. Each outbreak has unique characteristics. This makes predictions difficult.

In Australia, several endemic insects are highly likely to be capable vectors. Susceptible agricultural and native hosts are present and environment conditions suitable. An incursion of *Xylella* spp. into Australia could cause outbreaks that spread rapidly with devastating consequences; or *Xylella* spp. could establish in asymptomatic hosts only to emerge after a lag period when conditions are favourable. Prevention of entry of *Xylella* spp. is a vital biosecurity strategy for Australia.

5.3 Exotic vectors to Australia

Within the Australian context, the most important exotic vectors of *Xylella* spp. are currently *Homalodisca vitripennis*, the glassy-winged sharpshooter; and *Philaenus spumarius*, the meadow spittlebug. The department records both insect species on the top 42 unwanted National Priority Plant Pests (NPPP) list together with *Xylella* spp. (DA, 2019b). A recent departmental import risk analysis of cut flower and foliage imports assessed both insects as having the potential to establish and spread in Australia (DAWE, 2021d). However, the Inspector-General notes that, according to the science, all xylem sap-sucking insects (exotic and native) can potentially vector *Xylella* spp. Therefore, the establishment and spread of competent exotic vectors is not a prerequisite for a *Xylella* spp. outbreak.

Exotic insect vectors can arrive as egg masses, nymphs or adults with plant materials on which they live and overwinter, and as hitchhikers in alternative types of goods, conveyances, cargo containers and passenger baggage.

There are 2 possible scenarios for exotic vectors and their involvement in any future outbreak dynamics of diseases caused by *Xylella* spp.:

1. Infectious, exotic vectors arrive in Australia and establish and spread in parallel with *Xylella* spp.:
 - EFSA conducted a PRA in which it assessed the probability of entry of *Xylella* spp. from countries where *Xylella* spp. is reported. It found the risk to be moderate for infectious insect vectors carried with plant commodities or travelling as hitchhikers (EFSA, 2015).
 - The department explicitly considers this scenario as a possibility although of unspecified likelihood. It encourages importers and the wider public to look out for the glassy-winged sharpshooter and the meadow spittlebug (DAWE, 2021e).
2. Competent exotic vectors arrive in Australia separately from *Xylella* spp. and alter any time-lagged, subsequent outbreak dynamics of *Xylella* spp.

The glassy-winged sharpshooter and the meadow spittlebug are not known to be present in Australia, and the department has not detected established populations during post-border surveillance activities. However, both species have successfully invaded neighbouring countries. The glassy-winged sharpshooter is now endemic in Pacific Islands (Hoddle and Van Driesche, 2009) and the meadow spittlebug has been present in New Zealand possibly since the 1960s (Hamilton and Morales, 1992; Archibald et al., 1979). *Xylella fastidiosa* is not known to be present in the Pacific Islands or New Zealand.

The regular air and sea travel connecting Australia and Pacific nations is putting Australia at an enhanced risk from these pest species. However, there have been few at-border detections over the past 16 years, according to the department's 'incidents' data. Incidents are recorded as detections of pests during at-border inspection of biosecurity risk materials (goods and conveyances) to prevent the entry of pests into Australia.

Between 2005 and 2012 the department recorded 3 incidents of dead glassy-winged sharpshooter in the incidents database. One incident (2012) related to a vessel from a country where *Xylella* spp. is present. However, the dead glassy-winged sharpshooter was not tested for *Xylella* spp. Since 2016 and up until recently, there have been 6 recorded incidents of live (eggs and adults) and dead (adults) meadow spittlebug – 3 from countries where a *Xylella* spp. outbreak is current. Testing for *Xylella* spp. is not done on eggs and dead specimens collected at the border. Eggs cannot carry *Xylella* spp.; transovarial transmission is not possible; and dead specimens do not pose a threat. Live meadow spittlebug adults tested negative for *Xylella* spp.

In a different study, the department's science services group tested 12 potential vectors intercepted over an 18-month period from mid-2016 to late 2017 and found no *Xylella* spp. in any of the insects. The study found that, based on historical interception data, fewer than 10 potential vectors are typically intercepted annually.

Overall, the likelihood of arrival of potential insect vectors appears to be low. The likelihood is possibly slightly greater for the meadow spittlebug than for the glassy-winged sharpshooter. Going forward, however, insect vectors of *Xylella* spp. detected during at-border inspections should be routinely tested for *Xylella* spp. using the department's molecular (polymerase chain reaction (PCR)) testing capability. Testing should form a routine part of the department's assurance and verification activity for *Xylella* spp. and its vectors and will provide additional intelligence on the threat to Australia.

5.4 Australian native vectors

Two decades ago, Luck et al. (2002) and Merriman et al. (2001) listed the xylem sap-feeding insects native to Australia that could potentially transmit Pierce's disease of grapevine. The results and conclusions from these studies still stand today, with implications for any other host plant species:

... major insect vectors of [Xylella spp.] occur in the Hemipteran subfamily Cicadellinae and are commonly known as sharpshooters. Thirteen species of Cicadellinae have been recorded in Australia. Nine species belong to the genus Ishidaella and are distributed through Queensland, NSW, Victoria, Tasmania and Western Australia. ... four species are restricted to the tropics of Queensland the Northern Territory and are members of the Conoquinula and Cofana genera. ... all of them have the potential to transmit Pierce's disease because they are strict xylem-feeders ... (Luck et al., 2002)

Similarly, Rathé et al. (2012) reported that there are over 200 native xylem sap-feeding insects in Australia, predominantly in Queensland and New South Wales, that are potential vectors of *Xylella* spp. (Figure 5). A research project currently underway in Victoria aims to understand the biology and population dynamics of potential vectors of *Xylella* spp. in crop stands of host plant species (Trebicki, 2021). The research project will provide plant industries with important information on how to mitigate and manage the potential spread of *Xylella* spp. in Australia. The research includes annual field surveys for xylem sap-feeding insects in Victoria, South Australia, New South Wales and Queensland.

The research findings will help inform peri-border surveillance for potential vectors of *Xylella* spp. if the pathogen arrives in Australia via the nursery stock pathways. However, standard insect capture techniques and PCR testing methods already provide practical methods for monitoring presence of *Xylella* spp. in any present xylem sap-feeding insect population, as has been demonstrated for several situations in Europe.

6. *Xylella* spp. pathways to Australia

Xylella spp. can arrive in Australia via infected plant material or infected exotic insects. Mitigation measures are focused on potential pathways for entry, on a risk-assessed basis. In designing, implementing and assessing preventative biosecurity measures for *Xylella* spp., the department uses its judgment to decide whether the measures:

- can be generic to mitigate risk in legal import pathways as well as prevent illegal entry of potentially infected plant material
- prevent inadvertent entry of insect vectors arriving as ‘hitchhikers’
- are relevant for host plants of *Xylella* spp. or high-risk countries or both.

6.1 Nursery stock

By far the largest quantity of *Xylella* spp. risk materials arrive in Australia as deliberate (legal) import of agricultural and horticultural nursery stock through well-established plant import processes.

The department’s biosecurity policy position has long been to manage the increasing risk from diseases caused by *Xylella* spp. by preventing entry of *Xylella* spp. It aims to prevent entry by introducing and updating import conditions for an increasing number of plant host species in the nursery stock group of commodities (Table 2). Live plants and plant materials (vegetative propagative material and tissue cultures) imported as nursery stock are considered high-risk, as they are used for planting and propagation in fields, gardens and greenhouses, where the probability of transmission by sap-feeding insect vectors is greatest.

The Inspector-General notes that mitigating the risk of entry of *Xylella* spp. into Australia through regulation of the nursery stock pathway is in line with scientific pest risk assessments conducted elsewhere (e.g. EFSA et al., 2021; DEFRA, 2020; Afechtal et al., 2018; EFSA Panel on Plant Health, 2015).

A significant change in the regulation of nursery stock was the introduction of the 2015 emergency measures, the details of which are available on the department’s website (DAWE, 2021c). All nursery stock imports are subject these measures, except for some bulbs produced under a certification scheme in the Netherlands.

Under the emergency measures, plant host species of *Xylella* spp. are currently regulated at the plant family level. This has greatly increased the number of regulated plant species (confirmed and potential hosts) to over 20,000. The department chose this cautionary approach to act as a buffer given the rapidly growing number of internationally confirmed plant hosts of *Xylella* spp. The Inspector-General observes that, to the best of our knowledge, Australia is the only country that regulates at the plant family level.

To better manage the *Xylella* spp. risk offshore, under the emergency measures the National Plant Protection Organisation (NPPO) of the exporting country must issue phytosanitary certificates with specific wording prescribed by the department (DAWE, 2021c). The phytosanitary certificate attests that plants were tested offshore for *Xylella* spp. using prescribed molecular methods; or certifies country freedom from *Xylella* spp. Onshore post-entry quarantine (PEQ) growth and screening measures only apply to nursery stock that arrives without a phytosanitary certificate that meets Australian standards. In addition to the emergency measures, all other current import conditions for the plant species apply (DAWE, 2021c).

Import volumes are an important component of risk. For this review the department provided data records on nursery stock imports from the Agriculture Import Management System (AIMS). Import data is recorded as 'lines' in AIMS. A line record may be for a few or thousands of plants of one or several species. Therefore, a line record gives only an indication of import trade volumes and may not necessarily list all species covered in the import documents supplied by the importer. Issues of data resolution and accessibility for routine analytical and risk management purposes are discussed in chapter 13 of this review.

The department provided the following statistics, which give a broad summary of the import trade in nursery stock (across the 2015–2021 financial years), as indicated by the number of lines recorded in AIMS:

- 32.5% of nursery stock imports are from high-risk countries or regions: The top 5 exporting countries are India, US, Netherlands, Germany and Israel
- 67.5% of nursery stock imports are from low-risk countries: The top 5 exporting countries are China, Indonesia, Sri Lanka, New Zealand and Thailand.

Since the introduction of emergency measures in 2015, imports from low-risk countries or regions have increased steadily (Figure 6), and more nursery stock is imported as tissue culture plantlets (Figure 7). The trend towards tissue culture appears to have accelerated during the period of the COVID-19 pandemic, possibly driven by reduced airfreight availability and increasing freight cost, and strong Australian consumer demand for ornamental plants.

Figure 6 Changes over time in the number of nursery stock consignments (lines in AIMS) from high-risk and low-risk countries/regions regulated under the emergency measures

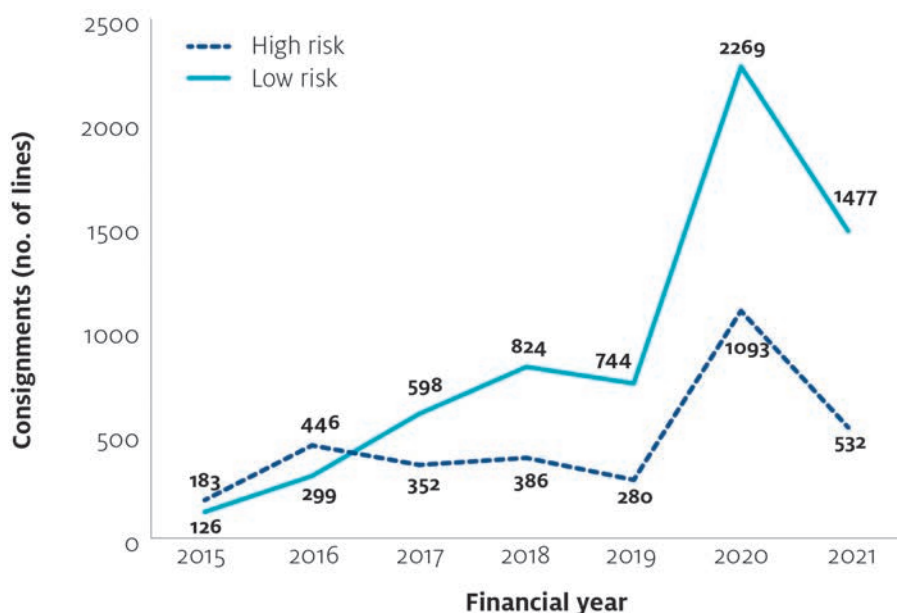
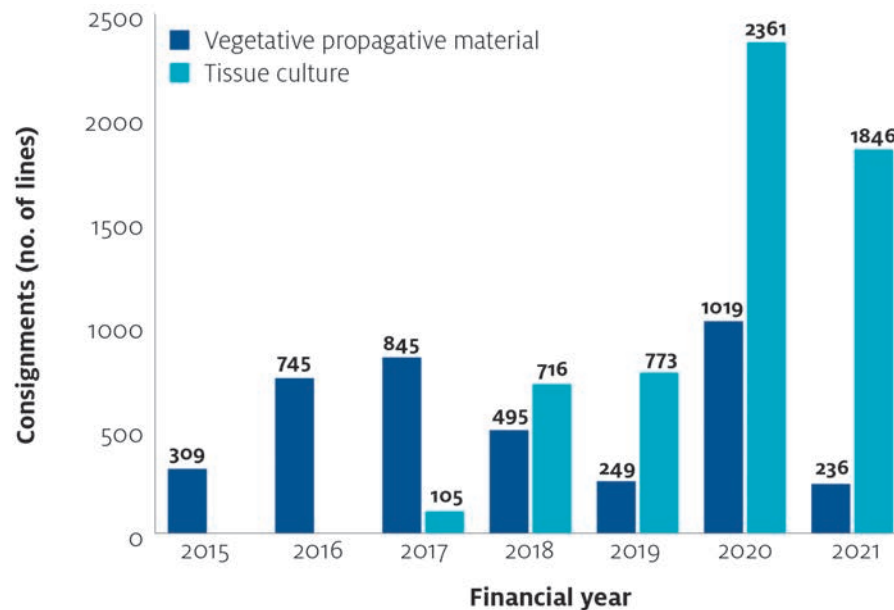


Figure 7 Changes over time in the number of nursery stock consignments (lines in AIMS) imported as vegetative propagative material and tissue culture



Based on data from the 2015–2021 financial years, most nursery stock consignments arrive in Australia by airfreight in Melbourne (65%), followed by Perth (17%), Sydney (11.5%), and Brisbane (5%).

The department’s biosecurity officers do a visual inspection of all imported nursery stock on arrival, regardless of the plant form (vegetative propagative material or tissue culture), to assess whether the nursery stock is free from bacterial and fungal infection, disease symptoms, live arthropods, and other extraneous contamination of biosecurity concern. Remedial actions used at the border to manage identified unacceptable biosecurity risk are treatment (if an effective treatment is available), export or destruction. Nursery stock imported as vegetative propagative material undergoes mandatory treatment to manage arthropod risk.

According to the emergency measures published on the department’s website (2021c), onshore PEQ measures required under the 2015 emergency measures (briefly, growth and screening at a government or private PEQ facility depending on plant material type) appear to only apply to nursery stock consignments that arrive without an acceptable phytosanitary certificate. However, the department clarified to the Inspector-General that so called ‘high-risk’ nursery stock (chapter 8.4) do *not* require a phytosanitary certificate (hence offshore PCR testing) because it is PCR tested onshore during the mandatory PEQ period. The Inspector-General observes that greater clarity and strengthened biosecurity control can be achieved by simplifying the conditions for nursery stock: to mandate offshore PCR testing and phytosanitary certification for *any* nursery stock from high-risk countries/regions.

In most cases – that is, irrespective of the emergency measures – the onshore risk is primarily managed according to any other import conditions for a plant species and not the onshore emergency measures, assuming most consignments arrive with an acceptable phytosanitary certificate (the department’s data provided for this review did not elucidate the numbers of nursery stock consignments that arrived without acceptable phytosanitary certificate and were therefore directed to PEQ growth and screening under the 2015 emergency measures).

So, nursery stock imports are managed onshore in multiple ways depending on the import conditions that apply for the plant species. Broadly, nursery stock may:

- be released from the department's biosecurity on documentation and inspection if all current import conditions are met. This commonly applies to most nursery stock consignments although the department was unable to provide data on the proportion and type consignments (e.g. vegetative propagative material or tissue cultures from high-risk or low-risk countries or regions) released on documentation and inspection
- undergo mandatory growth and disease screening in the department's high-security PEQ facility at Mickleham for a minimum of 3 months to 2 years. Depending on import conditions, plant species may be tested for *Xylella* spp. using molecular methods based on polymerase chain reaction (PCR) during the PEQ period at Mickleham
- undergo growth and disease screening at a department-approved arrangement site operated by a state/territory. Depending on import conditions, plant species may be PCR tested for *Xylella* spp. during this period
- undergo a short period of growth and disease screening at a department-approved arrangement site operated by a private commercial entity (e.g. a wholesale nursery operated by the importer or associated business) in a plant house, glasshouse, polyhouse, igloo or tunnel house, excluding screen houses.

The department was not able to provide data on the proportions of consignments (lines in AIMS) or import volumes (e.g. size and number) for each of the above paths apart from consignments undergoing growth and disease screening at the department's PEQ facility at Mickleham – about 4% of all nursery stock consignments. While the information might be recorded somewhere in the department's different systems, it is not readily accessible. The Inspector-General observes that this data is essential to understand and mitigate risk. Therefore, the department should be able to efficiently access the details of consignments from point of entry through to the different types of quarantine growth and screening and sites (government or private) until release from the department's biosecurity control.

There are significant exceptions to the general handling of imported nursery stock (assessed in detail in chapter 9), adding complexity to the regulation of nursery stock. Exceptions include:

- bulbs imported from the Netherlands under a certification scheme
- high-health tissue cultures of agriculturally significant species imported from the UK and the US
- ex-media tissue cultures of ornamental host plants from approved sources, including from high-risk countries
- orchids – *Phalaenopsis* spp. nursery stock from Taiwan (DAWE, 2021f).

To date, there have been no at-border detections of *Xylella* spp. bacteria (confirmed by molecular diagnostic tests) or plant symptoms that would indicate a potential infection. While visual inspection to detect *Xylella* spp.-like symptoms is important, *Xylella* spp. infection is only reliably detected using molecular diagnostic tests, such as real-time PCR testing.

Under Australia's emergency measures, the internationally recognised PCR tests by Harper et al. (2010) and Minsavage et al. (1994) must be generally applied offshore. Regarding onshore testing, based on the department's data the Inspector-General estimates that only about 4% of nursery stock consignments are currently tested for *Xylella* spp. presence using these PCR tests.

6.2 Cut flowers

Commercial quantities of fresh cut flowers and foliage have been imported into Australia for about 50 years. Stakeholders have previously raised cut flower imports as a potential pathway for serious insect pests, including vectors of *Xylella* spp., to enter Australia.

To manage the biosecurity risk associated with imported cut flowers and foliage, the department recently completed pest risk analyses (PRAs) and amended the import conditions for fresh cut flowers and foliage (DA 2019c; DAWE, 2021d).

Following amendments to import conditions for fresh cut flowers and foliage which came into effect on 1 March 2018, there has been a dramatic reduction in pest detections on imported consignments. Pest detections across all consignments of fresh cut flowers and foliage were reduced from 56% in September 2017 to 12% in March 2021 (DA, 2019c; DAWE, 2021d).

The department considers the *Xylella* spp. risk associated with cut flowers negligible due to the different end-use (ornamental display), fumigation to mitigate vector entry, and the required devitalisation treatment to prevent propagation of plant materials (DAWE, 2021d).

This position is supported by international research and detailed in the PRA conducted in 2015 by the European Food Safety Authority (EFSA Panel on Plant Health, 2015).

Given the detailed work the department has done to assess and mitigate pest risks for fresh cut flower and foliage imports, for this review the Inspector-General sees no significant merit in exploring whether additional risk mitigation measures may be necessary to mitigate *Xylella* spp. risks of cut flowers that are not effectively addressed by the existing measures.

6.3 Fruit and seed

The department does not regulate fruit for *Xylella* spp. Transmission of *Xylella* spp. from infected fruit has been generally regarded as not epidemiologically significant because fresh fruit is transported, stored cold and sold soon after harvest for human consumption. However, there is high uncertainty owing to insufficient research on the likelihood of bacterial survival in fruit and potential transmission (EFSA Panel on Plant Health, 2015).

Transmission of *Xylella* spp. via infected botanical seeds had long been considered unlikely, though there has been a high degree of uncertainty due to the lack of extensive studies (EFSA Panel on Plant Health, 2015). Research published very recently (April 2022) provided evidence for seed transmission of *Xylella fastidiosa* in pecan (*Carya illinoensis*) (Cervantes et al., 2022). The results of the study demonstrate the ability of *Xylella fastidiosa* to colonise seeds and be efficiently transmitted from well-developed seeds to pecan seedlings.

In response to the findings by Cervantes et al. (2022), the department implemented emergency measures for *Carya* seed for sowing in May 2022 (Table 2). The Inspector-General did not assess recent measures introduced for *Carya* seed but notes that these should be considered in the department's draft pest risk analysis for bacterial pathogens in the *Xylella* spp. genus.

Finding: Fruit and the majority of seeds, except for pecan seed, are not regarded as risk pathways for *Xylella* spp. according to the department's current policy. The department should closely consider the evolving research regarding potential *Xylella* spp. infection of fruit and seed in its pest risk assessments and implement appropriate pathway monitoring, including random sampling and testing, and updates to current policy, as required.

6.4 Passengers and mail

This review did not specifically examine risk factors and mitigation measures for the passenger and international mail pathways. This is not to say that risks for the introduction of *Xylella* spp. to Australia do not exist for these pathways. The department has provided evidence in various forms over many years that shows that plant material may be deliberately or inadvertently brought to Australia in passengers' luggage or in mail.

Previous reviews by Inspectors-General have examined and made recommendations for these areas. A current review, *Efficacy and adequacy of department's X-ray scanning and detector dog screening techniques to prevent entry of biosecurity risk material into Australia*, will also examine some relevant risk mitigation measures (IGB, 2022b).

The department has in place a range of mitigation measures for illegal imports of plant material through these risk pathways. These largely involve generic measures applied to plant material rather than extra and specific measures for *Xylella* spp. host species.

In this review the Inspector-General has seen no significant merit in further exploring the adequacy of general plant-focused risk mitigation measures in the passenger and mail pathways to assess whether *Xylella* spp.-specific risks may be more effectively mitigated.

7. Regulatory framework

Biosecurity functions, arrangements, measures and actions to achieve the Australia's biosecurity policy goals operate under a national legislative framework and must conform to Australia's rights and obligations as a WTO member country.

7.1 Policy goals

Australia's nationally agreed biosecurity policy goal is defined in the 2019 Intergovernmental Agreement on Biosecurity (IGAB) as 'to minimise adverse impacts of pests and diseases on Australia's economy, environment and the community while facilitating trade and the movement of plants, animals, people and products' (COAG, 2019).

In 2021, the department articulated Australia's policy goal for the biosecurity system as 'A risk-based biosecurity system that effectively, efficiently and sustainably protects Australia's health, economic, environmental and national security interests against the threats of today and tomorrow, consistent with the appropriate level of protection' (DAWE, 2021g).

The appropriate level of protection (ALOP) is an important national biosecurity concept defined qualitatively in the *Biosecurity Act 2015* as 'a high level of sanitary and phytosanitary protection aimed at reducing biosecurity risks to a very low level, but not to zero'. The ALOP is applied in the department's pest risk assessments and reflects Australia's risk-based approach to preventative biosecurity.

7.2 Legislation

At the Commonwealth level, Australia's regulatory framework includes the *Biosecurity Act 2015* and subordinate legislation made under the Act. The department administers the *Biosecurity Act 2015* and has the sole regulatory responsibility for preventing the entry (beyond the international border) of biosecurity risk material into Australia, except for human biosecurity risks, where the Department of Health has the lead.

The *Biosecurity Act 2015* contains the basic laws granting legal authority to Australia's national plant protection organisation (the department) from which sanitary and phytosanitary regulations are derived. It provides the Commonwealth with powers to assess and manage the risk of pests and diseases entering Australian territory and causing harm to animal, plant and human health, the environment and the economy.

The Biosecurity Regulation 2016 made under the Act prescribes information relating to the exercise of powers by officials and sets out the necessary information and reporting requirements that those regulated by the Act are required to provide. The Biosecurity

Regulation works in conjunction with several regulations and legislative instruments, including the Biosecurity (Conditionally Non-Prohibited Goods) Determination 2021, Biosecurity (Reportable Biosecurity Incidents) Determination 2016, and the Training and Qualifications of Biosecurity Officers Determination 2016, among others.

