SCIENTIFIC OPINION

efsa JOURNAL

ADOPTED: 1 December 2022

doi: 10.2903/j.efsa.2023.7736

Pest categorisation of *Xylella taiwanensis*

EFSA Panel on Plant Health (PLH),
Claude Bragard, Paula Baptista, Elisavet Chatzivassiliou, Francesco Di Serio, Paolo Gonthier, Josep Anton Jaques Miret, Annemarie Fejer Justesen, Alan MacLeod, Christer Sven Magnusson, Panagiotis Milonas, Juan A Navas-Cortes, Stephen Parnell, Roel Potting, Emilio Stefani, Hans-Hermann Thulke, Wopke Van der Werf, Antonio Vicent Civera, Jonathan Yuen, Lucia Zappalà, Jianchi Chen, Quirico Migheli, Irene Vloutoglou, Franz Streissl and Philippe Lucien Reignault

Abstract

The EFSA Plant Health Panel performed a pest categorisation of *Xylella taiwanensis*, a Gram-negative bacterium belonging to the *Xanthomonadaceae*. The pathogen is a well-defined taxonomic entity, and it is the causal agent of the pear leaf scorch. *X. taiwanensis* is present in subtropical and temperate areas of the island of Taiwan, where it affects low chilling pear cultivars of the species *Pyrus pyrifolia* (Asian pear). No other plant species are reported to be affected by the pathogen. The pathogen is not known to be present in the EU territory and it is not included in the Commission Implementing Regulation (EU) 2019/2072. The main pathway for the entry of the pathogen into the EU territory is host plants for planting (except seeds); another possible pathway might be represented by putative insect vectors, though their identity remains unknown. The cultivated area of *P. pyrifolia* in the EU territory is very limited. Conversely, the genetically related *P. communis* is widely cultivated in most EU Member States and there is no information so far on the susceptibility of its several cultivars. Should the pest establish in the EU, economic impact is expected, provided that suitable insect vectors are present and *P. communis* is as susceptible to infection as *P. pyrifolia*. Phytosanitary measures are available to prevent the introduction and spread of the pathogen into the EU, since plants for planting from Taiwan is a closed pathway; nonetheless, putative vectors, if confirmed and identified, may represent an additional risk of the pathogen's introduction and spread. The lack of knowledge on whether *X. taiwanensis* can infect *P. communis*, the identity and presence of suitable vectors in the EU lead to key uncertainties on entry, establishment, spread and impact. *X. taiwanensis* satisfies the criteria that are within the remit of EFSA to assess for this species to be regarded as a potential Union quarantine pest.

Keywords: insect vectors, pear leaf scorch, pest risk, plant health, plant pest, Asian pear, *Pyrus pyrifolia*

Requestor: European Commission

Question number: EFSA-Q-2021-00332

Correspondence: plants@efsa.europa.eu

Panel members: Claude Bragard, Paula Baptista, Elisavet Chatzivassiliou, Francesco Di Serio, Paolo Gonthier, Josep Anton Jaques Miret, Annemarie Fejer Justesen, Alan MacLeod, Christer Sven Magnusson, Panagiotis Milonas, Juan A Navas-Cortes, Stephen Parnell, Roel Potting, Philippe L Reignault, Emilio Stefani, Hans-Hermann Thulke, Wopke Van der Werf, Antonio Vicent Civera, Jonathan Yuen and Lucia Zappalà.

Declarations of interest: If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

Acknowledgements: EFSA wishes to acknowledge the contribution of Oresteia Sfyra to this opinion.

Suggested citation: EFSA PLH Panel (EFSA Panel on Plant Health), Bragard C, Baptista P, Chatzivassiliou E, Di Serio F, Gonthier P, Jaques Miret JA, Justesen AF, MacLeod A, Magnusson CS, Milonas P, Navas-Cortes JA, Parnell S, Potting R, Stefani E, Thulke H-H, Van der Werf W, Civera AV, Yuen J, Zappalà L, Chen J, Migheli Q, Vloutoglou I, Streissl F and Reignault PL, 2023. Scientific Opinion on the pest categorisation of *Xylella taiwanensis*. EFSA Journal 2023;21(1):7736, 22 pp. https://doi.org/10.2903/j.efsa.2023.7736

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.

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1. Introduction

1.1. Background and terms of reference as provided by the requestor

1.1.1. Background

The new Plant Health Regulation (EU) 2016/2031, on the protective measures against pests of plants, is applying from 14 December 2019. Conditions are laid down in this legislation in order for pests to qualify for listing as Union quarantine pests, protected zone quarantine pests or Union regulated non-quarantine pests. The lists of the EU regulated pests together with the associated import or internal movement requirements of commodities are included in Commission Implementing Regulation (EU) 2019/2072. Additionally, as stipulated in the Commission Implementing Regulation 2018/2019, certain commodities are provisionally prohibited to enter in the EU (high risk plants, HRP). EFSA is performing the risk assessment of the dossiers submitted by exporting to the EU countries of the HRP commodities, as stipulated in Commission Implementing Regulation 2018/2018. Furthermore, EFSA has evaluated a number of requests from exporting to the EU countries for derogations from specific EU import requirements.

In line with the principles of the new plant health law, the European Commission with the Member States are discussing monthly the reports of the interceptions and the outbreaks of pests notified by the Member States. Notifications of an imminent danger from pests that may fulfil the conditions for inclusion in the list of the Union quarantine pest are included. Furthermore, EFSA has been performing horizon scanning of media and literature.

As a follow-up of the above-mentioned activities (reporting of interceptions and outbreaks, HRP, derogation requests and horizon scanning), a number of pests of concern have been identified. EFSA is requested to provide scientific opinions for these pests, in view of their potential inclusion by the risk manager in the lists of Commission Implementing Regulation (EU) 2019/2072 and the inclusion of specific import requirements for relevant host commodities, when deemed necessary by the risk manager.