The *Biosecurity Act 2015* and its subordinate legislation came into force on 16 June 2016. The *Biosecurity (Consequential Amendments and Transitional Provisions) Act 2015* provided transitional powers from the *Quarantine Act 1908* to the new Act. The 2015 *Xylella* spp. emergency measures were implemented under the *Quarantine Act 1908*, which preceded the *Biosecurity Act 2015*.

Key provisions of the *Biosecurity Act 2015* to manage the risk associated with *Xylella* spp. include the following:

- **Section 119:** Under the provisions of Division 2 (Goods are subject to biosecurity control), section 119 (Goods brought into Australian territory are subject to biosecurity control), goods brought into Australia by air or sea are subject to biosecurity control until they are released from biosecurity control.
- **Sections 123, 126 and 127:** Under the provisions of Division 4 (Assessment of level of biosecurity risk), section 123 (Biosecurity risk assessment powers), section 126 (Asking questions about goods) and section 127 (Requiring documents relating to goods to be produced), goods subject to biosecurity control may be assessed for their level of biosecurity risk, and biosecurity officers may request information, verbally or in writing, in relation to the goods to fully assess risk.
- **Section 125:** Under the provisions of Division 4 (Assessment of level of biosecurity risk), section 125 (Inspection and taking samples), a biosecurity officer may inspect goods, take samples or direct or arrange for an appropriate person to take samples, and carry out tests or arrange for an appropriate person to test the samples.
- **Section 174:** Under the provisions of Division 2 (Prohibited goods and conditionally non-prohibited goods), section 174 (Conditionally non-prohibited goods), goods can be imported if certain conditions are satisfied; that is, goods are conditionally non-prohibited. If goods are conditionally non-prohibited, the level of biosecurity risk associated with the goods can be reduced through biosecurity measures to achieve a level of residual biosecurity risk consistent with Australia's ALOP.
- **Section 176:** Under the provisions of Division 3 (Permits to bring or import goods into Australian territory), section 176 (Application of this Division), conditionally non-prohibited goods may require a permit to be brought or imported into Australia.

7.3 International obligations and standards

Australia's biosecurity arrangements and measures must conform to its rights and obligations as a WTO member country. Rights and obligations derive principally from the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and are recognised in the *Biosecurity Act 2015*. All WTO members are signatories to the SPS Agreement, which entered into force with the establishment of the WTO in 1995.

The SPS Agreement gives each WTO member the right to introduce or maintain biosecurity measures that the member considers adequate to achieve an appropriate level of sanitary (human and animal health) or phytosanitary (plant health) protection for its territory (the member's ALOP). The articulation of Australia's ALOP in the *Biosecurity Act 2015* is in accordance with Australia's rights and obligations under the SPS Agreement.

According to the SPS Agreement, biosecurity measures to achieve the ALOP must:

- be based on sound risk assessments underpinned by scientific evidence, including the potential damages in the event of entry, establishment and spread
- account for the objective of minimising negative trade effects
- be applied consistently and not constitute arbitrary or unjustifiable treatment or a disguised restriction on trade.

International standards and measures for plant health recognised by the WTO are those of the International Plant Protection Convention (IPPC), which came into effect for the first time in 1952. The IPPC develops and promotes the implementation of internationally agreed science-based standards in the regulation of plants and plant products as they move across international borders. It is the sole organisation setting global standards for plant health, including protocols for diagnostics and phytosanitary treatments (Giovani et al., 2020). As a WTO member country, Australia, represented by the department, participates in international standard setting.

The IPPC has adopted 44 International Standards for Phytosanitary Measures (ISPMs), 29 diagnostic protocols and 39 phytosanitary treatments (IPPC, 2021). Table 4 summarises key international standards that apply in the context of this review.

Table 4 Summary of ISPM standards relevant for this review

Standard	Description
ISPM1	<p>ISPM1 (Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade) describes basic and operational principles to aid in understanding the International Plant Protection Convention (IPPC) and the international phytosanitary system. Principles relate to the rights and obligations of contracting parties to the IPPC.</p> <p>The department introduced the <i>Xylella</i> spp. emergency measures (DAWE, 2021c) in accordance with ISPM1 and the governing IPPC. Accordingly, a contracting party has ‘the sovereign authority to regulate, in accordance with international agreements, the entry of plants and plant products ... and may prescribe and adopt phytosanitary measures ... and can take ... appropriate emergency action on the detection of a pest posing a potential threat to its territories’.</p> <p>The standard requires emergency measures to be evaluated and justified in a pest risk analysis (PRA):</p> <p style="padding-left: 40px;">Contracting parties may adopt and/or implement emergency actions, including emergency measures, when a new or unexpected phytosanitary risk is identified. Emergency measures should be temporary in their application. The continuance of the measures should be evaluated by a pest risk analysis or other comparable examination as soon as possible, to ensure that the continuance of the measure is technically justified.</p>

Standard	Description
ISPM2 and ISPM11	<p>ISPM2 (Framework for pest risk analysis) provides guidance on what is involved in the PRA process, including the evaluation of scientific and economic evidence to underpin phytosanitary regulations:</p> <p>Pest risk analysis provides the rationale for phytosanitary measures for a specified PRA area. It evaluates scientific evidence to determine whether an organism is a pest. If so, the analysis evaluates the probability of introduction and spread of the pest and the magnitude of potential economic consequences in a defined area, using biological or other scientific and economic evidence. If the risk is deemed unacceptable, the analysis may continue by suggesting management options that can reduce the risk to an acceptable level. Subsequently, pest risk management options may be used to establish phytosanitary regulations.</p> <p>ISPM11 (Pest risk analysis for quarantine pests) provides the details on what is involved in a PRA, including determining a quarantine pest. The standard describes the stages of the PRA process:</p> <p>Stage 1 (initiating the process) involves identifying the pest(s) and pathways that are of quarantine concern and should be considered for risk analysis in relation to the identified PRA area.</p> <p>Stage 2 (risk assessment) begins with the categorization of individual pests to determine whether the criteria for a quarantine pest are satisfied. Risk assessment continues with an evaluation of the probability of pest entry, establishment, and spread, and of their potential economic consequences (including environmental consequences ...).</p> <p>Stage 3 (risk management) involves identifying management options for reducing the risks identified at Stage 2. These are evaluated for efficacy, feasibility and impact in order to select those that are appropriate.</p>
ISPM6	<p>ISPM6 (Surveillance) describes the requirements for a national surveillance system, including:</p> <ul style="list-style-type: none"> • general and specific surveillance and respective protocols • supporting infrastructure (phytosanitary legislation and policies, prioritisation, planning, resources, documentation, training, auditing, communication and stakeholder engagements, pest diagnostics, information management systems).
ISPM7	<p>ISPM7 (Phytosanitary certification system) 'contains requirements and describes components of a phytosanitary certification system to be established by national plant protection organizations (NPPOs)':</p> <p>Phytosanitary certificates are issued for exported or re-exported consignments to provide assurance to an NPPO that the consignments meet the phytosanitary import requirements.</p> <p>The NPPO of the exporting country has the sole authority to undertake phytosanitary certification ...</p>
ISPM12	<p>ISPM12 (Phytosanitary certificates) is a standard that specifies 'requirements and guidelines for the preparation and issuance of phytosanitary certificates (phytosanitary certificates for export and phytosanitary certificates for re-export)':</p> <p>Phytosanitary certification is used to attest that consignments meet phytosanitary import requirements and is undertaken by an NPPO. ...</p> <p>A phytosanitary certificate for export is usually issued by the NPPO of the country where the plants, plant products or regulated articles were grown or processed. ...</p>

Standard	Description
ISPM27 and annex DP25	<p>ISPM27 (Diagnostic protocols for regulated pests) provides a ‘framework for the content of diagnostic protocols, their purpose and use, their publication and their development’.</p> <p>Annex DP25 (<i>Xylella fastidiosa</i>) is a diagnostic protocol for <i>Xylella</i> spp. covering pest and taxonomic information, guidance on detection (where, how, when), identification methods, keeping of records and evidence, contact points for further information, acknowledgements and references. The protocol describes serological (DAS-ELISA) and molecular detection methods (conventional polymerase chain reaction (PCR), real-time PCR and loop mediated isothermal amplification (LAMP)).</p>
ISPM32	<p>ISPM32 (Categorization of commodities according to their pest risk) describes criteria relating to production method, degree of processing and intended end-use to group commodities according to their pest risk. Plants for planting are classified into the high-risk commodity category.</p>
ISPM36	<p>ISPM36 (Integrated measures for plants for planting) provides additional guidance on managing the pest risk in plants for planting, as:</p> <p>[These] are generally considered to pose a higher risk than other regulated articles. Integrated measures may be used to manage the pest risks that plants for planting pose as a pathway for regulated pests and to ensure they meet phytosanitary import requirements. The use of integrated measures involves national plant protection organizations (NPPOs) as well as producers, and relies on pest risk management measures applied throughout the production and distribution processes.</p> <p>The standard specifies integrated measures for production situations, training, examination of plant materials, packaging and transportation, audits, records management and corrective actions, as well as the responsibilities of the NPPO of the exporting and importing countries.</p> <p>Annex 1 of ISPM36 lists factors that affect the pest risk of plants for planting, noting that the actual risk depends on specific circumstances, including the plant species, genetics, age, area of origin and other factors relating to production and end-use. The pest risk associated with different plant material types was ranked broadly from <i>lowest to highest</i> pest risk:</p> <ol style="list-style-type: none"> (1) meristem tissue culture [lowest] (2) in vitro culture (3) budwood/graftwood (4) unrooted cuttings (5) rooted cuttings (6) root fragments, root cuttings, rootlets or rhizomes (7) bulbs and tubers (8) bare root plants (9) rooted plants in pots [highest]. <p>Growing conditions that can affect pest risk were also ranked broadly from <i>lowest to highest</i> pest risk:</p> <ol style="list-style-type: none"> (1) growth chamber [lowest] (2) greenhouse (3) screen house (4) field grown in containers (pots, tubs etc.) (5) field grown (6) plants collected from the wild [highest].

Source: IPPC, 2021.

7.4 Conditions for importing goods

Setting import conditions

Imports are subject to biosecurity measures to reduce the level of biosecurity risk associated with the goods to an acceptable level in accordance with Australia's ALOP. There are 2 principal ways to set import conditions for goods:

1. The Director of Biosecurity can grant, on application by a person, an import permit for specific goods that specifies the import conditions that must be complied with to reduce the level of biosecurity risk to an acceptable level (section 179 of the *Biosecurity Act 2015*).
To manage the risk of *Xylella* spp., importers of live plants (except orchid tissue cultures imported in accompanied baggage) require an import permit issued by the department prior to the arrival of the goods into Australian territory.
2. The Director of Biosecurity and Director of Human Biosecurity can determine conditions for classes of goods in the Biosecurity (Conditionally Non-prohibited Goods) Determination 2021 (Goods Determination) (section 174 of the *Biosecurity Act 2015*). The Goods Determination is a legal instrument that stipulates conditions for classes of goods and, in some cases, the alternative conditions for goods:
 - The Goods Determination defines live plants as 'living plants, and part of living plants, including seeds and germplasm'.
 - Live plants are listed under Division 1 (Animals, plants, biological material and infectious agents) as a class of goods.
 - Section 12 (Conditions – general) specifies that live plants must not be brought or imported into Australian territory unless the goods are covered by an import permit or the alternative conditions are complied with.
 - Alternative conditions are specified in section 26 (Alternative conditions – live plants for use as nursery stock), which sets out that live orchids do not require an import permit when brought into Australia as tissue culture in accompanied baggage, and in section 30 (Alternative conditions – packaging), which lists types of permissible packaging for live plants.

Standard and specific conditions

Import conditions specify standard requirements such as appropriate documentation (e.g. import declarations and phytosanitary certificates) and cleanliness (e.g. clean packaging free of any contaminants); and more specific requirements pertaining to different risk attributes of goods, such as the pest-free status of the country of origin and how goods were produced and handled. Risk reduction measures set out in the import conditions can include treatment (e.g. fumigation to reduce arthropod risk) and quarantine growth and screening of plant materials. A high-level overview of the biosecurity processes and conditions for the importation of plants and plant products is given in Appendix A.

The 2015 *Xylella* spp. emergency measures for nursery stock are phytosanitary import conditions to specifically target the threat from *Xylella* spp. (DAWE 2021i). They operate together with all other import conditions for live plant imports and were introduced in accordance with Australia's rights and obligations under the IPPC and as outlined in ISPM1 (Table 1, Table 2, Table 4). The *Xylella* spp. emergency measures will lose the 'emergency label' once the department has evaluated and justified the measures in the *Pest risk analysis for bacterial pathogens in the genus Xylella*, announced in August 2018 (DAWR, 2018a).

7.5 Pest risk analysis

The WTO SPS Agreement describes a risk assessment as:

The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing WTO member ..., and of the associated potential biological and economic consequences.

The PRA is in accordance with Australia's international obligations as a WTO member and signatory to the IPPC. The international standard ISPM1 (Table 4) requires the department to evaluate and justify the 2015 *Xylella* spp. emergency measures for nursery stock and tissue culture:

The continuance of the [emergency] measures should be evaluated by a pest risk analysis or other comparable examination as soon as possible, to ensure that the continuance of the measure is technically justified.

The commencement of the department's *Pest risk analysis for bacterial pathogens in the genus Xylella* was announced in August 2018, with an original completion date in 2019 (DAWR, 2018a). The Inspector-General notes that, at the time of conducting this review, the delivery of the PRA for Australia's No. 1 priority plant pest was still listed as a short-term, high-priority action in the [National Xylella Action Plan 2019–2029](#) with a possible, yet unspecified, completion date in 2022 (DA, 2019a).

The science of *Xylella* spp. and its hosts and vectors is well advanced and has been expanding rapidly over the past decades. Key research conducted overseas, especially in country's affected by *Xylella* spp. (US and Europe) is easily accessible electronically by the department. Reviews of the science have been undertaken for multiple recent PRAs conducted overseas to implement *Xylella* spp. measures. For example:

- An in-depth scientific PRA has been available to EU countries since 2015 (EFSA Panel on Plant Health, 2015). This PRA has since been updated and amended on numerous occasions (EFSA et al., 2021; EFSA, 2020, 2018, 2016; EFSA Panel on Plant Health et al., 2019, 2018). The findings and updates are publicly available to anyone. They include evaluations of biosecurity risk pathways, mitigation options, a frequently updated host plant database, diagnostics and surveillance protocols.
- Morocco published its PRA on *Xylella fastidiosa* in 2018 (Afechtal et al., 2018).
- The UK released a draft rapid PRA in 2020 (DEFRA, 2020).

Over 20 years ago, the Australian grape and wine sector commissioned a risk assessment report (Merriman et al., 2001). The report is now outdated in many aspects but appears to be still used as a reference by Australian biosecurity stakeholders. Outdated are assessments that:

- focused primarily on Pierce's disease of grapevine
- considered the risk associated with legal imports as negligible
- portrayed illegal imports of host plant material by travellers and in mail consignments as the greatest risk
- speculated that the use of antibiotics could cure infection in hosts.

However, the report also identified an increased risk for *Xylella fastidiosa* associated with the importation of alternative hosts (those other than grapevine). This is supported by the current science (e.g. EFSA Panel on Plant Health, 2015). Concerningly, in conversations with the Inspector-General, some industry participants echoed outdated ideas regarding *Xylella* spp. risk and risk mitigation in the biosecurity system. This highlighted the need for completion and publication of the up-to-date PRA that commenced in 2018 (Table 2). The department has explained to the Inspector-General the draft PRA has been substantially completed.

In 2013, the Australian grape and wine sector requested that the department undertake a risk assessment and policy review of *Vitis* spp. propagative materials (DAFF, 2013). The 2013 review is available in the department's plant risk analyses webpages (DAWE, 2019), but it appears to be less widely known than the industry-commissioned work (e.g. Merriman et al., 2001). Risk management measures recommended in the department's 2013 review included mandatory on-arrival inspection and treatment as appropriate for the type of plant material, mandatory growth in government PEQ, and active pathogen testing, including molecular testing. The review linked *Xylella fastidiosa* to both vegetative propagative materials and tissue cultures of *Vitis* spp. with and concluded 'that certain pathogens (bacteria, phytoplasma, viroids and viruses) may not be excluded from the pathway and remain associated with micropropagated plantlets (tissue culture)' (DAFF, 2013).

Clearly, it is in the national interest that the department publish, as a matter of priority, a comprehensive PRA reflecting the current state of scientific knowledge for vegetative propagative materials as well as tissue cultures, risk pathways and exposure within the Australian context.

In some consultations between the department and the Inspector-General the meeting of international obligations was seen as the most important driver for the PRA. However, the significance of the PRA extends beyond the requirement for meeting international obligations. The PRA can be a powerful piece of communication of benefit to many participants in the biosecurity system because the PRA:

- provides impetus for the department to critically assess and compile contemporary global knowledge on *Xylella* spp. risk mitigation
- is a key reference for stakeholders – industry, community and governments – that gives the Australian context and perspective
- gives a compelling summary of the contemporary evidence for *Xylella* spp. being Australia's No. 1 plant pest and the need for strong biosecurity measures for different types of nursery stock imports as indicated by their risk attributes (Table 4)
- supports agile and regulation-based responses under the *Biosecurity Act 2015*.

Delay in the completion of a PRA is not unique to *Xylella* spp. In a previous Inspector-General review on Australia's No. 2 priority plant pest, khapra beetle, the department advised that most formal PRAs take between 18 and 36 months to complete (IGB, 2021a). The department currently has risk assessments – full, partial or in draft – for 12 of the top 42 NPPPs. The department advised that not all the top 42 NPPPs are subject to formal PRAs.

The department should complete, in a timelier manner, those PRAs for which a timetable has been planned and public commitment made to stakeholders (Table 2). To meet planned timelines, the department should consider approaching the analysis in more manageable phases or even as a continuous process:

- The department could undertake a rapid PRA of bacterial pathogens in the genus *Xylella* covering the most important risk attributes and measures and release the full PRA at a later stage. Examples of this approach are the rapid PRA published by the UK (DEFRA, 2020) and the condensed PRA published by Morocco (Afechtal et al., 2018).
- The PRA of bacterial pathogens in the genus *Xylella* spp. could be split into 2 parts, similar to the recent import risk analysis of the cut flowers pathway (DA, 2019c; DAWE 2021d). In the case of the PRA for *Xylella* spp., part 1 could cover plant materials for propagation excluding tissue culture and part 2 could assess plant materials derived by micropropagation, including tissue cultures. This split would be in line with current emergency measures, which specify separate conditions for tissue cultures (see emergency measures, appendix 1; DAWE, 2021c) and nursery stock, excluding

tissue cultures (see emergency measures, appendix 2; DAWE, 2021c), and other policy settings (e.g. arrangements for ex-agar tissue cultures; DAWE 2020a, 2021h).

- The PRA could be updated regularly in response to the evolving science of the *Xylella* spp. pathosystem. An example is new evidence for transmission of *Xylella fastidiosa* from seeds to seedlings in pecan (Cervantes et al., 2022). The EU has been publishing regular updates of its risk assessment as new evidence comes to hand, as explained above.

Finding: The quality and rigour of the department's completed risk assessments has been widely regarded as exemplary. However, the timetable for the PRA of *Xylella* spp. has not met the reasonable expectations of stakeholders regarding timeliness and flow-on relevance and actionability.

The delay in completing the PRA has resulted in prolonged lack of clarity on the risk posed by the significant import trade in tissue culture derived plantlets ex-media, and the level of biosecurity controls achieved by the requirement of offshore PCR testing of some plant host species but not others. The completion of the PRA should pay particular attention to the biosecurity threat and import risk implications of the asymptomatic nature of *Xylella* spp. in many host plant species.

A change in the department's approach for such key risk assessments may be required for streamlined, agile and regulation-based responses under the *Biosecurity Act 2015* and to support biosecurity stakeholders.

Recommendation 1

The department should complete the *Xylella* spp. pest risk analysis by the end of 2022 to support streamlined, agile and regulation-based responses under the *Biosecurity Act 2015* and adequately inform biosecurity industry participants and other key stakeholders.

8. Regulation of nursery stock

8.1 Standard conditions for nursery stock

Nursery stock is subject to standard import conditions to manage the risks from a wide range of pest and disease threats, including *Xylella* spp.

The department advised that the standard conditions for nursery stock imports are as follows:

- The department issues an import permit before the nursery stock arrives. Nursery stock consignments that arrive without an import permit, including where an application is under consideration, are required to be exported from Australian territory or destroyed in an approved manner.
Orchid tissue cultures imported in accompanied baggage are exempt from these requirements – currently they do not require an import permit.
- The exporting country's National Plant Protection Organisation (NPPO) must issue a phytosanitary certificate attesting the general health of the plant material or providing specific assurance statements required by Australia.
Orchid tissue cultures imported in accompanied baggage are exempt from this requirement – currently they do not require a phytosanitary certificate.
- Each consignment must be packed in clean, new packaging and clearly labelled with the full botanical name of the species.
- All plant material must be free from soil, disease symptoms and other extraneous contamination of biosecurity concern.
- All tissue cultures must be free from any bacteria, fungal infection, live insects, nematodes, disease symptoms and other extraneous contamination of biosecurity concern.
- On arrival, a biosecurity officer carries out a visual phytosanitary inspection for freedom from bacterial and fungal infection, disease symptoms, live arthropods and other extraneous contamination of biosecurity concern.
- If pests or disease symptoms are found, a risk assessment is carried out. As a result of the risk assessment, the consignment may be required to undergo remedial treatment (if an effective treatment is available), export or destruction to ensure that the biosecurity risk is managed.
- For non-tissue cultures, all plant materials must undergo mandatory treatment to manage arthropod risk (insects, spiders) either by methyl bromide fumigation or an insecticidal dip, depending on the plant material type.

- Depending on the import permit conditions, some plant species require further growth in government PEQ for disease screening. Others can undergo PEQ at a state/territory or private site operating under an approved arrangement. Some plant species imported as tissue cultures or from approved high-health sources are exempt from PEQ. Depending on permit conditions, the PEQ screening period ranges from a minimum of 3 months to 2 years.

8.2 *Xylella* spp. emergency measures and other import conditions for nursery stock

In November 2015, the department implemented emergency measures for nursery stock because of the increasing risk presented by the global spread and expanding host range of *Xylella* spp. (Figure 1 and Figure 3). Table 2 gives the timeline of updates to import conditions and other decisions the department took in response to the global spread of *Xylella* spp. The details of the emergency measures, including exact wording, are published on the department's website (DAWE, 2021c). The measures introduced in May 2022 for pecan seed (DAWE, 2022a) are not discussed here.

The 2 most significant changes introduced with the 2015 emergency measures were:

- the requirement for NPPO-issued phytosanitary certificates attesting offshore PCR testing or country freedom
- the regulation of *Xylella* spp. plant host species at the plant family level.

Offshore certification aims to reduce risk before goods arrive onshore, although this requirement is not applied consistently. It does not apply to bulbs produced under the Bloembollkeuringdienst (BKD) certification scheme and for a range of agriculturally significant crops that undergo mandatory PEQ at the department's Mickleham facility. The department has not provided information to the Inspector-General detailing the list of species of agriculturally significant crops that are exempt from the requirement of offshore certification – including offshore PCR testing for *Xylella* spp. – and the rationale for this decision. The Inspector-General observes that exemptions from the emergency measures are counter-intuitive to the intention to reduce risk before goods arrive onshore and weaken the measures.

Regulation at family level has increased the list of regulated plant species (confirmed and potential hosts) to over 20,000. The 2015 emergency measures for nursery stock were amended in 2016, 2019, 2020, and 2021, primarily by extending the list of regulated plant families and number of high-risk countries or regions. Importantly, all other current conditions apply for a regulated plant species.

Emergency measures

The *Xylella* spp. emergency measures use 3 main risk attributes to prescribe emergency import conditions for nursery stock:

- plant family – whether the plant belongs to a regulated plant family for *Xylella* spp.
- country of origin – whether the plant comes from a high-risk or a low-risk country or region
- type of plant material – whether the plant is a vegetative propagative material or a tissue culture.

To better manage risk offshore, regulated plants and plant materials generally require a phytosanitary certificate issued by the NPPO of the exporting country regarding freedom from *Xylella* spp. infestation, with specific wording prescribed by the department (exceptions are discussed in chapters 8.2, 8.4 and 9.1). A comparative

overview of import conditions in 2009 and 2015 targeting *Xylella* spp. is given in appendix B, Table 9.