1.1.2. Terms of reference

EFSA is requested, pursuant to Article 29(1) of Regulation (EC) No 178/2002, to provide scientific opinions in the field of plant health.

EFSA is requested to deliver 53 pest categorisations for the pests listed in Annex 1A, 1B, 1D and 1 E (for more details see mandate M-2021-00027 on the Open.EFSA portal). Additionally, EFSA is requested to perform pest categorisations for the pests so far not regulated in the EU, identified as pests potentially associated with a commodity in the commodity risk assessments of the HRP dossiers (Annex 1C; for more details see mandate M-2021-00027 on the Open.EFSA portal). Such pest categorisations are needed in the case where there are not available risk assessments for the EU.

When the pests of Annex 1A are qualifying as potential Union quarantine pests, EFSA should proceed to phase 2 risk assessment. The opinions should address entry pathways, spread, establishment, impact and include a risk reduction options analysis.

Additionally, EFSA is requested to develop further the quantitative methodology currently followed for risk assessment, in order to have the possibility to deliver an express risk assessment methodology. Such methodological development should take into account the EFSA Plant Health Panel Guidance on quantitative pest risk assessment and the experience obtained during its implementation for the Union candidate priority pests and for the likelihood of pest freedom at entry for the commodity risk assessment of High Risk Plants.

1.2. Interpretation of the terms of reference

Xylella taiwanensis is one of a number of pests listed in Annex 1A to the terms of reference (ToR) to be subject to pest categorisation to determine whether it fulfils the criteria of a potential Union quarantine pest for the area of the EU excluding Ceuta, Melilla and the outermost regions of Member States referred to in Article 355(1) of the Treaty on the Functioning of the European Union (TFEU), other than Madeira and the Azores, and so inform EU decision-making as to its appropriateness for potential inclusion in the lists of pests of Commission Implementing Regulation (EU) 2019/2072. If a pest fulfils the criteria to be potentially listed as a Union quarantine pest, risk reduction options will be identified.

2. Data and methodologies

2.1. Data

2.1.1. Literature search

A literature search on *Xylella taiwanensis* was conducted at the beginning of the categorisation in the ISI Web of Science bibliographic database, using the scientific name of the pest as search term. Papers relevant for the pest categorisation were reviewed, and further references and information were obtained from experts, as well as from citations within the references and grey literature.

2.1.2. Database search

Pest information, on host(s) and distribution, was retrieved from the EPPO Global Database, the CABI databases and scientific literature databases as referred above in Section 2.1.1.

Data about the import of commodity types that could potentially provide a pathway for the pest to enter the EU and about the area of hosts grown in the EU were obtained from EUROSTAT (Statistical Office of the European Communities).

The Europhyt and TRACES databases were consulted for pest-specific notifications on interceptions and outbreaks. Europhyt is a web-based network run by the Directorate General for Health and Food Safety (DG SANTÉ) of the European Commission as a subproject of PHYSAN (Phyto-Sanitary Controls) specifically concerned with plant health information. TRACES is the European Commission's multilingual online platform for sanitary and phytosanitary certification required for the importation of animals, animal products, food and feed of non-animal origin and plants into the European Union, and the intra-EU trade and EU exports of animals and certain animal products. Up until May 2020, the Europhyt database managed notifications of interceptions of plants or plant products that do not comply with EU legislation, as well as notifications of plant pests detected in the territory of the Member States and the phytosanitary measures taken to eradicate or avoid their spread. The recording of interceptions switched from Europhyt to TRACES in May 2020.

GenBank was searched to determine whether it contained any nucleotide sequences for *Xylella taiwanensis* which could be used as reference material for molecular diagnosis. GenBank® (https://www.ncbi.nlm.nih.gov/genbank/release) is a comprehensive publicly available database that as of August 2019 (release version 227) contained over 6.25 trillion base pairs from over 1.6 billion nucleotide sequences for 450,000 formally described species (Sayers et al., 2020).

2.2. Methodologies

The Panel performed the pest categorisation for *Xylella taiwanensis* following guiding principles and steps presented in the EFSA guidance on quantitative pest risk assessment (EFSA PLH Panel, 2018), the EFSA guidance on the use of the weight of evidence approach in scientific assessments (EFSA Scientific Committee, 2017) and the International Standards for Phytosanitary Measures No. 11 (FAO, 2013).

The criteria to be considered when categorising a pest as a potential Union quarantine pest (QP) is given in Regulation (EU) 2016/2031 Article 3 and Annex I, Section 1 of the Regulation. Table 1 presents the Regulation (EU) 2016/2031 pest categorisation criteria on which the Panel bases its conclusions. In judging whether a criterion is met the Panel uses its best professional judgement (EFSA Scientific Committee, 2017) by integrating a range of evidence from a variety of sources (as presented above in Section 2.1) to reach an informed conclusion as to whether or not a criterion is satisfied.

The Panel's conclusions are formulated respecting its remit and particularly with regard to the principle of separation between risk assessment and risk management (EFSA founding regulation (EU) No 178/2002); therefore, instead of determining whether the pest is likely to have an unacceptable impact, deemed to be a risk management decision, the Panel will present a summary of the observed impacts in the areas where the pest occurs, and make a judgement about potential likely impacts in the EU. Whilst the Panel may quote impacts reported from areas where the pest occurs in monetary terms, the Panel will seek to express potential EU impacts in terms of yield and quality losses and not in monetary terms, in agreement with the EFSA guidance on quantitative pest risk assessment (EFSA PLH Panel, 2018). Article 3 (d) of Regulation (EU) 2016/2031 refers to unacceptable social impact as a criterion for quarantine pest status. Assessing social impact is outside the remit of the Panel.

Table 1: Pest categorisation criteria under evaluation, as derived from Regulation (EU) 2016/2031 on protective measures against pests of plants (the number of the relevant sections of the pest categorisation is shown in brackets in the first column)

Criterion of pest categorisation	Criterion in Regulation (EU) 2016/2031 regarding Union quarantine pest (article 3)
Identity of the pest (Section 3.1)	Is the identity of the pest clearly defined, or has it been shown to produce consistent symptoms and to be transmissible?
Absence/presence of the pest in the EU territory (Section 3.2)	Is the pest present in the EU territory? If present, is the pest in a limited part of the EU or is it scarce, irregular, isolated or present infrequently? If so, the pest is considered to be not widely distributed.
Pest potential for entry, establishment and spread in the EU territory (Section 3.4)	Is the pest able to enter into, become established in, and spread within, the EU territory? If yes, briefly list the pathways for entry and spread.
Potential for consequences in the EU territory (Section 3.5)	Would the pests' introduction have an economic or environmental impact on the EU territory?
Available measures (Section 3.6)	Are there measures available to prevent pest entry, establishment, spread or impacts?
Conclusion of pest categorisation (Section 4)	A statement as to whether (1) all criteria assessed by EFSA above for consideration as a potential quarantine pest were met and (2) if not, which one(s) were not met.

3. Pest categorisation

3.1. Identity and biology of the pest

3.1.1. Identity and taxonomy

Is the identity of the pest clearly defined, or has it been shown to produce consistent symptoms and/or to be transmissible?

Yes, the identity of the pathogen is clearly defined. The pathogen has been shown to produce consistent symptoms on its host plants and it is transmissible.

Xylella taiwanensis (Su et al., 2016) is a Gammaproteobacterium belonging to the order of *Xanthomonadales* and family of *Xanthomonadaceae*. Its first description stems from 1993, when it was identified as a strain of *Xylella fastidiosa* affecting Asian pear (*Pyrus pyrifolia*) in Taiwan, although serologically different from a known *X. fastidiosa* isolate causing the alfalfa dwarf disease used for comparison (Leu and Su, 1993). Eight years later, Mehta and Rosato (2001) inferred the phylogenetic relationship among a large set of *X. fastidiosa* isolates from different hosts. Based on 16S rDNA and 16S–23S intergenic spacer (IGS) sequences and, on values of less than 20% in DNA–DNA hybridisation, the presumptive *X. fastidiosa* strain from Asian pear was deemed possibly as a different species of the same genus. Finally, the randomly amplified polymorphic DNA (RAPD) profiles (Su et al., 2008a,b) and the analyses of sequences of the 16S rRNA gene and 16S–23S internal transcribed spacer (ITS) (Su et al., 2012) supported the separation of the Taiwanese pear isolate into a different genomic group, separated from the known *X. fastidiosa* strains. Therefore, Su et al. (2016) proposed a novel species inside the *Xylella* genus, namely *Xylella taiwanensis*, which is the current official name of the pathogen, mainly based on ANI (average nucleotide identity) of whole genome sequence, whose type strain is: PLS229^T (=BCRC 80915^T = JCM 31187^T).

The EPPO code[1] (Griessinger and Roy, 2015; EPPO, 2019) for this species is XYLETA (EPPO, 2022, online).

[1] An EPPO code, formerly known as a Bayer code, is a unique identifier linked to the name of a plant or plant pest important in agriculture and plant protection. Codes are based on genus and species names. However, if a scientific name is changed, the EPPO code remains the same. This provides a harmonised system to facilitate the management of plant and pest names in computerised databases, as well as data exchange between IT systems (Griessinger and Roy, 2015; EPPO, 2019).

3.1.2. Biology of the pest

The key biological features of *X. taiwanensis* are described in Table 2.

Table 2: Important features of the life-history strategy of *Xylella taiwanensis*. The information sources are given in the footnote below the table

Disease cycle	Infection process and relation to host	Other relevant information
Overwintering phase of the pathogen	Latently present on Asian pear trees (*Pyrus pyrifolia*), infecting the xylem; also present, presumably, in the foregut if its putative overwintering vector(s).	*X. taiwanensis* is described as the causal agent of pear leaf scorch: therefore, during the winter season, symptoms cannot be observed in leafless trees. *X. taiwanensis* is presumably transmitted by insect vectors, similar to all known *X. fastidiosa* subspecies. Horizontal transmission is also possible by budding infected buds on healthy trees.
Primary inoculum	Known source of primary inoculum is the infected plant material of *P. pyrifolia*. Putative sources of primary inoculum may be insect vectors, as for *X. fastidiosa*. Such vectors are suspected, but have not been identified so far.	Though it is well established that *X. fastidiosa* is vectored by a high number of Cicadomorpha sap-feeding insects, there is no knowledge of specific insect-species being vectors of *X. taiwanensis*
Penetration into the host plant(s)	Pathogen penetration into its host plant(s) occurs via insect vectors, when they feed on plant parts (presumably leaves). Horizontal transmission also occur by budding.	There is no knowledge on how the pathogen may penetrate into its host plant(s) through pruning. There is no knowledge of *X. taiwanensis* infection via pollen.
Secondary inocula	Evasion of the pathogen may occur through its vector(s). Xylem-feeding Cicadomorpha may aid pathogen evasion and transfer the inoculum to new plants (horizontal transmission) or other parts of the same plant.	Although *X. taiwanensis* is expected to be transmitted by one or more insect vectors*, since they have not been identified yet, transmission parameters (acquisition, latent period and transmission of secondary inocula) have not been described.
Pathogen latency	*X. taiwanensis* may be asymptomatically harboured in infected pear trees and plant parts such as scions and budwood.	The duration of pathogen latency in its host plant(s) is unknown, although symptoms of the disease appeared 10–17 months after experimental inoculation.

*: Leu and Su (1993).

Based on other similar pathogens, xylem-feeding Cicadomorpha known to feed on *Pyrinae*, or specifically on *Pyrus* spp. (e.g. sharpshooter leafhoppers, froghoppers, spittlebugs) could potentially act as vectors of the pathogen. However, specific insect-vector species able to spread the pest have not been identified yet. Known vectors of *X. fastidiosa* (i.e. *Kolla paulula*, *Bothrogonia ferruginea*) are present in the areas of Taiwan where *X. taiwanensis* occurs (Tuan et al., 2016). However, there is uncertainty whether these *X. fastidiosa* vectors feed on nashi pears and on the ability and efficiency of the transfer of *X. taiwanensis*.