Offshore certification requirements differ broadly for high-risk and low-risk countries or regions:

- For high-risk countries/regions, plant materials need to be certified as PCR tested offshore using internationally recognised protocols.
- For low-risk countries/regions, offshore PCR testing is not required, and country freedom certification is sufficient. The NPPO must state that the plants were grown only in that country/region, which is free from *Xylella* spp.
- If a phytosanitary certificate does not meet Australian requirements, plants must undergo a period of PEQ growth and screening, the type and duration of which depends on the plant species and plant material type.

Whether regulated plants and plant materials require any further onshore biosecurity actions under the emergency measures will depend on whether they meet the offshore certification requirements:

- If consignments arrive without an acceptable phytosanitary certificate, plant materials are directed to onshore growth and screening or treatment at a quarantine facility (government or private).
- In most cases, consignments arrive with a phytosanitary certificate that meets Australian requirements. In these cases,

'all other current import conditions for the plant species will apply' (DAWE, 2021c).

Exceptions

- The department advised that so-called 'high-risk' plant species such as *Vitis* spp. and *Citrus* spp., among others (chapters 8.4 and 10.1) do not require a phytosanitary certificate issued by the NPPO of the exporting country that confirms offshore PCR testing for *Xylella* spp., and do not require to be PCR-tested offshore, but undergo onshore PEQ and PCR testing.
- The emergency measures do not apply to some plant host species imported as bulbs from the Netherlands – a high-risk country according to current policy. Bulbs produced under the BKD certification scheme have been temporarily exempt from the emergency measures since 2015 and do not require offshore PCR testing for *Xylella* spp. (see chapter 9.1 for further details).

Other current import conditions

Other current import conditions for plant species in the nursery stock group of commodities (DAWE, 2021c) are diverse and target a wide range of quarantine pests and diseases, not just *Xylella* spp. All other conditions apply in addition to (or technically in place of) the 2015 emergency measures. This adds layers of complexity to the regulation of nursery stock. Exemptions apply, and it appears that the emergency measures can be superseded by other current import conditions. For example:

- Imports of agriculturally significant 'high-risk' crops (chapter 8.4) such as *Vitis* spp., *Citrus* spp., and *Solanum* spp., among others, undergo mandatory growth and screening at the department's high-security PEQ facility at Mickleham and mandatory PCR testing for *Xylella* spp. during the PEQ period (except for a limited number of vegetative propagative materials of species that can be hot water treated instead of PCR tested).
- Both vegetative propagative materials and tissue cultures of this group of crops are subject to the PEQ measures regardless of the country/region of origin's *Xylella* spp. status and the 2015 emergency measures.

- In addition, these so-called ‘high-risk’ plant species (chapter 8.4) do not require a phytosanitary certificate issued by the NPPO of the exporting country that confirms offshore PCR testing for *Xylella* spp., and do not require to be PCR-tested offshore (requirements under the emergency measures). Excluded from this exemption are a small number of imports of plant materials of ‘high-risk’ species produced under offshore high-health arrangements (chapter 9.3).

Finding: Agriculturally important plant species classified by the department as ‘high-risk’ are technically exempt from the department’s emergency measures (except for a few plant materials of high-risk species produced under offshore high-health arrangements) and undergo mandatory onshore PEQ and onshore PCR testing. This removes the offshore biosecurity control intended by the emergency measures.

- Some ornamental plant hosts of *Xylella* spp. (e.g. genera *Chrysanthemum* and *Syringa*) undergo mandatory growth and screening at the department’s high-security PEQ facility at Mickleham, even if the phytosanitary certificate meets Australian requirements (i.e. offshore PCR testing or country freedom certification for *Xylella* spp.). However, they are not PCR tested for *Xylella* spp. during the PEQ period.

The department explained that while the Mickleham PEQ facility primarily accepts ‘high-risk’ imports, it can also accept medium-risk imports.

- Import conditions can be non-complementary. For example, the genus *Triticum* (comprising different wheat species) belongs to the Poaceae family, which is currently regulated as a plant host family of *Xylella* spp. under the emergency measures. However, *Triticum* germplasm for propagation can only be imported as seed, so no import conditions have been established for the nursery stock pathway. The department does generally not regulate true botanical seeds for *Xylella* spp., except for the recent changes made to the regulation of *Carya* spp. seed (DAWE, 2022a).

Finding: The different layers of import conditions (emergency measures and all other current import conditions) introduce a level of complexity into the regulation of nursery stock that reduces regulatory clarity and increase staff workload. The department should examine the interactions between the *Xylella* spp. emergency measures and all other import conditions for host species of *Xylella* spp. to derive a streamlined regulatory framework for nursery stock in which conditions complement rather than supersede each other, thereby reducing complexity.

Ornamental hosts of *Xylella* spp.

The largest group of nursery stock for which the *Xylella* spp. risk is primarily, or exclusively, managed through the 2015 emergency measures is the group of ornamental/alternative hosts of *Xylella* spp. Most ornamental species are released from the department’s biosecurity control on documentation and inspection if *all other current import conditions* are met, as explained above. Ornamentals mostly arrive in large quantities in Australia as bulk tissue cultures (also discussed in chapters 6.1 and 9.2) and are not subject to onshore PCR testing, unlike the comparatively low number of plants directed to the department’s PEQ facility at Mickleham for growth, screening and testing (4% of all nursery stock consignments).

The Inspector-General regards onshore testing for *Xylella* spp. as an important tool for confirmatory testing and/or monitoring to understand the effectiveness of offshore measures. This is particularly so because of the cryptic nature of *Xylella* spp. – many plant hosts have long asymptomatic periods or remain fully asymptomatic and disease symptoms are non-specific. This means that countries could unknowingly have *Xylella*

spp. narrowly or widely distributed in regional ecosystems. So, to understand whether the emergency measures have reduced the risk of *Xylella* spp. entering Australia, it would be prudent for the department to undertake, as a minimum, random sampling and on-arrival testing for *Xylella* spp. in line with the intent stated in the notification of amended emergency quarantine measures for *Xylella* spp.:

The department will reserve the right to undertake testing to verify that a consignment is free of Xylella spp. (DAWE, 2021c).

Such data would show which consignments, if any, were infected with *Xylella* spp. bacteria. Currently, there is a lack of scientific clarity internationally on the level of *Xylella* spp. risk posed by tissue culture. Therefore, it is not recommended at this stage that sampling and testing be implemented as a regulated step, with consignment entry requiring pathogen-free test results. Rather, a planned pathway monitoring program should be implemented, appropriately sampling all origins and suppliers of *Xylella* spp. host plants. As a starting point, any ornamental hosts directed to the department's PEQ facility at Mickleham should undergo PCR testing for *Xylella* spp. as part of routine practices.

An added benefit would be to heighten awareness and precaution of importers and their suppliers. Routine random sampling and testing for *Xylella* spp. should be similar to, or consistent with, the department's compliance-based intervention scheme (DAWE, 2022b).

Large quantities of tissue cultures of ornamental plant hosts of *Xylella* spp. are released into Australia after assessment of import documents and inspection. In consultation meetings with the Inspector-General, the department argued that the *Xylella* spp. risk associated with tissue cultures is very low compared with vegetative propagative materials, implying that PCR testing of tissue culture consignments of ornamentals was not a priority. However, the Inspector-General's search of the scientific literature did not yield any result that would support this assessment, and the department has not provided any scientific evidence to support its position. Notably, the risk analysis of the EFSA Panel on Plant Health (2015) recommended that the *Xylella* spp. risk of both plant material types (vegetative propagative material and tissue cultures) be managed in the same way:

In the absence of scientific data on in vitro plants [tissue cultures] as a pathway for X. fastidiosa spread, the Panel noted that in vitro plants, unless originating from countries with appropriate certification schemes, present similar risk to other plants for planting. The bacterium grows in the xylem and is difficult to cultivate in artificial media; thus, it could easily pass undetected through the in vitro production processes (EFSA Panel on Plant Health, 2015).

A 2013 risk assessment and review of policy for *Vitis* spp. propagative materials conducted by the department found that *Xylella fastidiosa* can be associated with both 'dormant cuttings' and 'tissue cultures' (DAFF, 2013) and concluded:

This review considers that certain pathogens (bacteria, phytoplasma, viroids and viruses) may not be excluded from the pathway and remain associated with micropropagated plantlets (tissue culture). In contrast, it considers that fungal or fungal-like pathogens are not on the pathway of micropropagated plantlets (DAFF, 2013).

Finding: The department has not demonstrated sufficient scientific clarity regarding the risk posed by *Xylella* spp. potentially infecting different types of tissue culture, including tissue culture plantlets free of media. Therefore, the department should re-examine its risk management of tissue cultures of different species for consistency. This should be done as part of finalising the current PRA for bacterial pathogens in the genus *Xylella* spp. by the end of 2022.

Recommendation 3

The department should strengthen the biosecurity control achieved through mandatory phytosanitary certification for nursery stock by undertaking random on-arrival sampling and molecular testing for *Xylella* spp., similar to, or consistent with, the compliance-based intervention scheme.

Option for offshore approved source arrangement under the emergency measures

Under the emergency measures, the department introduced the option for an offshore approved arrangement for some vegetative propagative materials from high-risk countries/regions. The department clarified to the Inspector-General that plant genera for which current import conditions mandate growth, screening and testing at the department's PEQ facility at Mickleham *do not* qualify for this approved arrangement option. For other, existing approved source arrangements (i.e. unrelated to the emergency measures) for agriculturally important species from high-risk countries (chapter 9.3), the arrangements with the overseas production facilities reduce the time required for growth and screening at the department's PEQ facility at Mickleham.

To ensure the health of plants, the department sets the requirements for the approved arrangement. The requirements are detailed in appendix 4 of the emergency measures (DAWE, 2021c). In consultations with the Inspector-General, the department summarised the arrangement as follows:

The National Plant Protection Organisation (NPPO) of the exporting country will approve the arrangements and ensure that Australia's requirements are met. Several other parties, including the grower and testing laboratory will need to work with the NPPO to do this. It is anticipated that the supplier will contact the NPPO of the exporting country to establish the arrangements. Australian importers should contact their overseas suppliers to ensure that the work is initiated for the arrangements.

The department's website states:

... The Australian Department of Agriculture, Water and the Environment retains the right to monitor the arrangements by auditing and by sampling and testing consignments after they arrive in Australia. (DAWE, 2021c).

The department advised the Inspector-General that currently there are no overseas approved arrangements in operation and there have been no applications for approval since 2015.

The department may reconsider this option for an approved arrangement when completing the PRA for *Xylella* spp. Considerations should also include resourcing for additional audit requirements, as the department has had profound difficulties keeping audit schedules of existing arrangements, as discussed in detail in chapter 9.

8.3 BICON

The BICON system is the department's biosecurity import conditions database for plant, animal, mineral and biological products. It superseded the import conditions (ICON) database, which was phased out in 2015 at the time the *Xylella* spp. emergency measures for the nursery stock group of commodities were introduced (Table 2). An important improvement that the introduction of BICON sought to achieve was functionality that would provide importers with the specific conditions that apply to their goods.

BICON is a repository of all current conditions that need to be met for conditionally non-prohibited goods landing in Australia. Depending on the goods, a BICON case includes multiple import scenarios, which relate to different types of goods, countries of origin,

commercial or non-commercial purpose, and end-use and other factors to differentiate conditions to meet Australia's biosecurity requirements. The department uses BICON to communicate when an import permit is needed for a specific import scenario and what fees and charges apply. Importers can apply for an import permit through a link in BICON. The BICON database houses all current requirements for nursery stock.

BICON:

- is a system to issue a legal instrument (import permits) for goods that do not have alternative conditions listed in the Biosecurity (Conditionally Non-prohibited Goods) Determination 2021 (Goods Determination), like all nursery stock except orchid tissue cultures imported in accompanied baggage
- provides the details of all current documentary and certification requirements for the goods (e.g. phytosanitary certificates)
- informs on onshore risk management activities that may apply (e.g. inspection, testing, PEQ requirements).

Since the introduction of the emergency measures in 2015, the department has reduced the number of BICON cases for *Xylella* spp. host material by 20 cases:

- May 2016: 86 BICON cases were recorded following a 'pilot' review of import conditions.
- December 2021: 66 BICON cases were recorded.
- The department advised that BICON cases are generally updated on an ongoing basis in response to new information and emerging risks, upon requests from industry to establish new import pathways, and as part of maintaining an up-to-date import conditions database. The department said that the number of BICON cases for *Xylella* spp. host material reduced because:
 - Import conditions for plant genera that share the same conditions were consolidated into the same case, which reduced the overall number of BICON cases for imported nursery stock.
 - Import conditions for nursery stock that are not traded were inactivated, which removed some BICON cases. In some instances, permits for a BICON case had not been issued for years. The decision to inactivate those BICON cases lessened resource requirements for maintenance. For example, inactivation removed the need to update cases regarding the management of *Xylella* spp., as the risk was removed by suspending the conditions.

The department also offers to re-establish conditions upon request by importers in BICON. However, this is subject to resource availability. For example, import conditions for *Agathis* spp. were suspended in 2021, as there had been no trade for at least 5 years, and BICON was updated with the following notice to importers:

Case: Agathis spp. (kauri, dammar) for use as nursery stock. Effective: 25 Nov 2021

Import conditions for Agathis spp. have been suspended due to inactivity (no recent trade). This genus will require a review of import conditions against associated biosecurity risks, including the bacterial pathogen Xylella, prior to importation. A review may be conducted by the department upon request, subject to resource availability. (DAWE, 2022c)

Staff interviewed for this review noted that the initial implementation of the 2015 emergency measures across 86 BICON cases was a significant task in terms of complexity and workload. This continues to be the case for BICON in some instances. Staff saw a reduction in the overall number of BICON cases as beneficial, as it reduced the number of different permit cases that need to be managed and maintained and hence workload.

The Inspector-General's observation is that the layers of complexity in the regulation of nursery stock, as discussed above, add significantly to internal workload and time allotted to the maintenance of BICON currency and simplicity. Streamlining of the regulation would free up scarce staffing resources for mission-critical tasks, save cost in the long run, and ensure the long-term policy and operational clarity of BICON. These improvements would enable a sharper focus of staff on offshore and at-border risk monitoring and management.

While BICON should be current, it has been confusing to uncover in BICON a detailed policy reference regarding *Xylella* spp. risk material from 2013 (DAFF, 2013) – that is, before the establishment of both BICON and the *Xylella* spp. emergency measures – that refers to special import arrangements for *Xylella* spp. risk material that have not been current since 2019. Related wording within BICON adds to this confusion by implying that this BICON documentation was updated in late 2021. The 2013 review (including outdated information) is also available in the department's plant risk analyses webpages (DAWE, 2019).

While there is merit in making some historical documentation available within the department, it is not clear why historical documentation should continue to be included in publicly facing webpages that are intended to communicate current policy to stakeholders. The department should consider adding an archives tab to its main webpage so that users are not distracted from current policy and to clearly identify historical policy documents of significance.

The Inspector-General commends work that the department has already undertaken to consolidate and streamline import conditions to enhance overall clarity and regulatory efficiency.

Finding: The department should apply sufficient resources to the curation of BICON information to ensure both external user clarity and internal policy and operational regulatory clarity and use efficiency. The department should examine the broader implications of reducing regulatory complexity in the nursery stock group of commodities and consider whether BICON improvements could enable resources to be freed up for mission-critical departmental tasks and reduce burden on clients.

8.4 Risk groupings

The Inspector-General assessed various policy documents and work instructions maintained by the department. These aim to support biosecurity officers in decision-making and managing nursery stock imported into Australia. In the documents assessed, plant species of the nursery stock group of commodities are grouped into high-risk, medium-risk and low-risk groups. The risk groups have long been embedded in the department's language and narrative, and have been readjusted over time to suit new settings, such as new and emerging threats and policy changes, but they are not legislative provisions. Appendix D gives the risk descriptions and groups compiled for this review from different departmental sources.

The department advised that these risk groups have been in place since before the 1980s and are seen to capture the department's accumulated and ongoing assessments of the biosecurity risk associated with different types of nursery stock and any pest and disease threats, not just *Xylella* spp. It argued that the 'risk groups are a useful reference point to understand and communicate the relative risk posed by certain plants and nursery stock pathways'.

Based on the information provided by the department, the Inspector-General observes that the objectives and outcomes of the risk groups are vague and their usefulness is

unclear or even questionable. The risk groups are not the outcome of a specific import risk assessment; rather, they are used in general terms and try to cover, and do justice to, all regulated plant species and their pests and diseases. Clearly defined lists of plants or pathways and their respective risk group do not exist, only examples.

The main features of the department's risk groups are summarised below followed by a discussion.

High-risk group

- High-risk nursery stock can be thought of as a group of focal plant species of significance to Australia's agricultural and horticultural industries. High-risk species can introduce a range of plant pests and diseases that pose a significant threat – including *Xylella* spp. though not all plant hosts of *Xylella* spp. are 'high-risk'.
- Examples of genera in the high-risk group are *Malus* (apple), *Citrus* (oranges, mandarins and so on), *Solanum* (potato) and *Vitis* (grapes). However, some ornamental and other hosts of damaging pests and disease are also included in this group (Table 5).
- Biosecurity policies and procedures are more restrictive, rigorous and lengthy for this group. All plant materials of high-risk species – that is, vegetative propagative material and tissue cultures – undergo mandatory PEQ growth and disease screening before they are released from biosecurity control.
- High-risk nursery stock is generally only permitted to undergo PEQ in the department's PEQ facility at Mickleham or a state/territory operated PEQ facility where the expertise is available to conduct the required disease screening under strict quarantine conditions. During the PEQ period of 3 months to 2 years, plants are tested and screened for a range of quarantine pests and diseases and inspected visually.
- Imports of *Xylella* spp. host plant species of the high-risk group undergo up to 2 years of PEQ and are PCR tested for the pathogen during the PEQ period. They do not require a phytosanitary certificate by the National Plant Protection Organisation (NPPO) of the exporting country, and do not require to be PCR tested offshore. Thus, these imports are technically exempt from the 2015 emergency measures.
- Host plant species of the high-risk group do not qualify for the option to be produced under an offshore approved arrangement as described in appendix 4 of the 2015 emergency measures.

Medium-risk group

- Medium-risk nursery stock is a group of mostly ornamental plant species that generally pose a lower biosecurity risk than those plants listed as high-risk. They are generally not known to be hosts of significant pests and diseases. However, for medium-risk nursery stock that are regulated for specific pathogens, such as *Xylella* spp. and quarantinable *Phytophthora* spp., specific measures for the associated pathogen(s) still apply.
- Medium-risk nursery stock is permitted to undergo growth and screening in a privately owned third-party facility operating under a class 5.1.4, 5.2.4 or 6.1 approved arrangement with the department (DAWR, 2016a). The imported material generally only requires visual screening for pests and diseases for a period at a department-approved arrangement site. For a small subset of nursery stock, screening may be permitted to occur at an approved open field quarantine site. Approved arrangements are discussed in detail in chapter 10.2.

- Some *Xylella* spp. host plant species of the medium-risk group, which subject to the emergency measures, undergo PEQ in the department's high-security PEQ facility at Mickleham but may not be PCR tested for *Xylella* spp. during this period.
- Some are PCR tested for *Xylella* spp. during the PEQ period. For example, vegetative propagative material of *Coffea* spp. (coffee plants) would be PCR tested during PEQ, but there is no requirement for tissue cultures of *Coffea* spp. to be PCR tested. Ornamental *Coffea* spp. are thought to be the source of the *Xylella* spp. outbreak in Europe (e.g. EFSA Panel on Plant Health, 2015).
- The Mickleham PEQ facility primarily accepts high-risk imports, but it can also accept medium-risk imports.

Other/low-risk group

- Low-risk plant species are not known to host significant pathogens of biosecurity concern and are in a form (tissue cultures) that pose a lower biosecurity risk. Low-risk nursery stock is sometimes communicated as being a subset of medium-risk nursery stock.
- Low-risk nursery stock must still meet all import/permit conditions but does not require growth and disease screening in Australia. An example of low-risk nursery stock is orchids imported as tissue culture in accompanying baggage.

Regarding the threat from *Xylella* spp., the categorisation of plant hosts of *Xylella* spp. into medium-risk or low-risk groups seems counterintuitive, as the department's own publications communicate an emergency (DAWE, 2021c) and urgency in mitigating the risk of entry of Australia's No. 1 national priority plant pest (DAWE, 2021e; DAWE, 2020a; DA, 2019a; DAWR, 2017a). Because all host plant species can potentially introduce Australia's No. 1 priority plant pest, it appears more intuitive for all hosts of *Xylella* spp. to be communicated, or be considered, as high-risk.

Further ambiguity arises when the imported *Xylella* spp. risk material is grouped as being of medium-risk or low-risk but the import is from a high-risk country/region. For example, tissue culture imports of *Lomandra* spp., Australian natives of the asparagus family, and *Philodendron* spp. can fall simultaneously into a high-risk country/region group and medium/low-risk nursery stock group. Some medium-risk ornamentals (e.g. *Syringa* spp.) are screened at the department's high-security PEQ facility at Mickleham, suggesting that these plants are regarded as high-risk (8.2).

Many ornamental hosts (also referred to as alternative hosts) of *Xylella* spp. are aggregated in the medium-risk or even low-risk group. Yet the greatest potential risk to Australia is likely to be the import of Australia's No. 1 priority plant pest on alternative, possibly asymptomatic, hosts (Luck et al., 2002). The source of the ongoing outbreak in European countries is believed to be an ornamental species, possibly an ornamental coffee plant imported from a *Xylella* spp. risk country (DG Sante, 2016; DAWR, 2017a).

The Inspector-General recognises that the risk groupings do not direct the specific conditions that are prescribed on an import permit to manage *Xylella* spp. and other diseases of biosecurity concern. The department has argued in consultations with the Inspector-General that the risk groups aim to capture 'the complexity of regulating multiple plant types for multiple pathogens, and these pathogens have different global distributions, and the department has a requirement to accept equivalence in measures (under the IPPC)'.

However, if the complexity embedded in current policy arrangements cannot be described and defined, ambiguity is the outcome. This is particularly troubling given that internal work instructions, with which all staff must comply, explicitly refer to the risk groupings (see appendix D for details). To enable staff compliance with an instruction, all

definitions must be clear so they can be understood in the same way by anyone working with the instruction.

The risk groups do not elicit an understanding of the assessed risk in nursery stock entry pathways or the effectiveness of the department's risk mitigation measures for *Xylella* spp. This diminishes their operational relevance. The Inspector-General made a similar observation in the recent review of the *Robustness of biosecurity measures to prevent entry of Khapra beetle into Australia* (IGB, 2021a).

Worryingly, the reliance on risk perceptions (as embedded ambiguous risk groupings, as discussed above) can create 'blind spots' where the true/actual risk is not recognised because the evidence is not fully assessed and appreciated. This can also incentivise misallocation of scarce resources, thereby weakening the overall effectiveness of risk mitigation. The *Xylella* spp. risk should be understood as the outcome of the likelihood of vegetative propagative material or tissue cultures being infected, the associated import volumes, and the type and level of intervention applied in high-volume as opposed to low-volume entry pathways. The department's own Risk Return Resource Allocation (RRRA) model can elicit such difficult questions of perceived risk (e.g. 'tissue cultures are not risky', 'illegal imports are most risky') versus evidence-based risk to (re-)prioritise and inject focus. Knowledge of risk exposure should be ascertained through various means, including the monitoring of pathways by sampling imported host material and testing for *Xylella* spp. infection.

The Inspector-General concludes that the department should discontinue the use of the current risk groups in favour of routinely leveraging its data to quantitatively explore what the risk (groups) might be. A contemporary understanding of risk will include communicating risk in terms of estimated/calculated likelihoods, rather than predetermined groups, and the level of confidence in the information assessed (e.g. DEFRA, 2020; EFSA Panel on Plant Health, 2015).

A coherent policy framework for the nursery stock group of commodities would clarify the essential components of a risk management program and could potentially characterise or group types of nursery stock according to the levels of intervention needed for Australia's ALOP. This would be informed by levels of actual biosecurity interventions and remove the need for the risk grouping terminology that is currently used.