3.1.3. Host range/species affected

The only known natural host plant of *X. taiwanensis* is *Pyrus pyrifolia*, also known as Asian, Chinese, Japanese or Oriental pear and Nashi. The genus *Pyrus* is divided into two geographical groups: the occidental pears (e.g. *P. communis*) and the oriental pears (e.g. *P. pyrifolia*, *P. ussuriensis*). *P. pyrifolia* cultivars are further classified into two major groups: the russet pear group (*Akanashi*), with yellowish-brown rinds, and the green pear group (*Aonashi*), with yellow-green rinds (Kikuti, 1924; Inoue et al., 2006). *X. taiwanensis* is reported to infect the low-chilling pear cultivar Hengshan, belonging to the russet pear group. There is no commercial production of *P. communis* in Taiwan and there are no reports of the pathogen infecting pear species other than *P. pyrifolia*.

3.1.4. Intraspecific diversity

X. taiwanensis is not divided into subspecies or pathovars or other intraspecific categories. A draft genome sequence of *X. taiwanensis* was made available by Su et al. (2014), and the complete genome sequence was published in 2021, together with a comparative analysis of virulence genes between *X. taiwanensis* and *X. fastidiosa* (Weng et al., 2021).

3.1.5. Detection and identification of the pest

Are detection and identification methods available for the pest?

Yes, methods for the detection and identification of *X. taiwanensis* are currently available.

Detection in the field is done by visual inspection. Typical disease symptoms are leaf scorching (i.e. necrosis of the leaf tissue, starting from the apical and lateral margins, then progressing towards the midrib), followed by dieback of twigs and branches, as described in Leu and Su (1993). However, similar symptoms can be caused by other pathogens as well.

X. taiwanensis is a fastidious bacterium, therefore it does not grow on most media developed for phytopathogenic bacteria; it slowly grows on PD2 and PW media (media also suitable for the growth of *X. fastidiosa*) and colonies develop to a 0.1–0.2 mm diameter in 14 days (Leu and Su, 1993). Morphologically, cells are rod-shaped, 0.2 to 0.5 × 1.1 to 3.4 μm and with rippled walls, therefore, of the same morphology as *X. fastidiosa*. Su et al. (2008a) developed a PCR-based method for the specific detection of *X. taiwanensis* and, for its identification, they applied a DNA fingerprinting method, amplified by arbitrary primers, in differentiating the pear leaf scorch bacterium from other *X. fastidiosa* strains (Su et al., 2008b).

3.2. Pest distribution

3.2.1. Pest distribution outside the EU

The only country, where *X. taiwanensis* is known to occur is Taiwan (see Figure 1). It is distributed in parts of the country, namely the following administrative areas: Taichung special municipality (districts of Dongshi, Houli, Xinshe, Heping), county of Chiayi, county of Miaoli (township of Cholan), county of Changhua, county of Hsinchu (urban township of Hsinpu) and city of Taitung.

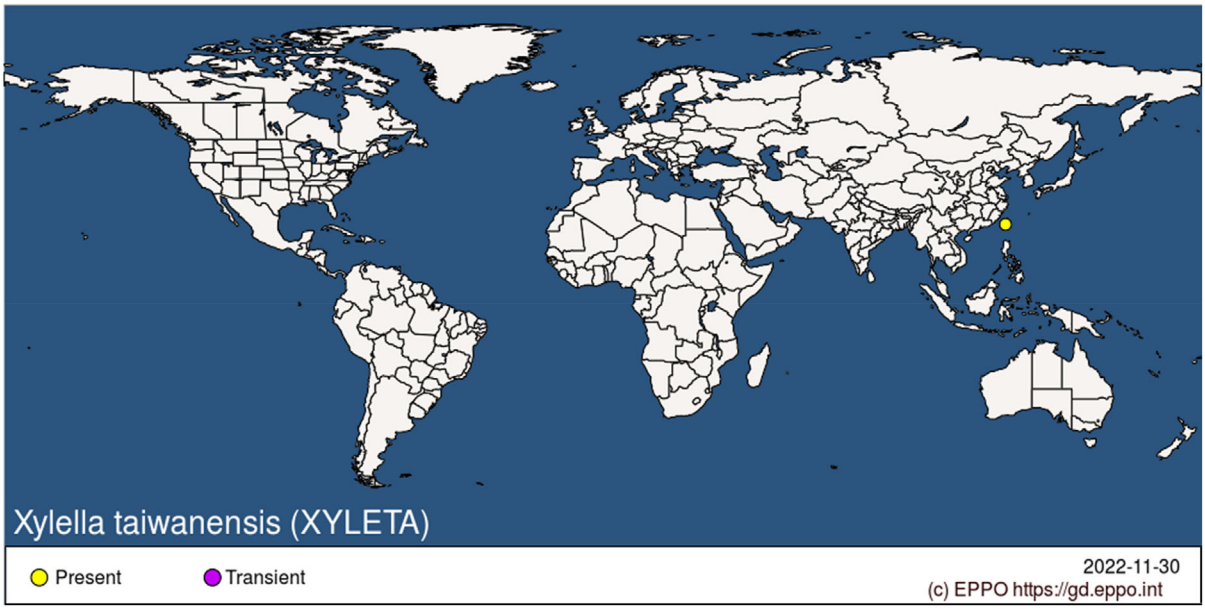

Figure 1: Global distribution of *X. taiwanensis* (Source: EPPO Global Database accessed on 30 November 2022)

3.2.2. Pest distribution in the EU

Is the pest present in the EU territory? If present, is the pest in a limited part of the EU or is it scarce, irregular, isolated or present infrequently? If so, the pest is considered to be not widely distributed.

X. taiwanensis is not known to be present in the EU territory.

3.3. Regulatory status

3.3.1. Commission Implementing Regulation 2019/2072

Xylella taiwanensis is not listed in Annex II of Commission Implementing Regulation (EU) 2019/2072, an implementing act of Regulation (EU) 2016/2031, or in any emergency plant health legislation.

3.3.2. Hosts or species affected that are prohibited from entering the union from third countries

A list of hosts included in Annex VI of Commission Implementing Regulation (EU) 2019/2072 is provided in Table 3.

Table 3: List of plants, plant products and other objects that are *Xylella taiwanensis* hosts, whose introduction into the Union from certain third countries is prohibited (Source: Commission Implementing Regulation (EU) 2019/2072, Annex VI)

List of plants, plant products and other objects whose introduction into the Union from certain third countries is prohibited			
	Description	**CN Code**	**Third country, group of third countries or specific area of third country**
8.	Plants for planting of … *Pyrus* L. …	ex 0602 10 90 ex 0602 20 20 ex 0602 20 80 ex 0602 40 00 ex 0602 90 41 ex 0602 90 45 ex 0602 90 46 ex 0602 90 47 ex 0602 90 48 ex 0602 90 50 ex 0602 90 70 ex 0602 90 91 ex 0602 90 99	Third countries other than Albania, Andorra, Armenia, Azerbaijan, Belarus, Bosnia and Herzegovina, Canary Islands, Faeroe Islands, Georgia, Iceland, Liechtenstein, Moldova, Monaco, Montenegro, North Macedonia, Norway, Russia (only the following parts: Central Federal District (Tsentralny federalny okrug), Northwestern Federal District (Severo-Zapadny federalny okrug), Southern Federal District (Yuzhny federalny okrug), North Caucasian Federal District (Severo-Kavkazsky federalny okrug) and Volga Federal District (Privolzhsky federalny okrug)), San Marino, Serbia, Switzerland, Turkey, Ukraine and the United Kingdom
9.	Plants for planting of … *Pyrus* L. and their hybrids, …	ex 0602 10 90 ex 0602 20 20 ex 0602 90 30 ex 0602 90 41 ex 0602 90 45 ex 0602 90 46 ex 0602 90 48 ex 0602 90 50 ex 0602 90 70 ex 0602 90 91 ex 0602 90 99	Third countries other than Albania, Algeria, Andorra, Armenia, Australia, Azerbaijan, Belarus, Bosnia and Herzegovina, Canada, Canary Islands, Egypt, Faeroe Islands, Georgia, Iceland, Israel, Jordan, Lebanon, Libya, Liechtenstein, Moldova, Monaco, Montenegro, Morocco, New Zealand, North Macedonia, Norway, Russia (only the following parts: Central Federal District (Tsentralny federalny okrug), Northwestern Federal District (Severo-Zapadny federalny okrug), Southern Federal District (Yuzhny federalny okrug), North Caucasian Federal District (Severo- Kavkazsky federalny okrug) and Volga Federal District (Privolzhsky federalny okrug)), San Marino, Serbia, Switzerland, Syria, Tunisia, Turkey, Ukraine, the United Kingdom (1) and United States other than Hawaii

3.4. Entry, establishment and spread in the EU

3.4.1. Entry

Is the pest able to enter into the EU territory? If yes, identify and list the pathways.

Yes, *X. taiwanensis* is able to enter into the EU territory on following pathways: plants for planting of *Pyrus pyrifolia other than seeds and vitroplants and xylem-feeding insect vectors*. The main pathway of entry is

- Plants for planting of *Pyrus pyrifolia* other than seeds and vitroplants.

Xyella taiwanensis is known to affect *Pyrus pyrifolia* cultivars in its geographic area of origin. Due to the wide host range of all known *Xylella* species and subspecies, there is high probability that *X. taiwanensis* may infect other *Pyrus* spp., e.g. *Pyrus communis*, but this represents an uncertainty due to lack of knowledge.

The pathogen could potentially also enter via insect vectors. For *Xylella fastidiosa*, it is known that it can colonise the foregut of insects and to be transmissible in a persistent manner (EFSA PLH Panel, 2019). However, this pathway for *X. taiwanensis* is of high uncertainty because there are no data on the identity of vectors of this species (see Section 3.1.2 (biology); Table 4).

Table 4: Potential pathways for *Xylella taiwanensis* into the EU 27

Pathways	**Life phase**	**Relevant mitigations [e.g. prohibitions (Annex VI), special requirements (Annex VII) or phytosanitary certificates (Annex XI) within Implementing Regulation 2019/2072]**
Description (e.g. host/intended use/source)		
Plants for planting of *Pyrus* spp., including rootstocks, cuttings, scions, budwood/budchips originating in infested third countries Excluded are seeds, vitroplants, tissue cultures.	Latent phase of *X. taiwanensis* that may be harboured in the xylem vessels of symptomless plants.	Annex VI of Regulation (EU) 2019/2072 prohibits the import of *Pyrus* spp. from certain third countries including Taiwan. Annex XI of Regulation (EU) 2019/2072 requires a phytosanitary certificate for the import of plants for planting including *Pyrus* spp.
Insect vectors once identified.	Living bacteria possibly colonising the foregut of xylem-feeding insects and transmissible in a persistent manner (like *X. fastidiosa*)	No relevant mitigation since potential vectors have not been identified yet.

Notifications of interceptions of harmful organisms began to be compiled in Europhyt in May 1994 and in TRACES in May 2020. As at 31/08/2022, there were no records of interception of *X. taiwanensis* in the Europhyt and TRACES databases.

3.4.2. Establishment

Is the pest able to become established in the EU territory?

Yes, the pest is able to become established in the EU territory where hosts are grown. Transfer from the pathway of entry is possible either directly e.g. by grafting or budding of infected plant material onto susceptible hosts grown in the EU or indirectly by putative insect vectors if present in the EU.