Table 5 List of *Xylella* spp. risk material (high-risk and medium-risk) directed to the department's PEQ facility at Mickleham between April 2020 and April 2022

Regulated plant family	Genus	Plant material type
Adoxaceae	Viburnum	Bare-rooted plant
Amaryllidaceae	Allium	Bulbs
Anacardiaceae	Pistacia	Tissue culture, budwood
Cannabaceae	Humulus	Tissue culture
Caprifoliaceae	Lonicera	Cuttings, tissue culture
Convolvulaceae	Ipomoea	Tissue culture
Ebenaceae	Diospyros	Budwood
Ericaceae	Vaccinium	Tissue culture
Hamamelidaceae	Distylium	Bare-rooted plant
Hydrangeaceae	Hydrangea	Bare-rooted plant
Lamiaceae	Vitex	Bare-rooted plant

Regulated plant family	Genus	Plant material type
Lauraceae	Persea	Budwood
Lythraceae	Lagerstroemia	Bare-rooted plant
Magnoliaceae	Magnolia	Bare-rooted plant, cuttings
Moraceae	Ficus	Bare-rooted plant
Oleaceae	Syringa	Tissue culture
Poaceae	Arundo	Tissue culture
Poaceae	Cynodon	Tissue culture
Poaceae	Pennisetum	Tissue Culture
Poaceae	Stenotaphrum	Tissue culture
Poaceae	Zoysia	Tissue culture
Rosaceae	Fragaria	Tissue culture
Rosaceae	Malus	Budwood
Rosaceae	Prunus	Budwood, tissue culture
Rosaceae	Pyrus	Budwood
Rosaceae	Rosa	Budwood
Rosaceae	Rubus	Tissue culture
Rutaceae	Citrus	Budwood
Sapindaceae	Acer	Budwood
Solanaceae	Solanum	Tissue culture
Vitaceae	Vitis	Cuttings

Finding: The department should discontinue the current complex approach to assigning intangible risk groups and move to one with an improved focus on the level of regulated, tangible pathway interventions necessary to mitigate risk – for example, high (PEQ at Mickleham), medium (commercial PEQ, detailed testing/monitoring) and low intervention (at-border clearance based on documentation and general inspection). Reporting of import volumes under each group would further contribute to clarifying risk.

Recommendation 2

The department should develop a policy framework for nursery stock. The framework would clarify the components of a risk management program for nursery stock (offshore and onshore) and the intended outcomes (e.g. resources and other inputs, activities and products and services delivered), as well as the contextual factors affecting its operations and actual outcomes and replace the risk grouping terminology that is currently used.

9. Approved source (offshore) arrangements

The department has multiple approved source (offshore) arrangements in place with overseas producers and Australian importers of *Xylella* spp. plant host species, as well as non-host species. These offshore arrangements are in place so that biosecurity risks are managed before the plants or plant materials are exported to Australia. This reduces the level of onshore intervention that would otherwise be required.

The Inspector-General assessed 3 types of approved source arrangements that produce *Xylella* spp. plant hosts for export to Australia: certified bulbs from the Netherlands, tissue cultures free of media, and high-health source arrangements. The department advised the Inspector-General that these approved source arrangements are not the same as the option for National Plant Protection Organisation (NPPO) approved arrangements under the emergency measures (chapter 8.2; DAWE, 2021c).

To be able to operate under an approved source arrangement, an offshore facility must be approved by the department. While there are differences in the details of how the department manages the 3 types of approved source arrangements, the general process can be described as follows:

- An overseas facility applies to become an approved source. In the application, the facility documents its operation and processes, including production practices, pest and disease screening and testing, traceability and record-keeping, and arrangements with the exporting country's NPPO. (The original applications and agreements for facilities that were approved under the *Quarantine Act 1908* appear to be difficult to retrieve from the department's archives and are no longer consulted. This has potential implications for business continuity.)
- The department assesses the application. The department states that it will conduct desktop audits for offshore facilities, but the type and frequency of audits is variable. In some cases the department conducts a desktop audit and then carries out a site audit to verify the findings of the desktop audit. (Some facilities or schemes were approved well over 20 years ago; others have undergone reapproval or the arrangement has been discontinued.)
- The department's documentation states that re-approvals are required every 2 to 3 years. However, the timing of re-approvals is variable and appears to be primarily driven by resourcing constraints and level of management discipline in the department rather than risk-based policy.
- Typically, the department requires the exporting country's NPPO to provide oversight of the arrangement. The NPPO must provide assurance that the facility is sanitary and well-maintained and produces high-quality plant materials. The department also

relies on the exporting country's NPPO to ensure that consignments from approved source facilities meet Australia's import conditions when issuing phytosanitary certification for a range of pests and diseases, including *Xylella* spp.

- Generally, the department does not conduct regular reviews of facilities, despite that being its policy. Notable exceptions are 3 site audits of 3 high-health facilities conducted in 2018 and 2019 (see chapter 9.3 for details).

The Inspector-General notes that the department treats the different types of approved source arrangements separately and does not have an umbrella policy framework under which all arrangements with overseas facilities are regulated and managed to ensure consistency and regulatory efficiency.

The Inspector-General was provided with one desktop audit (chapter 9.2) and 3 onsite audit reports of 3 high-health facilities (chapter 9.3). However, there was insufficient evidence that assurance and verification assessments are culturally embedded in the department's regulatory practice for *Xylella* spp. risk mitigation in approved source arrangements. The department did not provide evidence that it routinely completes assurance and verification assessments of approved source arrangements as part of its cooperative partnership with overseas NPPOs.

The ability of current departmental staff to access essential information and data from the department's document management and other information systems appears to be highly variable and sometimes problematic. The poor overall information management in critical biosecurity regulatory areas is cause for significant concern. It can potentially lead to significantly higher administrative costs, inconsistent regulation of clients in the same field of business, unclear or inconsistent communication, and unreliable risk mitigation.

Three approved source arrangements relevant for managing the risk of *Xylella* spp. are discussed below (chapter 9.2, Box 1).

9.1 Bulbs from the Netherlands

Most bulbs of ornamental species are imported into Australia from the Netherlands. The department advised that bulbs have been only considered a pathway for *Xylella* spp. since the introduction of the 2015 emergency measures. The Netherlands is regulated under the emergency measures because it belongs to the EU trading bloc (Table 2), although the status of *Xylella* spp. in the Netherlands is currently 'absent, confirmed by survey'.

The department regulates the genera *Narcissus*, *Hyacinthus* and *Hippeastrum*, which are produced under the Bloembollkeuringsdienst (BKD) certification scheme, because they are hosts of *Xylella* spp. at the plant family level. The BKD scheme can cover multiple growers. Plants must be produced in accordance with requirements to manage freedom from infection.

The BKD scheme produces bulbs of species regulated for *Xylella* spp. The Naktuinbouw (NAKT) schemes produce *Freesia* spp. – a genus currently not listed as a host by the department (DAWE, 2020c). In addition to the BKD and NAKT schemes, Australia also imports uncertified bulbs from the Netherlands and other countries.

Bulbs produced under the BKD scheme are exempt from the *Xylella* spp. emergency measures (DAWE, 2021c). The department informs on its website:

The department will temporarily delay implementation of X. fastidiosa emergency conditions for affected host certified bulbs (Narcissus, Hyacinths and Hippeastrum) produced under the Bloembollenkeuringsdienst (BKD) scheme from Netherlands. (DAWE, 2021c)

Internal department documentation shows that the temporary exemption has been in place since 2015, when the emergency measures were introduced. The department advised that the Netherlands' *Xylella* spp. status 'absent, confirmed by survey' was taken in consideration in the exemption 'consistent with a risk-based approach that balances operational feasibility and resource demand with the level of risk'.

Because of the exemption, bulbs produced under the BKD scheme do not require a phytosanitary certificate confirming offshore PCR testing for *Xylella* spp. In order to come to a business-as-usual arrangement, the department should review this exemption as part of completing the PRA for bacterial pathogens in the genus *Xylella* spp.

The department is apparently open to establishing additional approved source arrangements for certified and uncertified bulbs from the Netherlands:

The department will continue to collaborate with the NPPO [of the Netherlands], to determine if alternative approved arrangements can be established for both certified and non-certified bulbs. (DAWE, 2021c)

Upon arrival in Australia, the bulbs produced under the BKD scheme are grown in open quarantine at an industry-operated class 6.11 – Bulbs approved arrangement site (DAWE, 2020c).

At the class 6.11 facility, the certified bulbs can be inspected by industry participants:

The department has therefore altered its policy to permit biosecurity industry participants to perform final inspections at sufficient growth stage for certified bulbs. This is known as self-inspection.

The scope of this approved arrangement site allows the biosecurity industry participant to nominate how certified bulbs will be inspected – the biosecurity industry participant may choose to inspect the certified bulbs or to have the department continue to inspect the certified bulbs. (DAWE, 2020c)

Bulbs are also not PCR tested for *Xylella* spp. on arrival in Australia, during growth in open quarantine or at release from open quarantine. Operators of the class 6.11 facilities inspect growing plants visually and must submit digital photographs and accompanying information (e.g. plant species, importer name, date of planting and description of symptoms) to the department's phytopathology experts. The Inspector-General notes above that the cryptic nature of *Xylella* spp. infection means that visual assessment cannot accurately confirm the absence of the pathogen – molecular testing is needed. In the absence of confirmatory testing for *Xylella* spp., open quarantine seems a risky strategy for a cryptic pathogen that is potentially transmitted by common native insect vectors.

The department advised that the 2015 emergency measures (chapter 8.2) apply to uncertified bulbs and that other import conditions for uncertified bulbs from high-risk countries/regions are currently not published in BICON. Applications by importers are assessed on a case-by-case basis. This appears to be another exception, adding complexity to the regulation of nursery stock.

The department considers the *Xylella* spp. risk of bulbs to be lower compared to other plant forms for planting (e.g. cuttings and scions), although an evidence-based risk assessment has not been undertaken for this group of nursery stock. Notably, the most recent [host plant database by EFSA \(2022\)](#) does not list the genera *Narcissus*, *Hyacinthus* and *Hippeastrum*. In the absence of the department's PRA, it is unclear what the rationale is for listing these genera as hosts of *Xylella* spp. The consequences are regulatory burden, if not confusion, and use of scarce resources where they may not be needed. The department should clarify its *Xylella* spp. risk management of bulbs considering the current science; and streamline policy and operational requirements accordingly.

Finding: The department needs to urgently clarify whether the evidence supports listing *Narcissus*, *Hyacinthus* and *Hippeastrum* as *Xylella* spp. hosts. If these genera are to remain on the list of *Xylella* spp. risk imports then the department should immediately implement a PCR-based monitoring/diagnostic program for imported material entering and/or being grown in relevant open-field quarantine facilities.

9.2 Approved sources of tissue cultures free of media

Imports and policy settings

Approved overseas facilities for tissue cultures free of media produce large quantities of ornamental species that the department groups as ‘medium/low-risk’ (chapter 8.4). Bulk imports into Australia of consignments containing thousands of tiny plantlets support the nursery stock wholesale and retail sector. Of all nursery stock consignments exported to Australia in 2020–2021, approximately 60% were tissue cultured plantlets. Of all tissue cultures, around two-thirds could be tissue cultures free of media, although suppliers of tissue cultures free of media may also export tissue cultures in agar. The department’s data would ideally elicit such differences, as they may be important determinants of risk.

The department’s website lists 43 approved facilities for tissue cultures free of media (DAWE, 2020b). The department advised that most of the 43 facilities had been approved before the introduction of the *Biosecurity Act 2015* and the *Xylella* spp. emergency measures in 2015 and possibly before 2000.

The facilities are in:

- high-risk countries/regions: Costa Rica, Germany, India, Taiwan, the Netherlands, Poland, and the US
- low-risk countries/regions: China, Indonesia, Malaysia, New Zealand, Philippines, South Africa, Sri Lanka, and Thailand.

According to the department’s policy:

Approved facilities will be reviewed by the department every two years to ensure that the ownership and operational procedures remain unchanged, and that the company wishes to retain their approval to export tissue cultures free of media to Australia. (DAWE, 2020b)

In December 2020, the department updated stakeholders:

... due to a current backlog in the assessment of ex-agar facility applications, the review of existing facilities and other priorities, the Department of Agriculture, Water and the Environment advises that assessments for new facilities will be delayed. New applicants are advised that assessments will likely take a minimum of twelve months to finalise once all required information is received. (DAWE, 2020b)

The Inspector-General is concerned that the department was unable to provide evidence of consistent, regular, prescribed biannual reviews or reapplications for approval. The department advised that it had developed review guidelines and a checklist in 2019. Since then, only one facility in a high-risk country was reviewed (desktop audit) using the new guidelines and one additional review was commenced in November 2021. The rate of review progress is unacceptably slow, with potential consequences for risk mitigation. The department advised that it is currently reconsidering its approach to review of facilities producing tissue culture without media to ensure approval and renewal time frames are commensurate with biosecurity risk.

The guideline and checklist developed in 2019 cover confirmation of offshore testing

for *Xylella* spp. if the facility is in a high-risk country. The department advised that the guideline and checklist verify a facility's awareness of the requirement for offshore PCR testing (or country freedom certification) under the 2015 emergency measures. However, no evidence was provided to support this claim. The department's exclusive reliance on the information provided by the overseas facility and the assessment of the NPPO of the exporting country is of concern, especially when combined with the absence of any random sampling and testing of consignments on arrival in Australia as part of routine monitoring, assurance and verification activities.

The management of overseas facilities was the subject of a 2011 review by the Interim Inspector-General of Biosecurity. That review examined the pre-border processes and arrangements for the importation of plant nursery stock (IIGB, 2011). The department responded to the 2011 review by stating its intention to conduct desktop reviews and require reapplication for approval every 2 years. However, the information provided to the Inspector-General indicated the recommendations were not effectively implemented, despite the department marking all recommendations as 'completed' in April 2012. Issues with the accountable implementation of recommendations were recently discussed in an Inspector-General review (IGB, 2021b, 2021c).

The Inspector-General observes that the risk assessment of tissue cultures without media should be informed by the PRA, which should be completed by 2022 (see chapter 7.5). This means that the department's current risk management of facilities producing tissue cultures free of media is based on the unsubstantiated assumption of 'low risk', and they are considered a low priority compared with other verification activities – for example, the completion of onsite audits of high-health arrangements discussed in chapter 9.3.

Micropropagation

Using the stages of micropropagation described by Carrillo (2008; Table 6), tissue cultures free of media are rooted plantlets removed from their growing media (stage IV of micropropagation), with their roots washed, if grown in agar, but not yet transferred into soil. The plantlets are placed in plastic bags or other containers for ease of transport by air to Australia. They are then planted into soil under greenhouse conditions in Australia.

The department describes tissue cultures on its website as follows:

Plant tissue culture, or micro-propagation, is a plant form that is prepared under aseptic conditions, reducing the risk of pests and pathogens.

This plant form allows for the rapid propagation of plants and is an ideal method for transporting plants between countries.

Tissue cultures are formed by taking a tiny piece of a plant tissue such as a stem tip or meristem and placing it in a sterile nutrient medium, sometimes containing plant hormones. The plant tissue is then incubated under artificial lighting to produce clones of the parent material.

Tissue culture can be imported into Australia in agar or another sterile nutrient medium, or free of media from an approved overseas facility. (DAWE, 2021b)

Plant propagation by tissue culture is also termed 'micropropagation' to differentiate it from other types of propagation, such as vegetative propagation by cuttings, budwood, scions and so on. Table 6 summarises the different stages of micropropagation (Carrillo, 2008) and the department's management approach. Internationally, commercial and research tissue culture laboratories accept the stages as describing the procedural steps and processes, including when the cultural environment is changed.

Table 6 Stages of micropropagation and the department's management approach applied to each stage

Stages of micropropagation (Carrillo, 2008)	Department's management approach
<p>Stage 0: Mother plant selection and preparation</p> <p>This stage includes environmental and chemical pre-treatment of mother plants to improve growth, morphogenesis and rates of propagation of explants <i>in-vitro</i> and the application of procedures to detect and reduce or eliminate systemic bacterial and virus diseases in mother plants.</p>	<p>The department's emergency import conditions for tissue cultures from high-risk countries/regions require a phytosanitary certificate that states that mother plants were PCR tested and found free of <i>Xylella</i> spp. For low-risk countries/regions, the phytosanitary certificate must state that the tissue cultures were derived from plants and tissue cultures grown only in that country, which is free of <i>Xylella</i> spp. (DAWE, 2021c).</p>
<p>Stage I: Establishing an aseptic culture</p> <p>The objective of this state is to initiate an aseptic culture of explants. Explants (e.g. meristem tissue, shoot tips, lateral buds and leaf or stem segments) are transferred to the cultural environment (e.g. agar medium) free from obvious microbial contaminants.</p>	<p>Department-approved facilities for the export of tissue cultures free of media are required to produce plantlets in media free of antibiotics and microbial suppressants at all stages of production (DA, 2019d; DAWR, 2019a). Thus, this requirement applies also to the subsequent stages of micropropagation.</p>
<p>Stage II: Production of suitable propagules</p> <p>The objective is for the cultured tissue to produce new plant outgrowth (propagules), which can give rise to complete plants.</p>	<p>The department requires that plantlets for export are inspected by officers of the exporting country's National Plant Protection Organisation (NPPO) before the plantlets are removed from the growing media. The NPPO is required to provide a phytosanitary certificate stating that 'Prior to the removal of the plant tissue from media, the tissue cultures were inspected and found to be free of contamination. The plant tissue was aseptically transferred under supervision to sterile containers which were then sealed and not subsequently re-opened' (DA, 2019d; DAWR, 2019a).</p>
<p>Stage III: Preparation of growth in the natural environment</p> <p>The objective is to grow shoots or plantlets that are capable of carrying out photosynthesis and can survive without an artificial supply of carbohydrates. <i>In vitro</i> rooting is induced to prepare plants for the next stage.</p>	<p>Containers or plastic bags holding the rooted <i>ex-vitro</i> plantlets typically arrive in Australia by plane and are inspected by the department's biosecurity officers at the border. If the plantlets in the consignment are free of pests and diseases, considered to belong to the medium/low-risk group of species and the phytosanitary certificates and any other documentation are acceptable, the consignment is released. <i>Ex-vitro</i> plantlets are then transported to wholesale nurseries to be planted out for hardening before distribution to nurseries across Australia.</p>
<p>Stage IV: Transfer of the natural environment</p> <p>The objective of this stage is to successfully transfer the plantlets from the <i>in-vitro</i> to the <i>ex-vitro</i> environment. Plantlets are removed from their stage III containers. If grown in agar, gel is carefully washed from roots. Plantlets are transplanted into a rooting medium and kept under high humidity and reduced light intensity for hardening in greenhouse or growth chamber conditions.</p>	

Differing risk management for tissue cultures

While only approved facilities can export *ex-vitro* plantlets (without media) to Australia, no such requirement is in place for *in-vitro* plantlets (in agar). *Ex-vitro* plantlets of *Xylella* spp. host species are exclusively ornamentals. Consignments typically contain several thousand plants. The department advised that 84 different genera, including Australian natives, have been imported as *ex-vitro* plantlets since 2015 (Table 7).

There are important economic reasons for nursery stock supply chains to ship *ex-vitro* plantlets (Carrillo, 2008; Kitto, 1997). For example, they can transport larger volumes by air, and there are offshore cost savings in the transfer of thousands of plantlets from *in-vitro* growing media into transport bags/containers under sterile conditions.

Table 7 List of 84 plant genera imported from approved offshore facilities as tissue culture without media

<i>Adenium</i>	<i>Coccoloba</i>	<i>Hosta</i>	<i>Pilea</i>
<i>Aeschynanthus</i>	<i>Codiaeum</i>	<i>Hoya</i>	<i>Platynerium</i>
<i>Agaphantus</i>	<i>Cordyline</i>	<i>Iberis</i>	<i>Pogonatherum</i>
<i>Agastache</i>	<i>Dianella</i>	<i>Kalanchoe</i>	<i>Pseuderanthemum</i>
<i>Agave</i>	<i>Dieffenbachia</i>	<i>Lavendula</i>	<i>Pteris</i>
<i>Aglaonema</i>	<i>Digitalis</i>	<i>Lepidosperma</i>	<i>Radermachera</i>
<i>Alcantarea</i>	<i>Dorstenia</i>	<i>Ligularia</i>	<i>Salvia</i>
<i>Alocasia</i>	<i>Dracaena</i>	<i>Liriope</i>	<i>Sansevieria</i>
<i>Aloe</i>	<i>Echeveria</i>	<i>Magnolia</i>	<i>Schefflera</i>
<i>Alpinia</i>	<i>Epipremnum</i>	<i>Maranta</i>	<i>Scindapsus</i>
<i>Alternanthera</i>	<i>Erysimum</i>	<i>Monarda</i>	<i>Senecio</i>
<i>Anthurium</i>	<i>Euphorbia</i>	<i>Monstera</i>	<i>Spathiphyllum</i>
<i>Aphelandra</i>	<i>Fatsia</i>	<i>Nandia</i>	<i>Syngonium</i>
<i>Begonia</i>	<i>Ficus</i>	<i>Nepenthes</i>	<i>Trachelospermum</i>
<i>Blechnum</i>	<i>Fittonia</i>	<i>Nephrolepis</i>	<i>Tradescantia</i>
<i>Bouvardia</i>	<i>Gerbera</i>	<i>Pedilanthus</i>	<i>Tulbahia</i>
<i>Brunnera</i>	<i>Grevillea</i>	<i>Penstemon</i>	<i>Tupidanthus</i>
<i>Calathea</i>	<i>Haworthia</i>	<i>Peperomia</i>	<i>Viburnum</i>
<i>Calibrachoa</i>	<i>Helxine</i>	<i>Philodendron</i>	<i>Viola</i>
<i>Caryopteris</i>	<i>Hemerocallis</i>	<i>Phlox</i>	<i>Xanthosoma</i>
<i>Chlorophytum</i>	<i>Homalomena</i>	<i>Phormium</i>	<i>Yucca</i>

Finding: There is inconsistency in the regulations of tissue cultures of *Xylella* spp. host plants – different regulatory interventions apply depending on the stage of micropropagation (Table 6). The department’s approach would benefit from using the stages described by Carrillo (2008) to improve communication and regulatory clarity.

Recommendation 4

The department should re-examine the regulations of tissue cultures of *Xylella* spp. host plants for consistency with the regulation of other host plants. The re-examination should be underpinned by a sound analysis of the *Xylella* spp. risk associated with tissue cultures that will be conducted as part of completing the pest risk analysis.

Box 1 Tissue culture case study

Imports of tissue culture without media

The Inspector-General assessed the department's evidence for randomly selected consignments of tissue culture without media of *Xylella* spp. host plants (*ex-vitro* plantlets, Table 6) produced by 3 facilities in 2 high-risk countries. The facilities all appear to have been exporting to Australia for over 10 years.

The department's published documentation (DAWE, 2020b) requires that all facilities exporting tissue cultures without media must initially be approved by the department. They must seek re-approval every 2 years and seek approval for any significant changes to the facility. Also, desktop audits must be conducted by the department every 2 years. The assessment and approval documentation for the 3 exporting facilities does not indicate that the department has been regulating the facilities according to its published requirements. Two facilities were last re-approved in 2017. There is evidence that one of the facilities had also been re-approved in 2015 and the other facility was last re-approved in 2012.

In all cases, any apparent 'desktop audit' was only an assessment of a renewal application against an established checklist, based on information provided by the applicant and the exporting country's NPPO. The department explained that the NPPOs audit the system as part of the application process and provide the information to the department, although the department did not give the Inspector-General any information on that for this review.

The tissue culture facilities provided information that varied in quality and detail. However, it was reasonably clear to the Inspector-General that each tissue culture facility was a significant, professional business that is well-equipped with personnel, technology and processes. Information on the facilities is not routinely updated, and it is doubtful that information on personnel, mother-plant sourcing and other practices provided 5–10 years ago is likely to remain current in 2022. It is also doubtful that the approval requirement that 'a complete list of plant material cultures at the facility (genus and species) and which stock will be exported to Australia' would remain current, assuming that it was complete and current when supplied at the time of reapplication.

Each facility provided evidence of detailed attention to management of insect pests, fungal infection and virus diseases, with references to treatments and processes designed to minimise or control infection/ infestation. There was also some evidence of access to expert diagnostic laboratories and expert advice.

No facility made any reference to *Xylella* spp. risk mitigation or testing (despite 2 facilities being re-approved since 2015). Also, the overall practices for mother-plant (or stock-plant) sourcing that were described did not demonstrate consistency with the requirement to only use mother-plants tested and found free of *Xylella* spp. in the tissue culture production process.