3.4.2.1. EU distribution of main host plants

Xylella taiwanensis is known to affect some cultivars of *Pyrus pyrifolia* in its area of distribution. There is no knowledge of its pathogenicity and aggressiveness on *P. communis* or other *Pyrus* spp.: In the current literature, there is no experimental data on assessing, if *X. taiwanensis* is pathogenic

on *P. communis*. Conversely, *X. fastidiosa* may affect other *Pyrus* spp. (USDA, 2015; EFSA, 2023). *P. communis* is one of the most important fruit crops in the EU territory and it is extensively cultivated in the whole Mediterranean area and in the central and eastern EU Member states (see Appendix C). *P. pyrifolia* cultivars (Nashi pears) are cultivated in some EU Member states in very limited areas: specific data available in 2002 stated that the whole cultivation area in the EU territory was 96 ha (EUROSTAT, 2002, cited in Kaim et al., 2006). In Italy, for instance, the cultivation of Asian pear is no more commercially relevant (Ugo Palara, Consorzio Agrintesa, Faenza, Italy). Despite the negligible importance of *P. pyrifolia* in the EU, increasing interest is represented by new pear hybrids (*P. pyrifolia* × *P. communis* × *P. bretschneideri*) (Tozzi et al., 2018): new orchards and experimental fields are already established in Italy and France (CTIFL, 2022; Luigi Manfrini, University of Bologna, Italy).

3.4.2.2. Climatic conditions affecting establishment

The potential for establishment of *X. taiwanensis* is determined by the presence of suitable hosts and insect vectors.

Pear cultivars (*P. communis*) typically have chilling requirements of 800–1,000 h (NB: a chilling hour is the time, calculated in hours, where the pear tree in at a temperature of 7°C (average) or below. This is required for flowering, fertilisation and fruit development). *P. pyrifolia*, though quite tolerant to low temperatures; for a satisfactory productivity, it has a chilling requirement of 300–500 h. In its area of distribution, *X. taiwanensis* affects low-chilling pear cultivars, which are pear cultivars growing in sub-tropical areas, with a total amount of seasonal chilling hours between 200 and 400. Leu and Su (1993) first described the disease in the Taichung Municipality (districts of Dongshi, Heping and Xinshe), county of Miaoli (district of Cholan), and county of Chiayi, where the low-chilling pear cultivar Hengshan is grown; those areas have mild and short winters.

Nonetheless, considering the polyphagous nature of the known *X. fastidiosa* subspecies, and their relationships with several insect vectors, it may be assumed that the climatic conditions favouring the establishment of *X. taiwanensis* are those favouring the biology of its vector(s). The global Köppen–Geiger climate zones (Kottek et al., 2006) describe terrestrial climate in terms of average minimum winter temperatures and summer maxima, amount of precipitation and seasonality (rainfall pattern).

Three Köppen–Geiger climate zones Cfa, Cfb and Cfc exist in Taiwan which can also be found in Europe. The host plant *P. pyrifolia* and also *P. communis* are not grown in climate Cfc. Therefore, Cfc is omitted from Figure 2.

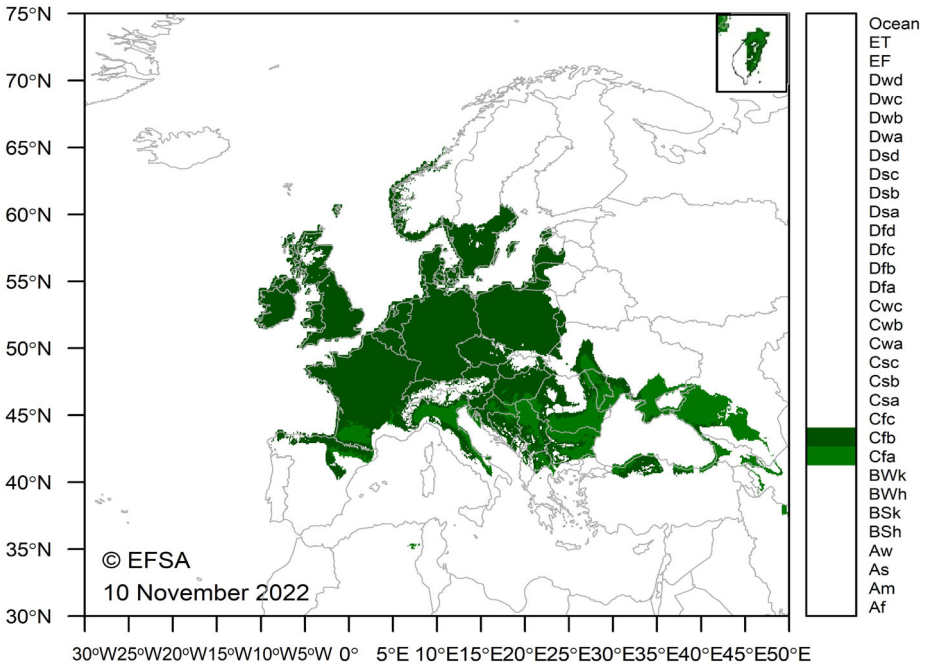

Figure 2: Distribution of two Köppen–Geiger climate types, Cfa and Cfb that occur in the EU and in Taiwan (in the right upper corner) where *Xylella taiwanensis* has been reported. The legend shows the list of Köppen–Geiger climates

3.4.3. Spread

Describe how the pest would be able to spread within the EU territory following establishment?

Spread within the EU territory over short and long distance may occur by human-assisted means and, possibly, by xylem-feeding insects. Plants for planting, including cuttings, scions, budchips/ budwood but excluding seeds and vitroplants are efficient means of spread.

Following its establishment, *X. taiwanensis* would be able to spread within the EU territory to both short and long distances by human-assisted and natural means, similar to *X. fastidiosa* species (e.g. *X. fastidiosa*). Movement of infected plant material and putative vectors aid the spread of the pathogen. There is no indication, whether pruning shears, grafting knives or other common tools may favour short distance dissemination of secondary inocula as is proven for *X. fastidiosa* in grapevine (Krell et al., 2007). Plants for planting, other than seeds, such as cuttings, scions, budchips/budwood, might be the most efficient mechanism of spread. Due to the nature of material, *in vitro* tissue cultures and meristems do not represent a means of pathogen's spread. Micropropagated plants, after the acclimatisation phase, might represent a risk of pest spread, if acclimatisation is not done under confined conditions. Climate may affect its spread since climatic conditions favouring movement and reproduction of the putative vector(s) is contemporarily aiding pathogen spread.