All approval documents referred to approval of the facility for 'low and medium risk tissue culture free of media', although there was no reference to *Xylella* spp. in any of the client re-approval applications or departmental approval documents (including for the 2 re-approvals provided in 2017). This is despite the fact that the department has explicitly stated that 'if a facility is in a *Xylella fastidiosa* high-risk country and intending to export plantlets that are regulated by the department for *Xylella fastidiosa*, the facility must also supply a copy of a laboratory test report', according to the document *Requirement for facilities to become an approved source to export tissue culture free of media to Australia* (DAWR, 2019a).

Finding: The regulation of overseas facilities that supply tissue culture free of media to Australia is non-current, incomplete and poorly focused and hence inefficient. This impedes biosecurity risk mitigation and the quality and efficiency of business processes for the approved facilities.

Recommendation 5

The department should overhaul the regulation of overseas facilities that supply tissue culture free of media. The regulatory regime should focus on the essential factors that require regulation at the stage of facilities approval. Approvals and reviews should be undertaken in a timely, contemporary manner and complement the regulatory requirements of the import permit process.

9.3 High-health arrangements

There are currently 3 high-health arrangements in place for agriculturally important germplasm and new varieties of *Phoenix dactylifera* (date palm), *Solanum tuberosum* (potato) and *Fragaria* spp. (strawberry) exported as tissue cultures from 2 high-risk countries listed under the *Xylella* spp. emergency measures (Table 8).

High-health arrangements are published in BICON. Facilities operating under high-health arrangements test for all pathogens of quarantine concern to Australia. The tested material of *Solanum tuberosum* and *Fragaria* spp. still requires growth and screening at the department's post-entry quarantine (PEQ) facility at Mickleham though for a reduced period. *Phoenix dactylifera* does not require onshore PEQ. The policy framework for high-health arrangements is more detailed than for tissue cultures without media; and regulation is stronger.

Table 8 Summary of high-health arrangements

Facility	Plant material	Approval	Status	Audit	Information
Date palm developments (England)	<i>Phoenix dactylifera</i> tissue culture	Early 1990s	Current	Site audit in December 2018	The audit report stated that facility and processes were of very high standard (DAWR, 2018b).
Driscoll's (USA)	<i>Fragaria</i> spp. tissue culture	2003	Current	Site audit in September 2019	The audit report stated that facility and processes met current requirements (DAWR, 2019b).
United Kingdom potato quarantine unit (Scotland)	<i>Solanum tuberosum</i> tissue culture	2013	Current	Site audit in December 2018	The audit report stated that the facility and processes were of very high standard (DAWR, 2018c).

High-health arrangements with overseas developers and suppliers of germplasm help Australian agricultural industries to source new germplasm and varieties of clean

nursery stock faster, which helps them to maintain commercial competitiveness. These high-health arrangements are therefore rather boutique and hence different from the bulk imports of tissue cultures without media for the nursery stock retail sector, as mentioned above.

Recent departmental onsite audits found that all 3 current facilities operated at a high standard and in line with the department's requirements (DAWR, 2018b, 2018c, 2019b). The screening and testing regime for *Xylella* spp. is similar to that of the department's PEQ facility at Mickleham.

In 2019, the department updated its *Framework for the approval of overseas facilities producing high-health nursery stock for export to Australia* (DA, 2019d). The revised framework includes requirements for the:

- approval process, which must be:
 - initiated by the facility and supported by Australian industry bodies
 - balanced against other department priorities and objectives, including availability of resources – for example, for offshore audits. In addition, where a current pathway exists for the commodity to be imported through the department's PEQ facility at Mickleham, such high-health pathways are not critical for the ongoing import of new germplasm into Australia
- testing laboratories, which are operated or authorised by the country's National Plant Protection Organisation (NPPO)
- production facilities, which must be suitable to maintain high plant health:
 - facilities must be constructed to minimise infestation with insects that can vector pathogens
 - there must be effective post management and monitoring of pests and diseases
- traceability and record-keeping systems, such as a laboratory information management system (LIMS)
- oversight and auditing:
 - the exporting country's NPPO audits, approves and oversees the arrangement in accordance with Australian requirements
 - the NPPO must audit the facility at least once per year and provide an annual summary to the department. The audit rate is increased in cases of noncompliance
- review of approvals and audits by the department:
 - the department reviews the approvals every 2 to 3 years
 - reviews include desktop audits and may include onsite audits undertaken by the department. Industry may need to cover the costs of reviews and audits in the future.

Four other high-health arrangements have ceased to operate since 2018. The department cancelled one arrangement for *Rubus* spp. tissue culture because there had been no trade for at least 5 years. Two arrangements (*Fragaria* spp. tissue culture and *Vitis* spp. dormant cuttings and tissue culture) were discontinued because the supplier was no longer able to meet the requirements of the current high-health framework (DA, 2019d). One arrangement for *Prunus* spp. budwood was suspended due to non-conformance in records keeping.

Finding: *Xylella* spp. risk is tightly managed in high-health arrangements for (so-called) high-risk nursery stock. However, there is disproportionately less rigour in managing the risk associated with ornamental/alternative hosts of *Xylella* spp.

10. Post-entry quarantine

10.1 Mickleham PEQ facility

The department's post-entry quarantine (PEQ) facility at Mickleham, Victoria, is the sole Australian Government facility that manages the biosecurity of imported 'high-risk' nursery stock (chapter 8.4). The duration of the PEQ period is prescribed in the import conditions, and ranges from a minimum of 3 months to 2 years for *Xylella* spp. host materials.

The Mickleham PEQ facility is a state-of-the-art high-containment facility equipped with growth chambers, plant houses, glasshouses and polyhouses; and laboratory facilities for the inspection, sampling and testing of live plant materials. On arrival, vegetative propagative plant materials (non-tissue cultures) are treated against arthropods. All *Xylella* spp. host materials are initially grown in glasshouses under temperature and humidity regimes that promote disease expression. This ensures that diseases are detected and can be eradicated. Some host plants of *Xylella* spp. are hot water treated upon arrival at the PEQ facility (e.g., *Saccharum* spp.). Depending on import conditions (chapter 8.2), host plants of *Xylella* spp. are tested during the PEQ period by polymerase chain reaction (PCR) using internationally recognised protocols for the detection of *Xylella* spp.:

- rimM gene sequence real-time PCR test of Harper et al. (2010)
- conventional PCR of Minsavage et al. (1994).

Design and operational requirements for PEQ stations for plants are detailed in the international standard ISPM34 (IPPC, 2010). The security level at Mickleham PEQ is designed to contain and, in the event of a detection, eradicate the pest or disease from the facility and hence prevent the entry of quarantine pests and diseases into Australia.

The policy statement in the department's guideline for the management of plant pests and diseases detected at the Mickleham PEQ facility states:

Pests or diseases that pose an unacceptable biosecurity risk must be managed via a systems approach which contains and ultimately sees the eradication of the pest from the PEQ facility, while minimising impact on other plants undergoing PEQ. The approach includes:

- *performing inspection and testing, isolation, containment, risk assessment, application of treatments and/or destruction of infested plants*
- *applying an appropriate treatment or additional controls on other plants that are susceptible to the pest, before release from biosecurity control (e.g., restarting the prescribed PEQ period and/or further testing).*

While this guideline provides a structured approach for managing pests or diseases that pose an unacceptable biosecurity risk found in PEQ, the timing and nature of the operational response must be tailored to suit the specific circumstance at hand. Biosecurity officers must use defensible decision-making in each stage of the process to reduce the risk of potential legal challenge. (DAWR, 2016b)

The Inspector-General observes that the ‘systems approach’ described in the guideline for the Mickleham PEQ facility (DAWR, 2016b) does not necessarily include the offshore components of the 2015 emergency measures – a phytosanitary certificate by the National Plant Protection Organisation (NPPO) of the exporting country and offshore PCR testing – to reduce the ‘unacceptable biosecurity risk’ posed by *Xylella* spp. before plant materials arrive onshore (chapter 8.2). A ‘systems approach’ should consider the biosecurity continuum.

Under the *Xylella* spp. emergency measures, the department advises importers:

There are scheduled fees associated with the growth of nursery stock in an Australian Government post-entry quarantine facility, which must be met by the importer. The importer is responsible for contacting the facility to confirm all arrangements, including space availability and number of plants, prior to the plant material arriving in Australia. Importers must clearly nominate the facility that their material will be sent to on the import permit application. (DAWE, 2021c)

The department advised that, between 1 July 2019 and 30 June 2021, a total of 177 consignments of *Xylella* spp. host materials were imported into the department’s PEQ facility at Mickleham either as vegetative propagative material or tissue culture. The top *Xylella* spp. host genera were *Prunus*, *Malus*, *Solanum*, *Vitis* and *Fragaria*.

The number of nursery stock consignments received at the Mickleham PEQ facility was only about 4% of all nursery stock consignments (lines in AIMS) exported to Australia during the above period. These are low-volume consignments shipped by airfreight courier services, typically containing a few plants only. In contrast, a single consignment of ‘medium-risk’ nursery stock exported as tissue culture free of media (chapter 9.2) for the retail sector can contain thousands of plantlets.

Essential to the efficient functioning of a state-of-the-art PEQ facility is the ability to trace plant materials from entry into PEQ, and through all steps in the inspection, screening, sampling and testing process, to the exit from the facility and the associated keeping and management of all records generated during the process. The department advised that staff at the Mickleham PEQ facility currently manage this complex process by updating and maintaining multiple spreadsheets owned by different laboratories within the facility. The Inspector-General notes that this is inefficient data and information management and a burden to highly skilled and motivated staff. The department should implement a contemporary laboratory information management system (LIMS) as a matter of urgency.

The Mickleham PEQ facility is currently the only laboratory in Australia that routinely tests plant materials for regulatory purposes for *Xylella* spp., if required by current import conditions (chapter 8.2). The facility could further add value to Australian biosecurity by becoming a leader as a national reference lab for *Xylella* spp., including standard setting, national sourcing and maintenance of genetic controls required for molecular testing for *Xylella* spp. The Mickleham laboratory would be a key facility in the event of an incursion of *Xylella* spp.

From the range of information assessed and the conversations with staff during a site visit of the Mickleham PEQ facility, the Inspector-General concludes that it seems very unlikely that *Xylella* spp. would enter Australia through this pathway.

Recommendation 6

The department should establish the Mickleham post-entry quarantine facility – the only Australian laboratory conducting routine regulatory testing for *Xylella* spp. – as the lead national reference laboratory for *Xylella* spp. This laboratory and other department diagnostic laboratories should urgently be equipped with a modern laboratory information system (LIMS).

10.2 Approved arrangements

The department has approved arrangements (AAs) in place covering state government and industry run PEQ facilities to manage the risk from *Xylella* spp. associated with the importation of nursery stock. The department describes AAs on its website as ‘voluntary arrangements entered into with the Department of Agriculture, Water and the Environment’:

These arrangements allow operators to manage biosecurity risks and/or perform the documentary assessment of goods in accordance with departmental requirements, using their own sites, facilities, equipment and people, and without constant supervision by the department and with occasional compliance monitoring or auditing. (DAWE, 2021h)

AAs have different classes, described by sets of conditions that allow for specific types of activities to be undertaken at a facility. The conditions are set according to the nature and level of biosecurity risk (DAWE, 2021h). AAs are legislatively provided for in Chapter 7 of the *Biosecurity Act 2015*. Here, the Inspector-General included only AA classes and sites at which nursery stock undergoes growth and screening before being released from biosecurity control. The AA class 6.11 – Bulbs is discussed in chapter 9.1.

As a general observation, the department’s data did not allow for identification of the nursery stock consignments that had undergone screening at specific AA sites. Where information is inaccessible or incomplete, the department’s ability to identify and rectify potential weaknesses in pathway risk management is compromised.

Class 2.4 – Fresh produce, nursery stock and cut flowers

Class 2.4 approved arrangement sites are utilised for the deconsolidation, handling, storage, inspection and treatment of fresh fruit and vegetables, cut flowers and nursery stock subject to biosecurity control. Only nursery stock is currently regulated for *Xylella* spp.

The sites must generally be located within the metropolitan area of a declared port (air or seaport) that has a permanently based biosecurity officer. Class 2.4 sites (international airports and cruise ship terminals and surrounds) are targeted for surveillance under the department’s National Border Surveillance (NBS) program (chapter 11.1).

Class 6.7 – Process management system for nursery stock

Some *Xylella* spp. risk materials can undergo quarantine growth and screening at class 6.7 sites operating under an AA that requires the biosecurity industry participant to comply with a process management system (PMS) document (DAWE, 2021h). A single PMS might apply across multiple physical AA sites operated by a biosecurity industry participant. In these cases, the PMS content defines which activities are authorised to be carried out at which AA site. At present, class 6.7 PMS arrangements for nursery stock are rarely used. Across the financial years 2015–2021, only about 0.5% of all nursery stock consignments have undergone screening at class 6.7 sites.

Class 6.7 PMS AAs relevant for this review are in:

- Western Australia for *Vitis* spp.
- South Australia for tree species of recreational and forestry importance, palms, conifers, aquatic plants, and others with an import permit
- Queensland for *Saccharum* spp.

The PMSs were originally developed and implemented as Compliance Agreements under the now repealed *Quarantine Act 1908*. The Compliance Agreements transitioned into PMS AAs when the *Biosecurity Act 2015* came into force.

A PMS is a document customised to a business because it is written by the business with input from the department to ensure that the department's requirements are reflected. A PMS can be thought of as a quality control system specific to an individual facility as opposed to a set of standardised conditions with the specific wording prescribed by the department. In standardised conditions the wording for specific operational requirements, processes and activities is the same regardless of the business or facility.

Therefore, even where a business makes minor variations to a class 6.7 PMS document (for example, a change in a procedural aspect not relevant to biosecurity) a regulatory change process will be initiated and undertaken by the department to make the variation to the class 6.7 PMS AA.

The need to service workloads associated with even minor variations in any one PMS, and considerations of regulatory efficiency, were recognised when the *Biosecurity Act 2015* came into force. At the time, the department worked on replacing the PMSs (non-standardised) with the standardised regulatory AA system (standardised sets of conditions) by 16 December 2017. However, the transition was put on hold to ensure business continuity, as the PMSs would have expired by that date.

As part of the class 6.7 PMS approval process, the department assesses the PMS document supplied by a business against its required biosecurity standards (e.g. production practices to ensure plant health, pest and disease screening and testing). As these standards have been developed by the department, it appears to be more efficient (with better regulatory equity) if the department simply applies the standards up-front to the business as AA requirements.

To improve regulatory efficiency and consistency, the department should consider replacing the class 6.7 PMSs (non-standardised) with the standardised, regulatory AA system (standardised sets of conditions supplied by the regulator).

The department advised that some of the facilities operating under a class 6.7 PMS AA are due to close. In anticipation of the closure of the Western Australia facility, *Vitis* spp. plant materials have undergone PEQ at the department's Mickleham PEQ facility for some time.

As class 6.7 PMS arrangements are rarely used – most have or are due to close – it seems prudent to use the department's high-security PEQ facility at Mickleham as the sole facility for plant materials considered 'high-risk', because *Xylella* spp. is Australia's No. 1 priority plant pest, requiring a high level of intervention; and only about 4% of all nursery stock consignments (lines in AIMS) are under PEQ at Mickleham.

Recommendation 7

The department needs should consider replacing the process management system (PMS) quality control approach for nursery stock with the standardised regulatory approach to approved arrangements under the *Biosecurity Act 2015* to achieve a more consistent, efficient and equitable regulatory regime for nursery stock.

Class 6.1 – Medium-risk nursery stock

Class 6.1 AAs manage 'medium-risk' nursery stock at privately owned, third-party sites (currently primarily state departments of primary industries and research organisations).

These AA sites include plant houses, glasshouses, polyhouses, igloos and tunnel houses but not screen houses. The department sets conditions for the structures at class 6.1 sites and specifies some procedural aspects. For example, risk mitigation includes maintaining a structural, insect-proof barrier between each consignment.

Medium-risk nursery stock undergoes a minimum of 3 months of PEQ at class 6.1 sites. Biosecurity officers conduct 2 visual inspections during the active growth of nursery stock before it is released from biosecurity control.

The department informed the Inspector-General that class 6.1 is being reviewed, and the intention is that facilities under this class will be transitioned into classes 5.1.4, 5.2.4 and 5.3.4. No date has been specified for this transition. The department's data did not allow for an identification of the consignments that had undergone screening at class 6.1 sites.

Class 5.2.4 – Biosecurity containment level 2, plant

Biosecurity containment level 2 sites are:

[AA] sites housing biosecurity goods that pose a moderate biosecurity risk. A low to moderate economic impact would result to people, the community, or environment should the goods (including live organisms) escape and spread outside the approved arrangement site. (DAWE, 2021h)

Class 5.2.4 AAs specify requirements for the physical security around storage, handling, risk and incident management, work practices, personnel, transport, biosecurity treatments and waste management. The class site is usually a permanent greenhouse structure covered in glass, polycarbonate or other transparent or translucent materials and may be attached to a laboratory. Activities permitted at class 5.2.4 are *in vivo* work with plants, virus indexing, growth of plants for active virus testing and plant breeding.

The department advised that around 80% of class 5.2.4 are research institutions, universities and state agriculture departments; and around 20% are commercial operations, including commercial nurseries. The department's data did not allow for identification of the consignments that had undergone screening at class 5.2.4 sites.

Class 5.1.4 – Biosecurity containment level 1, plant

Biosecurity containment level 1 sites are:

AA sites used for goods subject to biosecurity control of low hazard where standard safe containment practice is adequate to address biosecurity risk. (DAWE, 2021h)

Class 5.1.4 AAs specify requirements for physical security around handling, risk and incident management, work practices, personnel, transport, biosecurity control, treatment and waste management. The class includes open fields, greenhouses such as screen houses, flexible film plastic structures or permanent greenhouse structures, potting areas, waste disposal rooms/areas and instrument rooms. Activities permitted at class 5.1.4 are the containment of plants for disease screening before they are released from biosecurity control.

The department advised that around 80% of class 5.1.4 are commercial operations (including commercial nurseries) and around 20% are research institutions, universities and state agriculture departments. The department's data did not allow for identification of the consignments that had undergone screening at class 5.1.4 sites.

11. Monitoring, surveillance and diagnostics

11.1 Monitoring and surveillance

The investigations for this review have made it plain that molecular diagnostics (polymerase chain reaction (PCR) or other relevant analysis) must be used to detect any presence of the highly cryptic *Xylella* spp. pathogens in imported living plant material while the plants and plant materials are under the department's regulatory control. Offshore (pre-shipment) and on-arrival molecular testing should be used to support on-arrival visual inspections by biosecurity officers. It should also be used to support post-biosecurity monitoring and surveillance in higher risk entry points, such as wholesale nurseries that produce plants from imported *Xylella* spp. host material and any immediately surrounding nurseries.

The scope of this review does not include post-border biosecurity. However, the paucity of data for at-border monitoring of *Xylella* spp. warrants some discussion of the limited data available on post-border surveillance for *Xylella* spp. Therefore, the Inspector-General assessed data provided by the department's National Border Surveillance (NBS) program, which conducts surveys at and around first points of entry. Data available from the National Plant Health Surveillance Program (NPHSP), which is operating post-border as a shared responsibility between the department and the biosecurity agencies of state and territory governments, was also considered.

National Border Surveillance program

The National Border Surveillance (NBS) program is responsible for onshore early detection, delimiting and pest status surveillance activities at first points of entry and premises with approved arrangements. Detections are notified via the biosecurity pest and disease notification process to the Australian Chief Plant Protection Officer and Chief Environmental Biosecurity Officer to result in notifications of the relevant state and territory agencies. The NBS program has been operating since November 2016.

The operation and performance of the NBS program is outside of the scope of this review. However, the Inspector-General notes that the department's self-assessment of the NBS program has identified issues with the program's governance, adequacy of resourcing, staff capability, and data management systems. The NBS program has had difficulties delivering planned targeted surveillance. Generally, less than 50% of all planned surveillance visits to approved arrangement (AA) sites, seaports and international airports were conducted.

For *Xylella* spp. the following occurred:

- The department completed limited targeted post-border surveillance for *Xylella* spp. in 2017–2018 and 2021 and has scheduled further post-border surveillance in March/April 2022.
- Data was provided for 243 samples (insect vectors and plant hosts) taken in 2017–2018 and 2021 around 41 AA or first points of entry sites across Australia.
- All samples produced negative results to *Xylella* spp. using either loop mediated isothermal amplification (LAMP) (Optigene) or qPCR methods (as per Harper et al., 2010).

The department's draft *Surveillance procedure for Xylella fastidiosa and known or potential vectors* (DAWR, 2018d) describes the target sites for *Xylella* spp. surveillance under the NBS program as:

- international airports and surrounds, prioritised according to the number aircraft and volumes of passengers arriving
- seaports and cruise ship terminals and surrounds, prioritised according to the number of passengers arriving particularly from areas with high incidence of known vectors (e.g. glassy-winged sharpshooter arriving on cruise ships from the Pacific region – see chapter 5.3)
- AA sites located within the metropolitan area of an air or seaport:
 - class 2.4 AA sites used for the deconsolidation, handling, storage, inspection and treatment of fresh fruit and vegetables, cut flowers and nursery stock (chapter 10.2) are prioritised according to the:
 - volume (by weight and/or number) of consignments of fresh produce and/or cut flower imports per annum
 - number of susceptible host species present at a site.

Survey sites for *Xylella* spp. are selected based on the 'level of risk' (DAWE, 2018d). Under the NBS surveillance procedure for *Xylella* spp., higher risk sites are those with greater numbers of aircraft, cruise ships and passengers; arrivals from regions with high incidence of known vectors of *Xylella* spp.; volumes of consignments of fresh produce and cut flowers that could potentially introduce vectors; and sites with high diversity of *Xylella* spp. host plants and known susceptibility to the greatest number of *Xylella* subspecies.

The Inspector-General notes that the continuous improvement of the NBS program should envisage a significantly expanded practical program of at-border monitoring and immediate post-border surveillance for *Xylella* spp., which could be routinely undertaken, like the department's exotic mosquito monitoring and surveillance activities. The Inspector-General's research of international work (EFSA et al., 2020; Cruaud et al., 2018) indicates that there should be no insurmountable technical or resourcing challenges to implementing such a program for Australia's No. 1 priority plant pest. NBS program surveillance for *Xylella* spp. must be underpinned by routine at-border polymerase chain reaction (PCR) testing for *Xylella* spp. infection.

National Plant Health Surveillance Program

The National Plant Health Surveillance Program (NPHSP) is a shared responsibility of all Australian governments and covers the post-border component of the national plant health surveillance system. It aims for the early detection of high-priority exotic plants pests that have breached the border to provide opportunity for their eradication or containment (DAWE, n.d.).

The *National Operational Plan 2021–2026* of the NPHSP (DAWE, n.d.) specifies urban and peri-urban areas around international air and seaports as high-risk locations to be targeted in surveys.

Xylella spp. and its insect vectors have been surveyed under the NPHSP since 2016. Based on the findings from the NPHSP, there is no change in the *Xylella* spp.-free status of Australia.

The NPHSP relies on visual assessment of host plants for *Xylella* spp. Molecular testing of plant samples using internationally recognised PCR tests is only conducted if plant samples are suspected to show symptoms that could be caused by *Xylella* spp. As outlined above, this approach appears inadequate given the cryptic nature of *Xylella* spp. The *Xylella* spp. infection may be asymptomatic, and there is little likelihood that officers who have never seen *Xylella* spp. symptoms will detect infected plants.

Surveys of risk locations and PCR testing for *Xylella* spp.

It is worth noting the study by Luck et al. (2008), which was conducted for the Department of Primary Industry, Victoria. It is arguably the most comprehensive post-border field survey of *Xylella* spp. host plants conducted in Australia to date. The survey investigated symptomless *Xylella* spp. hosts that may harbour the pathogen. However, grapevine samples were also collected from Victorian vineyards for parallel screening. A total of 812 samples from 94 *Xylella fastidiosa* hosts were collected from 57 locations in Victoria, including regional botanic gardens, vineyards and wholesale plant nurseries. No *Xylella fastidiosa* was detected using PCR testing. In the absence of at-border PCR testing of current nursery stock imports, and general release after document assessment and inspection, it can be argued that Luck et al. (2008) targeted high-risk locations using the best available diagnostics to test for the presence of *Xylella* spp.