3.5. Impacts

Would the pests' introduction have an economic or environmental impact on the EU territory?

Yes, the introduction of *X. taiwanensis* may have an impact on the EU territory, provided that suitable insect vectors are present and that *P. communis* and other Pyrus species are as susceptible as *P. pyrifolia*.

Symptoms induced by *X. taiwanensis* on *P. pyrifolia* are leaf scorch (browning of leaf margins and tips, veins and tissue discoloration, wilting and early leaf abscission), dieback of productive spurs, twigs and branches and, eventually, death of infected trees within 3–6 years (Leu and Su, 1993). Disease symptoms have been observed on an average of 12%–20% (from 1.4% to 41%) of pear trees in the affected areas (Leu and Su, 1993) therefore, reducing tree vigour and productivity. A quantification of yield losses was not done, though a declining pear tree produces low-quality fruits. Furthermore, tree mortality may add to the crop losses. The disease is particularly severe in the subtropical/temperate lowlands of Taiwan, where low chilling, early ripening pears are cultivated. Disease impact is also favoured by the peculiar agronomic technique used to produce the low chilling cultivars. Briefly, mature buds of high-quality pear varieties are taken from mountainous areas and grafted onto water shoots of Hengshan pear cultivar in the subtropical/temperate lowlands. So, fruits from grafted varieties are harvested in June–July, compared to the normal ripening season in September. In the Chiayi County, this practice allows harvesting pears in April–May (Leu and Su, 1993). Therefore, the continuous budding of other cultivars onto Hengshan pears, season after season, increases the impact of the disease.

Pyrus pyrifolia is mainly cultivated in Asia and in North America. The cultivation of nashi pears has been promoted in the past for commercial production and for ornamental purposes in Europe (Iglesias, 1993; Pontoppidan, 1995; Bassi, 2000). However, the present commercial production of nashi pears in the EU is very limited.

Provided that suitable insect vectors are present in the EU and that *P. communis* and other Pyrus species grown in the EU territory are as susceptible as *P. pyrifolia*, *X. taiwanensis* is expected to have an economic and environmental impact.

3.6. Available measures and their limitations

Are there measures available to prevent pest entry, establishment, spread or impacts such that the risk becomes mitigated?

Yes, measures are available to prevent pest entry into the EU territory (see Sections 3.3.2 and 3.4.1).

Since putative insect vector(s) of *X. taiwanensis* have not been identified yet, phytosanitary measures targeting these insects are not available.

3.6.1. Identification of potential additional measures

Phytosanitary measures (prohibitions) are currently applied to *Pyrus* spp. for planting (see Section 3.3.2). Potential control measures on hosts that are imported are listed in Table 5. Additional potential risk reduction options and supporting measures are shown in Sections 3.6.1.1 and 3.6.1.2.

3.6.1.1. Additional potential risk reduction options

Potential additional control measures are listed in Table 5.

Table 5: Selected control measures (a full list is available in EFSA PLH Panel, 2018) for pest entry/establishment/spread/impact in relation to currently unregulated hosts and pathways. Control measures are measures that have a direct effect on pest abundance

Control measure/risk reduction option (Blue underline = Zenodo doc, Blue = WIP)	RRO summary	Risk element targeted (entry/establishment/spread/impact)
Require pest freedom	Plants for planting of *Pyrus* spp. (including cuttings, scions, budwood/bud-chips) should come from countries or areas that are officially free from *X. taiwanensis*	Entry
Growing plants in isolation	Description of possible exclusion conditions that could be implemented to isolate the crop from pests and if applicable relevant vectors. E.g. a dedicated structure such as glass or plastic greenhouses. Plant material should be produced in confined conditions, in dedicated premises that are insect proof. Micropropagated plants should be kept in dedicated, insect-proof glasshouses during their acclimatisation phase	Entry/spread/impact
Roguing and pruning	Roguing is defined as the removal of infested plants and/or uninfested host plants in a delimited area, whereas pruning is defined as the removal of infested plant parts only without affecting the viability of the plant. Any pear plant showing leaf scorch symptoms associated with *X. taiwanensis* should be removed and the remaining plants should be sampled and analysed for the pest presence.	Entry/spread/impact
Chemical treatments on crops including reproductive material	Use of chemical compounds against potential insect vectors (e.g. sap-feeding insects) during the cropping season.	Entry/establishment/spread/impact
Cleaning and disinfection of facilities, tools and machinery	The physical and chemical cleaning and disinfection of facilities, tools, machinery, transport means, facilities and other accessories (e.g. boxes, pots, pallets, palox, supports, hand tools). The measures addressed in this information sheet are washing, sweeping and fumigation. Cleaning and disinfection of pruning shears, grafting knives and other tools may kill the pest, thus avoiding the dissemination of secondary inocula.	Spread
Waste management	Uprooted diseased plants, plant debris, pruned plant parts and other plant material suspected to be infected by *X. taiwanensis* should be burned on-site.	Spread

Control measure/risk reduction option (Blue underline = Zenodo doc, Blue = WIP)	RRO summary	Risk element targeted (entry/establishment/spread/impact)
Heat and cold treatments	Controlled temperature treatments aimed to kill or inactivate pests without causing any unacceptable prejudice to the treated material itself. The measures addressed in this information sheet are: autoclaving; steam; hot water; hot air; cold treatment Heat treatment of dormant plant material (e.g. cuttings and scions) may reduce the endophytic population of *X. taiwanensis* and, in the meantime, kill the overwintering stadia of the putative vector(s).	Entry/spread
Post-entry quarantine and other restrictions of movement in the importing country	This information sheet covers post-entry quarantine (PEQ) of relevant commodities; temporal, spatial and end-use restrictions in the importing country for import of relevant commodities; Prohibition of import of relevant commodities into the domestic country. 'Relevant commodities' are plants, plant parts and other materials that may carry pests, either as infection, infestation or contamination. *Pyrus* spp. material imported for research and breeding purposes should be kept under post-entry quarantine, according to the Commission Delegated Regulation (EU) 2019/829 of 14 March 2019	Establishment/spread

3.6.1.2. Additional supporting measures

Potential additional supporting measures are listed in Table 6.