The Inspector-General observes that both monitoring within import-linked production nurseries and surveillance immediately surrounding such nurseries and other identified higher risk sites for *Xylella* spp. is currently necessary. However, the sole purpose of these activities would be to detect any presence (or absence) of *Xylella* bacteria. Therefore, markedly simplified techniques should be deployed.

There is a need for monitoring activity within nurseries that:

- randomly samples plants for consolidated diagnostic testing for *Xylella* spp. presence
- efficiently capture xylem sap-feeding insects for bulk PCR testing for *Xylella* spp. (Cruaud et al., 2018).

For both *Xylella* spp. monitoring and surveillance activities, any detection of *Xylella* spp. would immediately invoke more intensive and extensive plant and insect sampling, with the department focusing on traceback activities; and post-border biosecurity partners would need to consider options for additional post-border surveillance and other responses.

There is significant EU experience with *Xylella* spp. surveillance, including EFSA et al. (2020), that will provide valuable learnings for Australia's biosecurity agencies and industry involved with post-border surveillance programs.

Post-border biosecurity measures are not within the review's scope. However, the Inspector-General observes that the EU and other approaches are likely to be readily adaptable to peri-border (immediately post-biosecurity control of the department). For example, Cruaud et al. (2018) have successfully used insects to detect, monitor and predict the distribution of *Xylella fastidiosa* in the French island of Corsica. This work indicates that insects may be used as valuable sentinels in the detection and monitoring of the presence of *Xylella* spp. In conclusion, at-border testing for *Xylella*

spp. infection needs to be ramped up; and post-border surveillance needs to be significantly redesigned.

Finding: The highly cryptic nature of the *Xylella* spp. means that the department should routinely conduct PCR-based testing of recently imported *Xylella* spp. host plants in import-linked production nurseries; and vector-based surveillance adjacent to assessed higher risk sites.

Recommendation 8

The department should urgently design and implement a nursery stock pathway surveillance and molecular diagnostics program that includes major nursery stock sites closely linked to imports, nearby host plants of *Xylella* spp. and potential insect vectors present in the local environment.

11.2 Diagnostics

As part of informing on the regulation of nursery stock, the department's website states that the department will reserve the right to undertake testing to verify that a consignment is free of *Xylella fastidiosa* (DAWE, 2021c).

The department's main diagnostic function for *Xylella* spp. preventative biosecurity currently resides within the Mickleham post-entry quarantine (PEQ) facility, and some PCR diagnostic capability is available at its major biosecurity operational sites. The department has recently completed limited *Xylella* PCR testing for post-border surveillance conducted by its science and surveillance group, as discussed above.

This review did not seek to examine the department's overall diagnostic capability and capacity or, more specifically, its molecular diagnostic capability and throughput. The review's focus was on providing international, national and technical context to the *Xylella* spp. diagnostic work of the department. That work that is necessary for the department to appropriately fulfil its responsibilities to prevent *Xylella* spp. from entering Australia.

Substantial work has been done internationally through the International Plant Protection Convention (IPPC) to establish international diagnostic protocols. The diagnostic protocol for *Xylella fastidiosa*, ISPM 27 Annex 25, was adopted by the standards committee on behalf of the Commission on Phytosanitary Measures in 2018 (IPPC, 2018). The Inspector-General accepts that the department, in its own role and on behalf of other Australian biosecurity agencies, cooperates closely and well with international counterparts under the IPPC.

There has been considerable activity regarding Australia's national (largely post-border) diagnostic standards over the past 20 years. However, the latest version of the national diagnostic protocol for *Xylella* spp. is from 2010 and the national Subcommittee on Plant Health Diagnostics has listed it as 'under review' since December 2012 (SPHD, 2010). This protocol is currently being reviewed through a Horticulture Innovation project and the revised protocol is due for completion in October 2022. The department has also undertaken a review of the national diagnostic protocol process to ensure these documents continue to meet the needs of the diagnostics system. The Subcommittee on Plant Health Diagnostics has considered the review recommendation and is currently developing an implementation plan.

The department provided information confirming that the diagnostic methods recommended for *Xylella* spp. are the conventional PCR of Minsavage et al. (1994) and the real-time PCRs by Francis et al. (2006) and Harper et al. (2010). Of these, the test

by Minsavage et al. (1994) will detect both *Xylella fastidiosa* and *Xylella taiwanensis* and is currently recommended in the Australian national diagnostic protocol (SPHD, 2010; IPPC 2018). The real-time PCR of Harper et al. (2010) is also included, as it has a higher sensitivity of detection, despite being unable to detect *Xylella taiwanensis*, and has been verified by the department's post-entry quarantine (PEQ) laboratories. At the Mickleham PEQ facility, the department uses both the Harper et al. (2010) qPCR and the Minsavage et al. (1994) endpoint PCR to test host plants.

The Inspector-General has concluded that the department must take a more assertive position on its own significant *Xylella* spp. diagnostic responsibilities and capabilities. It is the only Australian organisation with a regular need to complete high-quality diagnostic tests for *Xylella* spp., where there is any reasonable likelihood of detection and where the consequences of diagnostic and regulatory failure (inappropriate release of infected plants) could be catastrophic.

The need for an agreed national diagnostics protocol for at-border biosecurity functions was identified in the import conditions review that the department conducted in May 2016 (DAWR, 2016c), following the introduction of the emergency measures. While the department's PEQ facility at Mickleham is well-equipped, laboratories at the border appear to be variably equipped to complete rapid, reliable, cost-efficient *Xylella* spp. diagnostic tests.

All laboratories that the department operates should be comparable and reviewed for standardisation, quality control and availability of positive controls. Access to positive control material is an issue nationally. All *Xylella* spp. testing laboratories should be using the same protocols and the same validated positive controls from the same source. It is pleasing to see that the department has recently been in discussions with stakeholders about ways of streamlining import requirements for viable samples of plant-related organisms, such as high-priority pests.

It is worth noting that, in the first instance, the department's *Xylella* spp. testing is for a 'yes/no' result for the presence/absence. There is no initial requirement to identify the subspecies or genetic strain because all subspecies in the genus *Xylella* are regulated. If there is a detection, the department uses multi-locus sequence typing or whole genome sequencing to identify the subspecies, as an additional measure to the mandated testing.

A 2020 internal review of the molecular diagnostic capacity and capability of the department's science and services group reported the results of qualitative surveys conducted with staff and described identified trends across the laboratory network (DAWE, 2021k). The reviewers found that the current capability was immature and uncoordinated. This warrants action before any serious adoption of new technology can take place. Among the challenges noted by the reviewers were:

(i) an immature and uncoordinated laboratory assurance framework for molecular diagnostics [that] hampered more in-depth analysis and recommendations for a future strategy.

(ii) the absence of a laboratory data management system or documented systems to allow quantitative analysis of current workloads and molecular diagnostic methods and results used. (DAWE, 2021k).

The 14 recommendations of the internal review focused on establishing the fundamentals of efficient, effective and quality assured basic molecular capacity and capability.

Finding: The department needs to take a significantly stronger, clearer position on diagnosis of *Xylella* spp. (Australia's No. 1 plant pest), given that PCR testing is an essential part of any reliable regulatory measures for assuring that *Xylella* spp. do not enter Australia in infected host plants. The diagnostic laboratory of the PEQ facility at Mickleham should be the department's internal reference laboratory, anchoring standards and capability for regional laboratories that should be capable of rapid, reliable processing of samples from imported consignments for 'yes/no' answers regarding *Xylella* spp. infection.

12. Assurance and verification

The department was unable to provide a comprehensive dossier of assurance and verification reviews that collectively covered essential aspects of the preventative biosecurity system for Australia's listed No. 1 plant pest – *Xylella fastidiosa*. The department has conducted 4 facility audits since 2018: one desktop audit (chapter 9.2) and 3 onsite audits (chapter 9.3). However, good-practice assurance and verification should be culturally embedded in regulatory practice to extend beyond any number of facility audits.

The Inspector-General's research for this review has involved a level of inquiring, searching and analysis for data and information and advice that would have been addressed in any reasonable internal assurance and verification assessment. It now appears that many of the complexities, inefficiencies, inconsistencies and potential risk-mitigation weaknesses for *Xylella* spp. could have been identified through internal assurance and verification reviews and routinely addressed by implementation of internal recommendations.

The Inspector-General considers that, over the past 5 years or so, the need for several assurance and verification reviews of *Xylella* spp. risk pathway(s) would have been reasonably indicated by the following:

- national listing of *Xylella* spp. as Australia's most important plant pest risk
- the department's long-espoused commitment to risk-return (apply resources where the greatest risk exists)
- expressions of concern by the Inspectors-General in multiple review reports about the need for the department to embed a continuous improvement culture and prioritised program of reform work
- existence elsewhere within the department (in Animal Biosecurity at least) of high-quality assurance and verification capability and processes.

The department has recently begun work to strengthen its commitment to assurance and verification in plant import pathways, as shown by the Strengthening Plant Imports Active Risk Management Capability project, funded through the Assurance, Verification and Enforcement work program of the Enhancing Australia's Biosecurity System budget initiative (DAWE, 2021i). The specified objectives of the project are to:

- develop a robust assurance and verification program to:
 - improve our ability to analyse biosecurity risk
 - actively detect and manage changing biosecurity risks
 - verify that biosecurity controls are effective both offshore and onshore

- ensure the regulatory practices of the department are appropriate, effective and operating as a whole system, learning lessons from the systematic circumvention of import requirements for imported prawns
- strengthen and enhance our enforcement capability by the effective use of new regulatory and enforcement tools available under the *Biosecurity Act 2015*.

The project's assurance and verification framework (DAWE, 2021i), which is intended to be used to achieve these high-level objectives, appears to structure the information and analysis along current risk groupings for nursery stock (high-risk, medium-risk and low-risk). The Inspector-General has doubts about the suitability of these groups. The rationale is detailed in chapter 8.4 of this report.

The department needs to target its assurance and verification activities appropriately and deliberately at the priorities of any basic biosecurity assurance and verification review. It should assess whether the department's risk mitigation measures are:

- appropriately designed
- in place
- working as designed
- effective
- efficient in delivery.

That is, there is a need for a strong focus on the actual risk reductions achieved, as demonstrated by the evidence. An effective assurance and verification program would be embedded in processes to continuously assess the evidence according to a regularly updated schedule of reviews.

Through various reviews conducted in recent years by the Inspector-General, it is evident that the department's Animal Biosecurity Division has an embedded, good-practice and effective verification and assurance program. A robust assurance and verification program improves that division's ability to analyse risk and to verify that biosecurity controls are effective. The division's assurance and verification activities aim to assess whether often longstanding biosecurity policies and controls should continue to apply by demonstrating that they remain effective at managing biosecurity risk and to ensure that the biosecurity outcomes from new import pathways are assessed. Findings are used to highlight potential residual biosecurity risks. Importantly, assurance and verification activities across the division are supported by ongoing funding.

Finding: The department has an uneven and inadequate overall commitment to assurance and verification that leads over time to cumbersome, inefficient and potentially ineffective pathway risk mitigation systems. Some good work is in place and some further developments are underway. The risk mitigation measures and processes for Australia's No. 1 plant pest, *Xylella* spp., should be an exemplar for other, lower ranked biosecurity risks to Australia's plant and animal industries and ecosystems.

Recommendation 9

The department should roll out a best-practice approach to assurance and verification across all biosecurity divisions, with the schedule of work and reports being routinely on the agenda of the Biosecurity and Compliance Board.

13. Data maturity, information management and staff capability

Live plants are a major biosecurity risk pathway. To adequately understand the pathway risk, and changes in the risk profile, the department must have available, and use, the quantitative information it routinely collects through its document processing, inspection and information management systems. Changes in risk profiles should be assessed by producing regular, ideally monthly, reports on trade pattern, including the number of nursery stock consignments imported from specific regions and countries; the types of plant materials (tissue cultures or vegetative propagative materials); the number of imports under approved source arrangements; and results from inspections, monitoring, screening and molecular testing for *Xylella* spp. and so on.

Data and information on nursery stock consignments arriving in Australia should be linked to information on onshore arrangements to support evaluations of biosecurity processes and conditions (Figure 8), and response functions. For example, the number of consignments in government post-entry quarantine (PEQ) or being screened at different approved arrangement (AA) sites of varying containment levels; and the number of those consignments released from biosecurity control after document assessment and visual inspection.

The Inspector-General assessed policy documents and information and found these surprisingly light on quantitative data. To design good policy and targeted risk management in the nursery stock pathway, the department must take better advantage of the capabilities provided by a data-driven world and the data it currently curates. The department has made great progress towards making accessible the data from its different database systems, although these data are not yet widely used to continuously assess changes in risk profiles and adapt accordingly.

A sound level of data maturity would be demonstrated if operational and policy staff, as well as senior biosecurity managers, could routinely use the best data and information currently available. For example, assurance and verification should be underpinned by regular (monthly) reports on the nursery stock pathway that link a range of different data fields, including the country of origin, types of plant materials (tissue culture or vegetative propagative material), approved source (offshore) arrangements, inspection and testing outcomes, and onshore arrangements (e.g. type of PEQ, release on documentation to nurseries), among others.

The department may also benefit from a shift from the apparent binary approach to data-based decisions – that is, it has good data or it does not – to an approach aligned with the European Food Safety Authority and UK Department for Environment,

Food and Rural Affairs approaches, whereby all available information (with varying confidence levels) is used in decision-making, but a judgement is applied as to the level of confidence that can be had in various decisions.

The department's current team of officers work every day with the complexity of the nursery stock regulation and a document management system that can be difficult to use in tracing past commitments and decisions. A well-organised information system with meaningful metadata and management protocols ensures timely, efficient access of both policy and regulatory officers to technical, policy, regulatory and client information, including the changes made over time.

Recommendation 10

The department should maintain adequate focus on improving the quality and timeliness of evidence-based decision-making (day-to-day, tactical, strategic) through routine access and analysis of available data and information. This needs to be supported by markedly improved information and data management systems.

Staff capability

The Inspector-General has again been impressed by the commitment, openness and helpfulness of the department's staff. This level of excellence has been evident, despite:

- staff on multiple occasions working with complexity and inconsistencies generated by the department's historical failure to continuously update its regulatory regime and maintain consistency of risk-based measures across plant forms of imported nursery stock and client types
- staff working every day with either inadequate information systems for technical and regulatory data or longstanding poor practice in information recording and accessibility in the corporate document management systems.

The establishment of the Biosecurity and Compliance Board provides a long-overdue opportunity for 'on-the-business' managers to collectively address systemic inefficiency, inconsistency and quality issues that plague the day-to-day work of 'in-the-business' managers and staff who are individually powerless to make the needed systemic changes.

The Inspector-General again heard staff concerns that the department had not achieved the right balance of staff flexibility and expert knowledge under the previous versions of the integrated workforce model (IGB, 2021c). The number of different roles held within a short period of years by many biosecurity officers – roles requiring a significant degree of technical and industry knowledge for officers to be excellent in performing their roles effectively and efficiently – is sometimes breathtaking.

A fully deployable workforce able to work in airports, seaports, warehouses, laboratories and logistics yards has dissipated focus on the primary role of biosecurity officers to 'mitigate biosecurity risk' and will be counter to Australia's interests. Within local teams, and to a reasonable extent within each individual officer, there must be sufficient technical, regulatory and industry knowledge for them to be alert to risk issues, including consignment characteristics and client behaviours that warrant additional attention. Recent Operations Division reforms (April 2021) appear to have gone a long way toward addressing staff concerns about becoming 'jacks of all trades' without adequate 'subject matter expertise' for specialist areas such as nursery stock imports. The Operations Division shift towards a stronger 'pathways approach' is helpful in narrowing the scope of operational areas in which staff must become expert.

Recommendation 11

The department should ensure an ongoing focus on its frontline workforce management arrangements, optimising the balance of staff flexibility and ongoing availability of subject matter expertise to enable optimal biosecurity risk mitigation.

14. Stakeholders and communication

The department provides a range of good quality general information about serious pests such as *Xylella* spp. (DAWE, 2021e). However, this review has highlighted several areas in which the department is not engaging in an efficient, clear and effective way with its international and domestic client base about regulated imports of *Xylella* spp. host plants. This type of engagement is an essential part of mitigating *Xylella* spp. Of particular concern are:

- confusing and obsolete information on the department's webpages:
 - relevant information for importers of nursery stock, and other stakeholders in *Xylella* spp. risk mitigation, is in too many different places on the department's website. For example, relevant website content includes:
 - [Live plant forms](#) (DAWE, 2021b)
 - [Approved sources of tissue cultures free of media](#) (DAWE, 2020b)
 - [Notification of amended emergency quarantine measures for Xylella](#) (DAWE, 2021c)
 - [Changes to import requirements to protect against Xylella](#) (DAWE, 2021i)
 - [Importing live plants \(nursery stock\)](#) (DAWE, 2021m)
 - some obsolete information is still being referenced – for example, the 2013 policy review on the importation of grapevine propagative material (DAFF, 2013), which contains outdated information and is referenced in BICON and in the department's plant risk analyses webpages (DAWE, 2019; see chapter 8.3 for details).
- uneven and probably ineffective engagement of critical offshore stakeholders
- inadequate understanding of key stakeholders at critical risk points for a potential *Xylella* spp. incursion; and the accountable roles that each stakeholder cohort can best play at each point
- non-completion of the pest risk analysis (PRA) on bacterial pathogens in the *Xylella* genus. This PRA will contribute to improving the organisation and rationalisation of public information – for example, directions, advice and supporting information on *Xylella* spp. and its risk management.

While it is admirable that the department provides public access to a range of information about *Xylella* spp., it is critical that we have clarity and consistency in regulations and related published information concerning serious threats to Australia's agriculture and ecosystems.

Recommendation 12

The department should review information on its website for importers of nursery stock and other stakeholders in *Xylella* spp. risk mitigation to ensure ease of access, cohesiveness and accuracy. Information should be consolidated to clarify approval and audit processes and improve overall communication.

Throughout this review, it has become increasingly clear to the Inspector-General that the prevention of entry of *Xylella* spp. into Australia relies strongly upon the actions of overseas plant production and export businesses and competent regulatory authorities (i.e. the overseas National Plant Protection Organisations (NPPOs)). It follows that the department needs to have a contemporary and effective relationships with these NPPOs through their key contact personnel. The Inspector-General saw no evidence that effective relationships were in place, except in the case of high-health facilities importing *Xylella* spp. host material from high-risk countries (see chapter 9.3 on approved source (offshore) arrangements).

For example, for approved offshore facilities exporting tissue culture (without media) of *Xylella* spp. host plants, including from high-risk countries (chapter 9.2), the department states that exporting accreditation must be renewed every 2 years, and the department will conduct desktop reviews every 2 years. Neither process appears to occur with any sound level of consistency and reliability. It is difficult to see how offshore production/exporting facilities would regard themselves as 'biosecurity industry participants' committed to preventing *Xylella* spp. arriving in Australia. A more practical re-approval timetable (maybe every 4–5 years) and process, the actual conduct of desktop audits at reasonably reliable intervals, and *Xylella* spp. monitoring for consignment (and feedback to exporters) would establish a mature, practical relationship with overseas exporters (who are a critical part of the *Xylella* spp. prevention systems).

During this review, the Inspector-General sought to gain an understanding of the level of both internal and external knowledge among key domestic stakeholders about the most likely entry pathways for *Xylella* spp. In the absence of any accurate mapping of nursery stock and other potential *Xylella* spp. risk pathways, it is very difficult for the department to have a shared understanding of the critical paths, critical regulatory control points and critical points of vulnerability in the preventative biosecurity system. Similarly, without a clear commitment to continuous improvement, including routine use of effective assurance and verification processes, it is very difficult for department staff to see how they can best contribute to ensuring a contemporary risk mitigation system.

During the review the Inspector-General learnt that there is significant post-border expenditure on *Xylella* spp. preparedness activities. However, the Inspector-General was not assured that peri-border (immediate near-border) and post-border stakeholders have a sufficiently acute and contemporary understanding of *Xylella* spp. in an international, at-border and peri-border context that would optimise targeting of post-border measures to respond to any incursion of *Xylella* spp. into Australia. Conversations with the nursery stock importing sector undertaken during this review gave the impression that there is insufficient focus on, and serious commitment to, accountable *Xylella* spp. prevention. The sector appears to rest on the idea that illegal pathways are the most probable, if not the only, pathways for *Xylella* spp. to arrive in Australia and focus primarily on ensuring that import consignments pass the current import conditions for relevant plant imports.

Key stakeholders must have a shared, accurate knowledge of what is best to be done ahead of, and in the moment of, any post-border detection of *Xylella* spp. The acuteness of knowledge should be made strikingly clear because of the:

- very wide host range for *Xylella* spp. combined with vastness of the Australian land

mass and distribution of commercial, ornamental and native host species

- cryptic nature of *Xylella* spp. infection
- low level of knowledge on native insects that can potentially vector *Xylella* spp. in each of the diverse agricultural regions of Australia
- specific nature of the pathways for entry into Australia of *Xylella* spp. host plants
- multiple entry points for *Xylella* spp. risk material (and linked rapid post-border distribution systems for some imported material).

As a means of sharpening both key stakeholder knowledge and the partnership between the department and domestic partners, more intense discussions are needed about the regulation of *Xylella* spp. host plants, risk pathways, probable incursion locations and critical early steps in addressing post-biosecurity detections and suspected incursions of *Xylella* spp.

Recommendation 13

As part of at-border and post-biosecurity preparedness for a potential response to a detection of *Xylella* spp., the department should complete a collaborative desktop exercise simulating an incident response covering the first 7–10 days after initial post-biosecurity detection.

15. Conclusions

When initiating this review, the Inspector-General was optimistic about the prospect of finding exemplar preventative biosecurity arrangements in place for Australia's listed *highest ranking plant biosecurity pest*. It was anticipated that recommendations to further strengthen Australia's protection against *Xylella* spp. would provide a solid basis for a systemic approach to preventative biosecurity measures for the other high-ranking plant (and animal) pests and diseases and the fundamental Australian approaches to mitigating plant pests and diseases more generally.

This review has not assured the Inspector-General that the foundation stones for excellent preventative biosecurity have been laid appropriately for Australia's top plant biosecurity pest (a bacterial disease). Substantial improvement is needed in the setting and delivery of measures to prevent the entry of *Xylella* spp. into Australia, which is most likely to occur through the managed introduction of nursery stock.

In summarising the diverse observations, findings and recommendations of the report, this chapter seeks to thread together the Inspector-General's overall observations across the full biosecurity continuum, from pre-export to Australia through to post-biosecurity release of imported *Xylella* spp. host plants. The Inspector-General observes:

- In the absence of a completed pest risk analysis (PRA) covering *Xylella* spp. risk to Australia, the Inspector-General has reviewed expert knowledge from Europe and elsewhere and concluded that the department has not demonstrated the level of expert knowledge about the *Xylella* pathosystem (including symptomatic and asymptomatic hosts, distribution and most common distribution mechanisms, and detectability) that could be expected for Australia's listed No. 1 plant pest.
- The department is not alone in relying on broad expert opinion expressing that *Xylella* spp. is unlikely to be introduced to new regions through imported tissue culture. Scientific evidence on the transmission of *Xylella* spp. through tissue culture is a critical gap in international knowledge that could cause a significant rethinking of the benefits (or not) of the expanded use of tissue culture to trade host plants of *Xylella* spp. globally.
- The department has apparently not adequately recognised the critical importance of the asymptomatic nature of *Xylella fastidiosa* infection in many plant hosts. While respecting the notification of *Xylella* spp. freedom by many countries based on no detection, the cryptic characteristics of *Xylella* spp. mean that onshore monitoring of imported plant hosts for *Xylella fastidiosa* infection is necessary. Over time, this monitoring data from different countries/regions would contribute significantly to *Xylella* spp. biosecurity knowledge for Australia and globally.

- Where a biosecurity pathway risk mitigation relies heavily on actions taken and certifications provided in exporting countries, there needs to be a practical re-authorisation and audit program to underpin the risk mitigation assurance provided by import permits and at-border inspections. The department's handling of the offshore arrangements for *tissue cultures without media* is unsatisfactory. If tissue culture is a pathway for *Xylella* spp. introduction then the department is not effectively mitigating that risk and has no measures in place to test or provide assurance that its processes are reliably in place or working.
- The department's post-entry quarantine (PEQ) facility at Mickleham is world-class and effectively handles the relatively small quantity of high-risk *Xylella* spp. plant hosts that enter Australia. The facility needs to be better utilised, including as the leading national *Xylella* spp. reference laboratory using a modern laboratory information system (currently lacking); and as an intelligence and technical expertise centre for *Xylella* spp., Australia's top-listed emergency plant pest.
- The department's handling of nursery stock and other *Xylella* spp. host plants is significantly impeded by the absence of a suitable overall policy framework and persistence of a range of hangover arrangements that existed before the *Biosecurity Act 2015* and the 2015 emergency measures for *Xylella* spp. This leads to inconsistency, confusion and added cost; and potentially residual biosecurity risk. The future biosecurity regulatory challenges for the department necessitate persistent diligence in updating and simplifying regulatory arrangements.
- The ongoing historical failure of the department's management to instil a strong information management culture has led to poor utilisation of the corporate document management system and biosecurity databases, adding significant inefficiency and inconsistency to day-to-day management of the nursery stock pathway. A direct result is that good personnel are managing information churn rather than improving the system under which *Xylella* spp. host plants and tissue culture derived plantlets are imported.
- Due to the cryptic nature of *Xylella fastidiosa* infection of host plants and minimal use of polymerase chain reaction (PCR) testing to verify the health status of plant imports, the department has very limited knowledge about the level of *Xylella* spp. approach to the Australian border or about its potential leakage through relevant pathways. Routine monitoring of imported *Xylella* spp. host materials using PCR testing is essential to check the effectiveness of offshore risk mitigation steps. This type of monitoring data will help to better target the significant post-border resources that multiple stakeholders are applying to prepare for a potential *Xylella* spp. incursion.
- As has been observed in other areas of border biosecurity, the department's historical push to optimise workforce agility has come at some expense to workforce specialist capability – too few officers hold the specialist skills and knowledge necessary to understand the peculiarities or complexities of nursery stock imports and importing businesses. Sustained corporate knowledge is essential to understand evolving threats and vulnerabilities for nursery stock imports and to deliver daily high-quality inspection services.
- Post-border preparedness, including shared responsibility of all participants in the biosecurity system, is currently a focal area for department. At the same time, there is a diffused focus on critical risk mitigation intervention points that are within the department's remit. The consequences are reduced accountability for *Xylella* spp. prevention and suboptimal returns from total Australian expenditure on *Xylella* spp. activities. As the Australian regulator and main organisation with active experience with *Xylella* spp., including targeted surveillance and diagnostics, the department

should take a stronger lead on preventative (including peri-border) biosecurity, including establishing PEQ Mickleham as a *Xylella* spp. hub or centre of excellence.

Recommendation 14

The department should complete a comprehensive overhaul of the preventative system for *Xylella* spp. host material to achieve the necessary regulatory clarity, clear focus on the best available risk mitigation measures (onshore and offshore), simplicity and consistency of pathway options and accountability of relevant industry parties for effective risk mitigation actions.

16. Glossary

Term	Description
AA	An AA (approved arrangement) is a voluntary arrangement between a participant in the biosecurity system (typically industry or state/territory governments) and the Department of Agriculture, Water and the Environment for which an approval is in force. The department sets the conditions for how biosecurity activities must be performed under an AA. AAs are regulated under Chapter 7 of the <i>Biosecurity Act 2015</i> .
ABARES	Australian Bureau of Agricultural and Resource Economics and Sciences
AIMS	Agriculture Import Management System
ALOP	Australia's ALOP (appropriate level of protection) is defined in the <i>Biosecurity Act 2015</i> as 'a high level of sanitary and phytosanitary protection aimed at reducing biosecurity risks to a very low level, but not to zero'.
Consignment	In this report, 'consignment' refers to a shipment of goods. Depending on context, a consignment can correspond to a line in AIMS. A line is a record type. The line record may be for a few or thousands of plants of one or different species.
Biosecurity and Compliance Board	The Biosecurity and Compliance Board supports the Biosecurity and Compliance executive to address significant and growing pressures faced by the biosecurity system due to cargo volumes, traveller requirements and department staffing levels.
EFSA	The EFSA (European Food Safety Authority) is the agency of the European Union that provides independent scientific advice and communicates existing and emerging risk associated with the food chain.
High-risk country	When referring to the department's <i>Xylella</i> spp. emergency measures in this report, the term 'high-risk countries' covers countries or regions where: <ul style="list-style-type: none"> • <i>Xylella</i> spp. has been officially confirmed to be present • there are unconfirmed historic records of <i>Xylella</i> spp. presence • there have been trading bloc arrangements with other <i>Xylella</i> spp. positive regions and unregulated movement of nursery stock. Current high-risk countries are listed on the department's website (DAWE, 2021c)
Instructional material	Instructional material contains information intended to direct and assist staff to perform their role effectively and efficiently.
IPPC	International Plant Protection Convention

Term	Description
ISPM	The ISPM (International Standard for Phytosanitary Measures), adopted under the IPPC, set out internationally agreed and harmonised plant health standards and phytosanitary measures.
LAMP	LAMP (Loop Mediated Isothermal Amplification) is a low-cost, rapid molecular testing method allowing onsite detection of pathogens.
Low-risk country	When referring to the department's <i>Xylella</i> spp. emergency measures in this report, low-risk countries include countries or regions other than high-risk countries.
LIMS	The LIMS (Laboratory Information Management System) keeps and manages records of all tests done on plant materials, results, lineage and distribution of the material in a manner that ensures traceability.
Line in AIMS	A line is a type of record in AIMS. A line record may be for a few or thousands of plants of one or different species.
NPPO	The NPPO (National Plant Protection Organisation) of a country is the competent and legally responsible body for regulatory plant protection functions. Australia's NPPO is the Department of Agriculture, Water and the Environment.
Nursery stock	The department defines 'nursery stock' as all live plants and plant materials, other than fruit or seed, for the purpose of propagation and planting. The nursery stock group of commodities include budwood, bulbils, bulbs, corms, tubers, cuttings, grafting wood, leaves, plants, rhizomes, roots, seedlings, slips, stems and tissue cultures. Plant tissue cultures are undifferentiated or partially differentiated plant cellular materials maintained on, or in, artificial substrates <i>in vitro</i> or under other laboratory conditions.
PCR	A PCR (polymerase chain reaction) is a molecular genetic technique to analyse and identify infectious agents, among other things.
Peri-border	Peri-border means all around the border – that is, near or in the vicinity of the border.
PEQ	Post-entry quarantine
Plant Health Committee	The Plant Health Committee is the national plant biosecurity policy and decision-making forum.
PRA	PRA (Pest Risk Analysis) is the process of evaluating biological or other scientific and economic evidence to determine whether an organism is a pest, whether it should be regulated, and the strength of any phytosanitary measures to be taken against it (revised IPPC, 1997; ISPM 2, 2007).
SPS Agreement	Provisions of the SPS Agreement (WTO Agreement on the Application of Sanitary and Phytosanitary Measures) identify the rights and obligations of WTO members in the application of sanitary or phytosanitary measures, including their 'appropriate level of protection' (ALOP).
SPHD	The SPHD (Subcommittee on Plant Health Diagnostics) is a subcommittee of Plant Health Committee. It sustains and improves the quality and reliability of plant pest diagnostics in Australia.
WTO	The WTO (World Trade Organization) recognises the IPPC as the relevant standard-setting body for phytosanitary measures (ISPMs).

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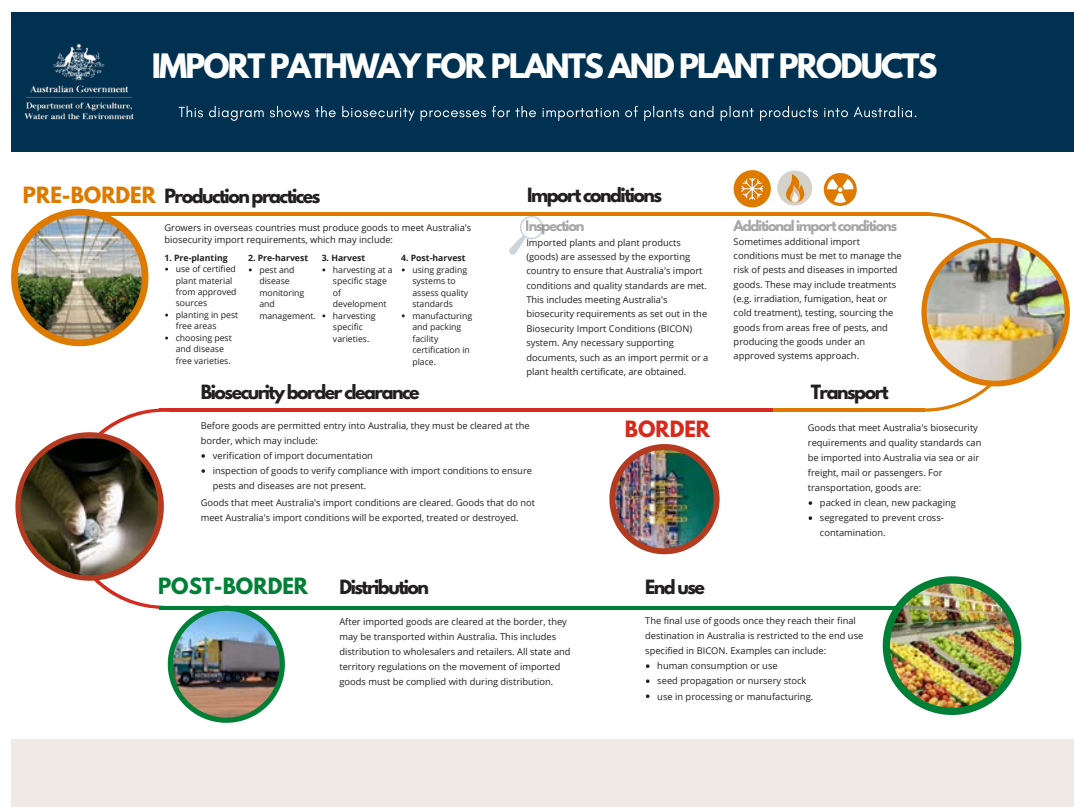
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18. Appendices

Appendix A: Overview of processes and conditions

Figure 8 gives a high-level overview of biosecurity processes and conditions for the importation of plants and plant products into Australia.

Figure 8 Overview of biosecurity processes and conditions



Source: DAWE, 2021.

Appendix B: Overview of changes in import conditions specific to *Xylella* spp.

Table 9 Overview of import conditions for the nursery stock group of commodities to manage the risk associated with *Xylella* spp. implemented in 2009 and 2015–2016

Risk attributes	2009: revised import conditions (DAFF, 2009; and ICON)	2015–2016: emergency measures (DAWE, 2021c; and BICON)	Inspector-General observations
<i>Xylella fastidiosa</i> strains	<i>Xylella fastidiosa</i> and subspecies known at the time.	All known subspecies of <i>Xylella fastidiosa</i> and <i>Xylella taiwanensis</i> .	
Host plants regulated for <i>Xylella</i> spp.	188 host species, including 36 ornamental hosts.	2015: 89 plant families. 2021: 106 plant families.	
Countries where <i>Xylella</i> spp. is known to be present	Status on 24 June 2009: North America (Canada, Mexico, US), Central America (Costa Rica) and South America (Argentina, Brazil, Paraguay, Venezuela), Asia (Taiwan, Turkey).	Over 20,000 confirmed and potential plant host species are currently regulated. This includes traded and non-traded species. Status on 15 November 2015: Countries and regions considered high-risk are all countries/regions in the Americas, including the Caribbean, all countries in Europe, India, Iran, Lebanon, Taiwan, and Turkey. High-risk country list expanded in July 2019 to include Israel.	The number of confirmed hosts, as well as vectors, of <i>Xylella</i> spp. and diversity in the genus <i>Xylella</i> has continued to increase as the pathogen has expanded its geographic range. Further changes in these risk attributes are to be anticipated (see chapter 5).

Risk attributes	2009: revised import conditions (DAFF, 2009; and ICON)	2015–2016: emergency measures (DAWE, 2021c; and BICON)	Inspector-General observations
<p>Countries where <i>Xylella</i> spp. is known to be present (high-risk countries/regions)</p>	<p>Nursery stock, other than tissue cultures, from countries where <i>Xylella</i> spp. is known to be present</p> <p>Plant material must be imported as budwood or cuttings only.</p> <ul style="list-style-type: none"> Whole rooted plants are not permitted entry. <p>Bulbs were not regulated as a pathway for <i>Xylella</i> spp. at this time/prior to 2015.</p> <p>Mandatory post-entry quarantine (PEQ) in a government PEQ facility.</p> <p>All plant material must be treated in accordance with one of the following options: plants are immersed in hot water at 50°C for 20 minutes (for <i>Vitis</i>) or 2 hours (for clonal grasses), or</p> <p>all plants must be tested for the presence of <i>X. fastidiosa</i> using PCR.</p>	<p>Conditions apply to cuttings, budwood, rooted plants, and some corms and bulbs.</p> <p>Option for production under an offshore approved arrangement (appendix 4 of emergency measures) in accordance with requirements to ensure freedom from infection, including phytosanitary certificate confirming molecular test for <i>Xylella</i> spp., instead of government PEQ at Mickleham:</p> <p>Molecular testing and phytosanitary certificate with the following additional declaration or equivalent words:</p> <p>‘Plant material in this consignment was produced under an arrangement approved by the exporting country’s NPPQ in accordance with Australian requirements. Plant material in this consignment was tested by PCR and found free of <i>Xylella fastidiosa</i> as indicated on laboratory test report number {insert number/code here}.’</p> <p>In addition, all other current import conditions for the plant species will apply.</p>	<p>The Inspector-General notes that the biggest change in regulation has been the introduction of the requirement for a phytosanitary certificate confirming PCR testing issued by the exporting country’s National Plant Protection Organisation (NPPO). The Inspector-General recommends that the department strengthen the biosecurity control achieved through mandatory phytosanitary certification by undertaking random onshore sampling and testing for <i>Xylella</i> spp. as part of routine onshore verification and assurance.</p> <p>As per ‘other current import conditions’ to manage a wide range of pests and diseases, not just <i>Xylella</i> spp., PEQ at the department, or a state/territory, PEQ facility is <i>mandatory</i> for some plant species described as high-risk nursery stock (chapter 8.4).</p> <p>The Inspector-General is concerned that there are significant exemptions from the requirement under the emergency measures of a phytosanitary certificate and offshore PCR testing (chapters 8.2 and 9.1). These should be reviewed as part of completing the pest risk analysis (PRA) for <i>Xylella</i> spp. and as part of developing an overarching policy framework for the regulation of nursery stock.</p>

2009: revised import conditions (DAFF, 2009; and ICON)	2015–2016: emergency measures (DAWE, 2021c; and BICON)	Inspector-General observations
Countries where <i>Xylella</i> spp. is known to be present (high-risk countries/regions) cont		
Options for consignments without an acceptable phytosanitary certificate: Plants will be grown for a minimum of 12 months in government PEQ before testing by PCR. All plants will be tested. A positive detection of <i>Xylella fastidiosa</i> will result in destruction of the consignment. In addition, any other current conditions for the plant species will apply.	OR Plants will be hot water treated at 50°C for 45 minutes. Following treatment, all other conditions for the plant species will apply.	The department advised the Inspector-General that there are currently no overseas approved arrangements under the emergency measures in operation and there has not been an application since the commencement of the emergency measures in 2015. The Inspector-General suggests that the department reconsider this option for an approved arrangement when completing the PRA for <i>Xylella</i> spp. Considerations should also include resourcing for additional audit requirements, as the department has had difficulties keeping audit schedules of existing arrangements.
OR Plants will be hot water treated at 50°C for 45 minutes. Following treatment, all other conditions for the plant species will apply.	OR Export or destroy.	

Risk attributes	2009: revised import conditions (DAFF, 2009; and ICON)	2015–2016: emergency measures (DAWE, 2021c; and BICON)	Inspector-General observations
<p>Countries where <i>Xylella</i> spp. is known to be present (high-risk countries/regions) cont</p>	<p>Tissue cultures of nursery stock from countries where <i>Xylella</i> spp. is known to be present</p> <p>All consignments must be accompanied by an official government phytosanitary certificate endorsed to indicate that the tissue cultures were derived from a mother plant(s) or mother/nuclear tissue culture(s) that have been tested for <i>X. fastidiosa</i> using Enzyme-linked immuno-sorbent assay (ELISA) or PCR testing and found free from <i>X. fastidiosa</i>.</p> <p>In addition, any other current import conditions for the plant species apply.</p> <p>Consignments not accompanied by the above certification will be (i) exported, (ii) destroyed or (iii) directed to a government PEQ facility where the material will be deflasked and all plants tested for the presence of <i>X. fastidiosa</i> using PCR.</p>	<p>All consignments must be accompanied by an official phytosanitary certificate issued by the exporting country's NPPO with the following declaration or equivalent words:</p> <p>'All tissue cultures in this consignment were derived from mother tissue cultures that were tested by PCR and found free of all <i>Xylella</i> species as indicated on laboratory test report number {insert number/code here}'.</p> <p>In addition, any other current import conditions for the plant species will apply.</p> <p>For consignments without acceptable phytosanitary certificate:</p> <p>Tissue cultures must be deflasked and grown for a minimum of 12 months in government PEQ before testing by PCR. All plants will be tested. A positive detection of <i>Xylella</i> spp. will result in disposal of the consignment. All other import conditions apply.</p> <p>OR</p> <p>Export or destroy.</p> <ul style="list-style-type: none"> The department will reserve the right to undertake testing to verify that a consignment is free of <i>Xylella</i> spp. 	<ul style="list-style-type: none"> Tissue cultures with an acceptable phytosanitary certificate, and which comply with all other conditions for the plant species, can be released on documentation following a verification inspection, except if import conditions mandate quarantine growth and screening. Release on documentation and inspection can apply to ornamental hosts of <i>Xylella</i> spp. – for example, those produced at offshore facilities approved by the department to export tissue cultures free of media to Australia (DAWE, 2021c; DAWE, 2020b). Ornamental or alternative hosts of <i>Xylella</i> spp. are not focal crops – they are not on the department's list of 'high-risk' plant species – but can equally cause economically costly introductions of <i>Xylella</i> spp. Since the introduction of the emergency measures, the department has not used its reserved right to take random samples and test that tissue culture consignments from high-risk countries are free of <i>Xylella</i> spp. The Inspector-General recommends that the department strengthens the biosecurity control achieved through mandatory phytosanitary certification by undertaking random sampling and testing for <i>Xylella</i> spp. as part of routine onshore verification and assurance.

Risk attributes	2009: revised import conditions (DAFF, 2009; and ICON)	2015–2016: emergency measures (DAWE, 2021c; and BICON)	Inspector-General observations
All other countries (low-risk countries/regions)	N/A		
Nursery stock and tissue cultures from all other countries	All consignments must be accompanied by an official government phytosanitary certificate from the country of origin, and be endorsed with the following additional declaration: ‘Plants were grown in {insert country of origin} which is free from <i>Xylella fastidiosa</i> .’		The introduction of separate conditions for tissue cultures and plants for planting (non-tissue cultures) in 2015–16 opens opportunity for the department to specifically assess their <i>Xylella</i> spp. risks in its PRA for bacterial pathogens in the genus <i>Xylella</i> . The EFSA Panel on Plant Health (2015) recommended to regulate tissue cultures in the same way as plants for planting, because of the ‘absence of scientific data on in vitro plants as a pathway for <i>X. fastidiosa</i> spread [...] The bacterium grows in the xylem and is difficult to cultivate in artificial media; thus, it could easily pass undetected through the in vitro production processes’. Further analysis, possibly research on the topic, is warranted to inform regulation.

2009: revised import conditions (DAFF, 2009; and ICON)	2015–2016: emergency measures (DAWE, 2021c; and BICON)	Inspector-General observations
<p>Risk attributes</p> <p>All other countries (low-risk countries/regions) cont.</p> <p>Nursery stock, other than tissue cultures, from all other countries</p> <p>See above.</p>	<p>Conditions apply to cuttings, budwood, rooted plants, and some corms and bulbs.</p> <p>Option for phytosanitary certificate instead of government PEQ (no offshore testing for <i>Xylella</i> spp. is required):</p> <p>A phytosanitary certificate with the following additional declaration:</p> <p>‘Plant material in this consignment and its parent stock were grown only in {insert country} which is free from <i>Xylella fastidiosa</i>.’</p> <ul style="list-style-type: none"> In addition, any other current import conditions for the plant species will apply. <p>Options for consignments without an acceptable phytosanitary certificate:</p> <p>Plants will be grown for a minimum of 12 months in PEQ (government or private) before testing by PCR. All plants will be tested. A positive detection of <i>Xylella fastidiosa</i> will result in destruction of the consignment. In addition, any other current import conditions for the plant species will apply.</p> <p>OR</p> <p>Plants will be hot water treated at 50°C for 45 minutes. Following treatment, any other conditions for the plant species will apply.</p> <p>OR</p> <p>Export or destroy.</p>	<p>The department advised that any nursery stock belonging to the ‘high-risk’ category of focal plant species (chapter 8) undergo government PEQ irrespective of the country of origin, as these plant species are regulated for a range of pests and diseases, not just for <i>Xylella</i> spp.</p> <p>Consignments with an acceptable phytosanitary certificate and which comply with any other import conditions for the plant species are released on documentation and inspection. This could potentially introduce <i>Xylella</i> spp. in asymptomatic plant materials.</p> <p>The Inspector-General recommends that the department strengthen the biosecurity control achieved through mandatory phytosanitary certification by undertaking random sampling and testing for <i>Xylella</i> spp. as part of routine onshore verification and assurance.</p>

2009: revised import conditions (DAFF, 2009; and ICON)	2015–2016: emergency measures (DAWE, 2021c; and BICON)	Inspector-General observations
All other countries (low-risk countries/regions) cont.	<p>Option for phytosanitary certificate instead of government PEQ:</p> <p>All consignments must be accompanied by an official government phytosanitary certificate with the following declaration or equivalent words:</p> <p>'All tissue cultures in this consignment were derived from plants and tissue cultures that grown only in {insert country} which is free from all <i>Xylella</i> species.'</p> <ul style="list-style-type: none"> In addition, any other current import conditions for the plant species will apply. <p>Options for consignments without an acceptable phytosanitary certificate:</p> <p>For consignments without acceptable phytosanitary certificate:</p> <p>Tissue cultures must be deflasked and grown for a minimum of 12 months in PEQ (government or private) before testing by PCR. All plants will be tested. A positive detection of <i>Xylella</i> will result in disposal of the consignment. All other import conditions apply.</p> <p>OR</p> <p>Export or destroy.</p>	<p>These conditions apply to many ornamental hosts of <i>Xylella</i> spp. produced at offshore facilities approved by the department to export tissue cultures free of media to Australia (DAWE, 2020b).</p> <p>Consignments with an acceptable phytosanitary certificate and which comply with any other import conditions for the plant species are released on documentation and inspection. This could potentially introduce <i>Xylella</i> spp. in asymptomatic plant materials.</p> <ul style="list-style-type: none"> Thus, the Inspector-General recommends that the department strengthen the biosecurity control achieved through mandatory phytosanitary certification by undertaking random sampling and testing for <i>Xylella</i> spp. as part of routine onshore verification and assurance.

Appendix C: BICON cases

Table 10 BICON cases impacted by the *Xylella* spp. emergency measures (2021)

Ananas comosus for use as nursery stock
Aquatic plants that are hosts of <i>Xylella fastidiosa</i> for use as nursery stock
Berberis, Mahonia and Mahoberberis for use as nursery stock
<i>Brassica oleracea</i> for use as nursery stock
Bromeliads for use as nursery stock
<i>Camellia</i> spp. for use as nursery stock
Candidatus <i>Liberibacter solanacearum</i> and <i>Xylella fastidiosa</i> hosts for use as nursery stock
Candidatus <i>Liberibacter solanacearum</i> hosts for use as nursery stock
<i>Cannabis</i> spp. for use as as nursery stock
<i>Castanea</i> spp. for use as nursery stock
<i>Chrysanthemum x morifolium</i> for use as nursery stock
Chrysoporthe hosts for use as nursery stock
Clonal grass for use as nursery stock
<i>Coffea</i> spp. for use as nursery stock
<i>Corylus</i> spp. for use as nursery stock
<i>Cyphomandra</i> spp. for use as nursery stock
<i>Dianthus caryophyllus</i> for use as nursery stock
<i>Dracaena sanderiana</i> for use as nursery stock
<i>Ficus carica</i> for use as nursery stock
Forestry or amenity species that are hosts of <i>Xylella fastidiosa</i>
Forestry or amenity species that are hosts of <i>Xylella fastidiosa</i> and sudden oak death
Forestry or amenity species that are hosts of <i>Xylella fastidiosa</i> , sudden oak death and <i>Ceratocystis</i>
<i>Fragaria</i> spp. for use as nursery stock
Guava rust hosts for use as nursery stock
Guava rust, <i>Xylella fastidiosa</i> and <i>Ceratocystis</i> spp. hosts for use as nursery stock
<i>Hibiscus</i> spp. for use as nursery stock
<i>Hoya kerrii</i> rooted leaves for display purposes
<i>Humulus</i> spp. for use as nursery stock
<i>Hypericum x inodorum</i> for use as nursery stock
<i>Ipomoea batatas</i> for use as nursery stock
<i>Juglans</i> spp. for use as nursery stock
<i>Lavandula</i> spp. for use as nursery stock
<i>Mangifera</i> spp. for use as nursery stock
<i>Manihot</i> spp. for use as nursery stock
<i>Mentha</i> spp. for use as nursery stock
Methyl bromide sensitive nursery stock that are hosts of <i>Xylella fastidiosa</i>
<i>Morus</i> spp. for use as nursery stock
<i>Olea</i> spp. (olives) for use as nursery stock
Ornamental hosts of fireblight for use as nursery stock

Table 10 BICON cases impacted by the *Xylella* spp. emergency measures (2021)

Ornamental virus hosts and <i>Xylella fastidiosa</i> hosts for use as nursery stock
Ornamental virus, sudden oak death and <i>Xylella fastidiosa</i> hosts for use as nursery stock
<i>Passiflora</i> spp. for use as nursery stock
<i>Persea</i> spp. for use as nursery stock
<i>Phoenix dactylifera</i> for use as nursery stock
<i>Pinus</i> spp. and <i>Pseudotsuga</i> spp. for use as nursery stock
<i>Pistacia</i> spp. for use as nursery stock
<i>Pome</i> species for use as nursery stock
<i>Prunus</i> spp. for use as nursery stock
<i>Punica</i> spp. for use as nursery stock
<i>Rhapis</i> spp. for use as nursery stock
<i>Rosa</i> spp. for use as nursery stock
<i>Rubus</i> spp. for use as nursery stock
<i>Rutaceae</i> for use as nursery stock
<i>Saccharum</i> spp. for use as nursery stock
<i>Saintpaulia</i> spp. for use as nursery stock
<i>Solanum tuberosum</i> for use as nursery stock
Tropical and temperate species that are hosts of <i>Xylella</i> and <i>Ceratocystis</i> for use as nursery stock
Tropical and temperate species that are hosts of <i>Xylella fastidiosa</i> for use as nursery stock
<i>Ulmus</i> spp., <i>Planera</i> spp. and <i>Zelkova</i> spp. for use as nursery stock
<i>Vaccinium</i> spp. for use as nursery stock
<i>Vitis</i> spp. (grape) for use as nursery stock
<i>Xylella fastidiosa</i> and <i>Ceratocystis</i> spp. hosts for use as nursery stock
<i>Xylella fastidiosa</i> and sudden oak death hosts for use as nursery stock
<i>Xylella fastidiosa</i> hosts for use as nursery stock
<i>Xylella fastidiosa</i> , sudden oak death and <i>Ceratocystis</i> spp. hosts for use as nursery stock
<i>Ziziphus jujuba</i> Mill. (Chinese jujube) for use as nursery stock

Appendix D: Risk definitions and groups

Table 11 Comparison of risk descriptions and groups for nursery stock compiled from the department's documents

Name and purpose of document	High-risk	Medium-risk	Low-risk/other risk
Pathway verification framework (DAWE, December 2021i)			
<p>A framework was developed under subproject 4, 'Pathway assurance, verification' of the project Strengthening Plant Imports Active Risk Management Capability, funded through the Enhancing Australia's Biosecurity System budget initiative.</p> <p>The purpose of the framework is to guide risk-based verification activities for managing the biosecurity risks associated with plant import pathways.</p> <p>It is intended to provide guidance on how to rank plant import pathways into verification categories: high, medium or low. Import pathway maps complement the framework.</p>	<p>Import pathways presenting a high to extreme biosecurity risk if not effectively managed are assigned to the high verification category.</p> <p>The document states: 'The risk associated with such pathways may be difficult to detect and identify, or the effectiveness of existing control measures is hard to determine.</p> <p>If the phytosanitary measures for a pathway are complex in nature and difficult to administer, or they are performed by multiple entities with varying capabilities, the overall confidence of the performance of this pathway may be low. Such pathways should be assigned to the "high" verification category. Pathways with high risk, poor history of compliance and large import volumes should be the priorities in this category.'</p>	<p>Import pathways presenting a medium biosecurity risk are assigned to the medium verification category.</p> <p>The document states: 'Pests and diseases associated with medium risk pathways may be readily detected, identified and controlled using existing critical control points along the import pathway. These pathways should have phytosanitary measures well established and administered, providing a relatively high level of confidence in the effectiveness of control measures.</p> <p>A decline in compliance on the pathway may trigger the pathway to be moved to the "high" verification category if the compliance does not improve for a certain period. A highly compliant pathway may be re-classified into the "low" verification category.'</p>	<p>Import pathways presenting a low biosecurity risk are assigned to the low verification category.</p> <p>The document states: 'Pests and diseases associated with low-risk pathways can be readily detected, identified and controlled using existing control measures. These pathways often have simple and/or highly effective control measures, coupled with high level of compliance. A pathway with low volume of goods imported every year should fall into this category unless the risk is high.</p> <p>Pathways that do not fall into the "high" or "medium" category should be assigned to the "low" verification category. Great effort and resources are not necessary for pathways in this verification category. However, zero verification since the setup of import conditions is not appropriate either. Verification of these pathways should be scheduled and implemented where resources allow.'</p>

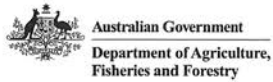
Name and purpose of document	High-risk	Medium-risk	Low-risk/other risk
Notification of amended emergency quarantine measures for <i>Xylella</i> (DAWE, 2021c)			
Advice issued on the department's website to notify stakeholders who import nursery stock and tissue cultures of the amended emergency quarantine measures to reduce the likelihood of entry of <i>Xylella</i> spp.	High-risk countries/ regions are those where <i>Xylella</i> spp. is known to be present: <ul style="list-style-type: none"> all countries in the Americas including the Caribbean all countries in Europe India Iran Israel Lebanon Taiwan Turkey. 	Not referenced.	Low-risk countries/ regions are those where <i>Xylella</i> spp. is not known to be present. The department also refers to these as 'all other countries and regions'.
Nursery stock manual (DAWE, 2021a; first published in 2015)			
A reference document to support the inspection and management of nursery stock imported into Australian territory. It is designed to provide biosecurity officers with the knowledge to undertake their tasks and responsibilities and to inform them of the broad reasons for current policy.	Plant species that can introduce plant pests and diseases of significant threat to Australia's agricultural and horticultural industries or the environment. <p>Examples include:</p> <ul style="list-style-type: none"> commercial food, fibre and energy crops (e.g. species of <i>Citrus</i>, <i>Malus</i>, <i>Musa</i>, <i>Prunus</i> and <i>Vitis</i>) tree species of recreational and forestry importance (e.g. species of <i>Eucalyptus</i>, <i>Ulmus</i> and <i>Quercus</i>) ornamental alternative hosts of fireblight, citrus canker, tristeza and huanglongbing (citrus greening), guava rust, moko disease, and black stem rust of wheat vegetatively reproduced grasses 	Plant species that generally pose a lower biosecurity risk than those classified as high-risk. Medium-risk species can undergo PEQ in a third-party approved arrangement facility, class 6.1. <p>Plant species in the category generally only require visual screening for disease symptoms. The minimum PEQ period is 3 months for most medium-risk species.</p> <p>Some examples include bulbs (<i>Lilium</i> and <i>Tulipa</i> species), orchids, bromeliads and ornamentals, not included as high-risk (e.g. <i>Yucca</i> and <i>Anthurium</i> species).</p>	Low-risk nursery stock is a subset of medium-risk plants. Low-risk plant species are not known to host significant pathogens of biosecurity concern and are in a form that pose a lower biosecurity risk. <p>While these plants must still meet all import/ permit conditions, low-risk nursery stock generally pose a lower disease risk and requires no PEQ growth on arrival in Australia.</p> <p>Examples of plants in this category include orchids imported as tissue cultured plantlets.</p>

Name and purpose of document	High-risk	Medium-risk	Low-risk/other risk
	<p>Examples include (cont):</p> <ul style="list-style-type: none"> • numerous hosts of exotic disease agents (e.g. <i>Phytophthora ramorum</i> (sudden oak death), <i>Xylella fastidiosa</i> and huanglongbing). <p>High-risk nursery stock is generally only permitted to undergo the post-entry quarantine (PEQ) period in the department's PEQ facility or state/territory operated PEQ facility, where the expertise is available to conduct the required disease screening. It generally requires active disease testing and screening in addition to visual inspections for pests and diseases. There are restrictions on the type of propagatable material that is permitted.</p>		
Inspecting plant material on arrival at the Mickleham post-entry quarantine facility, Biosecurity Act 2015 (DAWR, 2016b; first published in 2015)			
<p>A work instruction (<i>all staff must comply with it</i>) outlining procedures to inspect imported plants and seeds on arrival the department's PEQ facility at Mickleham.</p>	<p>Plant species that have been assessed as posing a high biosecurity risk by their potential to introduce plant pests and diseases that pose a significant threat to Australia's agricultural and horticultural industries or the environment.</p>	<p>Plant species that generally pose a lower biosecurity risk than those plants listed as 'high-risk'. These species can undergo PEQ in privately operated approved arrangement sites and generally only require visual screening for disease symptoms during the PEQ period.</p>	<p>Not referenced.</p>

Name and purpose of document	High-risk	Medium-risk	Low-risk/other risk
Management of imported plants at the Mickleham post-entry quarantine facility, Biosecurity Act 2015 (DAWR, 2016b; first published in 2015)			
<p>Instructional material (<i>all staff must comply with it</i>) outlining the processes and operational requirements for effectively managing live plants undergoing PEQ at the department's PEQ facility at Mickleham.</p> <p>This includes processes for arrivals into the facility PEQ growth and screening, release of material from PEQ, and facility management.</p>	<p>Plant species assessed as posing a high biosecurity risk by their potential to introduce plant pests and diseases that pose a significant threat to Australia's agricultural and horticultural industries or the environment.</p> <p>These species generally require active testing/ screening during PEQ period at the department's PEQ facility or PEQ facilities operating under an approved arrangement, prior to release from biosecurity.</p> <p>Examples of high-risk nursery stock include Citrus spp., clonal grasses, <i>Prunus</i> spp., <i>Malus</i> spp., <i>Pyrus</i> spp., <i>Fragaria</i> spp., <i>Rubus</i> spp., <i>Vaccinium</i> spp., <i>Solanum tuberosum</i>, <i>Vitis</i> spp.</p>	<p>Plant species that generally pose a lower biosecurity risk than those listed at 'high-risk'.</p> <p>These species can undergo a PEQ period in privately operated approved arrangement facilities and generally only require visual screening for disease symptoms during a PEQ period.</p> <p>Medium-risk plant genera are primarily ornamental species.</p>	Not referenced.
Inspecting medium-risk nursery stock undergoing post-entry quarantine growth in an approved arrangement site (DAWR 2019e; first published in 2017)			
<p>A work instruction (<i>all staff must comply with it</i>) outlining procedures for undertaking inspections of medium-risk nursery stock undergoing PEQ growth in an approved arrangement (AA) site.</p>	Not referenced.	<p>Plant species generally pose a lower biosecurity risk than those plants listed as high-risk.</p> <p>Note: These species can undergo their PEQ in privately operated PEQ facilities and generally only require visual screening for disease symptoms and one season of growth (i.e. 6 weeks to 3 months) in a PEQ facility.</p>	Not referenced.

Name and purpose of document	High-risk	Medium-risk	Low-risk/other risk
Inspecting tissue cultures of medium risk plants (DAWR, 2017b; first published in 2014)			
A work instruction (<i>all staff must comply with it</i>) describing the procedures for biosecurity officer undertaking inspections of imported tissue cultures of medium-risk plants.	Not referenced.	Plant species that generally pose a lower biosecurity risk than those plants listed as 'high-risk'. These species are permitted to undergo PEQ in privately operated AA sites and generally only require visual screening for disease symptoms during the PEQ period.	A commodity or contaminant is of low biosecurity risk if it poses minimal risk to Australia's environment, plant or health status if it were to establish and spread. Examples are common fungal contaminants of tissue culture media: <i>Penicillium</i> , <i>Aspergillus</i> , <i>Cladosporium</i> , <i>Rhizopus</i> , as opposed to bacteria, which are considered higher risk.

19. Agency response



ANDREW METCALFE AO
SECRETARY

12 July 2022

Mr Rob Delane
Inspector-General of Biosecurity
c/o Department of Agriculture, Fisheries and Forestry
GPO Box 858
CANBERRA ACT 2601

Dear Mr Delane

Rob

Thank you for your correspondence of 14 June 2022 providing your review report, *Effectiveness of preventative biosecurity arrangements to mitigate the risk of entry into Australia of the serious plant pest Xylella fastidiosa* and inviting management comments on the review findings. The department's management response to the recommendations in your report is at Attachment A.

I appreciate your insights into the department's preventative border measures to mitigate the risk of *Xylella fastidiosa* entering Australia. The department recognises and takes seriously the biosecurity risk the bacterial pathogen *Xylella* poses to Australia's agricultural industries and environment. Accordingly, the department has undertaken significant preventative and preparedness activities to manage these risks, and has updated import regulations over time as new information has become available.

As you are aware, in 2015 the department introduced emergency measures for *Xylella* based on information demonstrating increasing global and host distribution. We have since expanded these emergency measures several times to regulate 17 additional plant families and new geographic locations based on updated scientific information. Our world class Post Entry Quarantine centre in Mickleham is well established for the management of biosecurity risks, including *Xylella*, in nursery stock. In May 2022, the department immediately implemented regulatory control for pecan seed for sowing after the first credible evidence of *Xylella* transmission in pecan seed was published in April 2022.

Your review recognises the complexities inherently present in regulating the *Xylella* risk import pathways and provides valuable suggestions for improvements. Your review will assist the department in regulating *Xylella* entry pathways to maintain Australia's Appropriate Level of Protection. I am pleased to advise that the department is already pursuing the implementation of many of the improvements you have highlighted in your review through its Commonwealth Biosecurity 2030 reform agenda.

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The department has also assessed the report for prejudicial information and identified no material that should not be made publicly available.

Best wishes



Andrew Metcalfe AO
Director of Biosecurity

Attachment A

Department of Agriculture, Fisheries and Forestry—Agency response to the IGB review:
Effectiveness of preventative biosecurity arrangements to mitigate the risk of entry into Australia of the serious plant pest Xylella fastidiosa.

Attachment A: Department of Agriculture, Fisheries and Forestry—Agency response to the IGB review: Effectiveness of preventative biosecurity arrangements to mitigate the risk of entry into Australia of the serious plant pest *Xylella fastidiosa*.

Recommendation 1 — agreed

The department should complete the *Xylella* spp. pest risk analysis by the end of 2022 to support streamlined, agile and regulation-based responses under the *Biosecurity Act 2015* and adequately inform biosecurity industry participants and other key stakeholders.

The department is committed to completing the Pest Risk Analysis for Xylella spp. and will work towards issuing a draft Xylella spp. pest risk analysis by the end of 2022 for public consultation. The department notes that the timeframe specified in the recommendation cannot be met due to mandatory public consultation periods. Draft plant pest risk analyses are released for a 60-day period of public consultation. This component of the risk analysis process is an important step in checking that scientific evidence has been considered, regulatory options are appropriate and can be practically implemented.

Recommendation 2 — agreed

The department should develop a policy framework for nursery stock. The framework would clarify the components of a risk management program for nursery stock (offshore and onshore) and the intended outcomes (e.g., resources and other inputs, activities and products and services delivered), as well as the contextual factors affecting its operations and actual outcomes and replace the risk grouping terminology that is currently used.

The department acknowledges the significant complexity associated with regulation and operational risk management of nursery stock imports, which reflects the complexity of regulating numerous biosecurity risks on the nursery stock pathway (including but not limited to pathogens such as Xylella) and changes to risk profiles over time.

The department will explore avenues for a policy framework for nursery stock.

The department recognises that a review of the policy framework will inform opportunities for improved stakeholder communication, guide risk-based allocation of resources across critical control points on import pathways and enhance the consistency of import conditions. This will be complemented by broader work identified via Recommendations 3, 5, 7 and 12.

Recommendation 3 — noted

The department should strengthen the biosecurity control achieved through mandatory phytosanitary certification for nursery stock by undertaking random on-arrival sampling and molecular testing for *Xylella* spp., similar to, or consistent with, the compliance-based intervention scheme.

The department will consider this recommendation in the context of Recommendation 2 during the review of the policy framework for nursery stock, and Recommendation 1 in the completion of the Xylella spp. pest risk analysis.

The department agrees that random sampling and testing of imported consignments has the capacity to further our assurance and confidence in the effectiveness of offshore measures (including phytosanitary certification) in preventing the entry of Xylella into Australia, and notes that this will be considered alongside the pest risk management measures recommended under the department's final Xylella pest risk analysis when it is published (see Recommendation 1 and 4).

Recommendation 4 — agreed

The department should re-examine the regulations of tissue cultures of *Xylella* spp. host plants for consistency with the regulation of other host plants. The re-examination should be underpinned by a sound analysis of the *Xylella* spp. risk associated with tissue cultures that will be conducted as part of completing the pest risk analysis.

The department is examining the appropriate policy settings for regulation of tissue culture for Xylella spp. host plants as part of the work being conducted for the pest risk analysis.

Recommendation 5 — agreed

The department should overhaul the regulation of overseas facilities supplying tissue culture free of media. The regulatory regime should focus on the essential factors requiring regulation at the stage of facilities approval. Approvals and reviews should be undertaken in a timely, contemporary manner and complement the regulatory requirements of the import permit process.

The department has commenced work to develop a strategy that will underpin an assurance program for overseas facilities supplying tissue culture free of media.

Recommendation 6 — reference laboratory: noted; LIMS: agreed

The department should establish the Mickleham post-entry quarantine facility – the only Australian laboratory conducting routine regulatory testing for *Xylella* spp. – as the lead national reference laboratory for *Xylella* spp.; this laboratory and other department diagnostic laboratories should urgently be equipped with a modern laboratory information system (LIMS).

It is appropriate that the department maintains its substantial diagnostic capability and capacity at the Mickleham laboratory and shares its expertise to assist with confirmation of any suspected detections of Xylella by state and territory agencies (and vice versa).

As there is also significant expertise outside the Mickleham laboratory, further consideration is needed around the concept of establishing Mickleham as the lead national reference laboratory for Xylella spp.

The department will continue to collaborate with the Plant Health Committee on their strategic approach to diagnostic capability and reference laboratories.

The department is currently expanding deployment of its existing LIMS across all its diagnostic laboratories, including Mickleham.

Recommendation 7 — agreed

The department should consider replacing the process management system (PMS) quality control approach for nursery stock with the standardised regulatory approach to approved arrangements under the *Biosecurity Act 2015* to achieve a more consistent, efficient and equitable regulatory regime for nursery stock.

This will be considered as a component of Recommendation 2.

Recommendation 8 — agreed, noting the extensive program of work already undertaken.

The department should urgently design and implement a nursery stock pathway surveillance and molecular diagnostics program that includes major nursery stock sites closely linked to imports, nearby host plants of *Xylella* spp. and potential insect vectors present in the local environment.

The National Border Surveillance Program undertakes regular surveillance for Xylella at high-risk biosecurity entry point sites in urban environments along import risk pathways associated with nursery stock imports, focusing on exotic and native vectors and symptomatic plants.

The department funds the National Plant Health Surveillance Program, a national partnership arrangement with States and Territories who are responsible for post border surveillance activities to manage the residual risks associated with the nursery stock pathway and risks associated with illegal imports once goods have been released from biosecurity control.

The department will consider whether improvements to pathway surveillance programs can be made to enhance the department's assurance that management measures for Xylella risk pathways are effective.

Recommendation 9 — agreed, noting the extensive program of work underway.

The department should roll out a best-practice approach to assurance and verification across all biosecurity divisions, with the schedule of work and reports being routinely on the agenda of the Biosecurity and Compliance Board.

The department has already commenced work to enhance our assurance and verification framework and will soon publish a departmental Regulatory Assurance Strategy, signalling its intent to adopt a best practice approach to regulatory assurance. The strategy outlines the department's assurance posture and approach, supporting the department to deliver better regulation through continuous evaluation and improvement of our regulatory activities.

The strategy will be supported by a Regulatory Assurance Framework for the Biosecurity and Compliance Group, articulating what assurance will mean for the biosecurity system, the specific assurance activities aligned to the Group's identified and agreed priority risks, and ways to achieve assurance.

The department's Biosecurity and Compliance Board, supported by the Risk, Compliance and Assurance Sub-committee, will have oversight of progress. This includes endorsing the strategy and framework for the Biosecurity and Compliance Group and overseeing implementation across the Group's regulatory functions.

Recommendation 10 — agreed

The department should maintain adequate focus on improving the quality and timeliness of evidence-based decision-making (day-to-day, tactical, strategical) through routine access and analysis of available data and information. This needs to be supported by markedly improved information and data management systems.

The department is currently finalising a biosecurity risk management framework and is developing a biosecurity assurance strategy to inform decision making. Ongoing improvements to data management will further support this.

Recommendation 11 — agreed, noting current standard practices and work underway.

The department should ensure an ongoing focus on its frontline workforce management arrangements, optimising the balance of staff flexibility and ongoing availability of subject matter expertise to enable optimal biosecurity risk mitigation.

The department has invested considerably in its frontline workforce to enable optimal risk mitigation at our border. Amongst other things, a new Biosecurity Training Centre has been

established in partnership with Charles Sturt University and commenced operating on 4 July 2022. This will be supported by our Workforce Strategy to equip our people through training.

Deployment of a range of automation initiatives and tools such as the Scheduling and Workload Management System aims to simplify processes and create efficiencies to optimise biosecurity risk mitigation at our border.

Recommendation 12 — agreed

The department should review information on its website relevant for importers of nursery stock and other stakeholders in *Xylella* spp. risk mitigation to ensure ease of access, cohesiveness and accuracy. Information should be consolidated to clarify approval and audit processes and improve overall communication.

The department recognises that clear and consistent communication is critical to ensure compliance with import requirements and to partner with stakeholders to manage risks. The department will review the relevant information on its website, and undertake necessary updates to improve ease of access, cohesiveness and accuracy.

Recommendation 13 — agreed, noting this will be undertaken as a whole of program response.

As part of at-border and post-biosecurity preparedness for a potential response to a detection of *Xylella* spp., the department should complete a collaborative desktop exercise simulating an incident response covering the first 7-10 days after initial post-biosecurity detection.

The department has established biosecurity response and preparedness functions. There are also established national response arrangements for post border incursions.

Exercising is an important part of the continuous improvement process for all affected parties.

The department is currently delivering a multi-year exercise to explore the role of the Commonwealth during a nationally significant biosecurity emergency and enhance Australia's capability to respond to current and emerging biosecurity threats. This will include engagement through the National Biosecurity Committee (and its Biosecurity and Agricultural Emergency Network).

*The exercise program is taking an 'all hazards' approach with a range of plant and animal pest and disease scenarios and the outcomes will be applicable to any biosecurity response including *Xylella*.*

Recommendation 14 — agreed

The department should complete a comprehensive overhaul of the preventative system for *Xylella* spp. host material to achieve the necessary regulatory clarity, clear focus on the best-available risk mitigation measures (onshore and offshore), simplicity and consistency of pathway options and accountability of relevant industry parties for effective risk mitigation actions.

*The department is already working comprehensively across its preventative systems to address the biosecurity risk of *Xylella* spp., and as documented in responses to the above recommendations, the department will continue to improve these systems.*

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