Table 6: Selected supporting measures (a full list is available in EFSA PLH Panel, 2018) in relation to currently unregulated hosts and pathways. Supporting measures are organisational measures or procedures supporting the choice of appropriate risk reduction options that do not directly affect pest abundance

Supporting measure	Summary	Risk element targeted (entry/establishment/spread/impact)
Inspection and trapping	Inspection is defined as the official visual examination of plants, plant products or other regulated articles to determine if pests are present or to determine compliance with phytosanitary regulations (ISPM 5). The effectiveness of sampling and subsequent inspection to detect pests may be enhanced by including trapping and luring techniques. Field inspections are targeted to detect diseased plants and collect symptomatic plant material to perform lab analysis. Typical disease symptoms are leaf scorching (i.e. necrosis of the leaf tissue, starting from the apical and lateral margins, then progressing towards the midrib), followed by dieback of twigs and branches, as described in Leu and Su (1993). Best period to detect symptoms is from early July to autumn, therefore in high summertime. Despite the clear symptoms that are caused by the bacterium, visual inspections are not sufficient to confirm the presence of *X. taiwanensis* since the pathogen may be asymptomatically harboured in plant material for up to 16–17 months (Leu and Su, 1993).	Entry

Supporting measure	Summary	Risk element targeted (entry/establishment/spread/impact)
	The whole amount of plant material, other than seeds, meristem, vitroplants and tissue cultures imported for research purposes should be inspected.	
Laboratory testing	Examination, other than visual, to determine if pests are present using official diagnostic protocols. Diagnostic protocols describe the minimum requirements for reliable diagnosis of regulated pests. Diagnostic protocols are available to specifically detect *X. taiwanensis* in plant material (Su et al., 2008a)	Entry
Sampling	According to ISPM 31, it is usually not feasible to inspect entire consignments, so phytosanitary inspection is performed mainly on samples obtained from a consignment. It is noted that the sampling concepts presented in this standard may also apply to other phytosanitary procedures, notably selection of units for testing. For inspection, testing and/or surveillance purposes the sample may be taken according to a statistically based or a non-statistical sampling methodology. Plant material imported in limited amount as cuttings and intended for research purposes should not be sampled, but singularly analysed.	Entry
Phytosanitary certificate and plant passport	An official paper document or its official electronic equivalent, consistent with the model certificates of the IPPC, attesting that a consignment meets phytosanitary import requirements (ISPM 5) a) Export certificate (import) b) Plant passport (EU internal trade) Phytosanitary certificates and plant passports are recommended for any plant recognised as host of *X. taiwanensis*.	Entry/spread
Certified and approved premises	Mandatory/voluntary certification/approval of premises is a process including a set of procedures and of actions implemented by producers, conditioners and traders contributing to ensure the phytosanitary compliance of consignments. It can be a part of a larger system maintained by the NPPO in order to guarantee the fulfilment of plant health requirements of plants and plant products intended for trade. Key property of certified or approved premises is the traceability of activities and tasks (and their components) inherent the pursued phytosanitary objective. Traceability aims to provide access to all trustful pieces of information that may help to prove the compliance of consignments with phytosanitary requirements of importing countries. The plant material imported for research purposes should be kept in approved and certified premises.	Entry/establishment
Certification of reproductive material (voluntary/official)	Plants come from within an approved propagation scheme and are certified pest free (level of infestation) following testing; used to mitigate against pests that are included in a certification scheme In principle, this would be an efficient measure but currently, *X. taiwanensis* is not included in any certification scheme.	Establishment/spread/impact

Supporting measure	Summary	Risk element targeted (entry/establishment/ spread/impact)
Delimitation of Buffer zones	ISPM 5 defines a buffer zone as 'an area surrounding or adjacent to an area officially delimited for phytosanitary purposes in order to minimise the probability of spread of the target pest into or out of the delimited area, and subject to phytosanitary or other control measures, if appropriate' (ISPM 5). The objectives for delimiting a buffer zone can be to prevent spread from the outbreak area and to maintain a pest-free production place (PFPP), site (PFPS) or area (PFA). A buffer zone can prevent the spread of *X. taiwanensis*, though its extension is unknown.	Spread
Surveillance	A surveillance system may be put in place to identify disease symptoms as soon as they appear: nonetheless, its efficacy in hampering disease spread might not be really effective since symptoms appear several months after infection (Leu and Su, 1993).	Spread

3.6.1.3. Biological or technical factors limiting the effectiveness of measures

- The pathogen may have a long latent phase in its host plants and remain visually undetectable for a long time.
- The putative vector(s) are not known.
- Heat treatment of propagation material may not kill *X. taiwanensis* propagules present endophytically or the putative vectors possibly harboured on dormant cuttings.

3.7. Uncertainty

Key uncertainties:

- Uncertainty on the host status of *Pyrus* spp. other than *P. pyrifolia* grown in the EU.
- Uncertainty on the impact on pear production of *X. taiwanensis* in the EU since there is no information on the susceptibility of *Pyrus communis* and other *Pyrus* species grown in the EU.
- Uncertainty on the identity of potential insect vectors of *X. taiwanensis*.

4. Conclusions

Xylella taiwanensis is not known to be present in the EU. The pathogen satisfies the criteria that are within the remit of EFSA to assess for this species to be regarded as a potential Union quarantine pest (Table 7).

Table 7: The Panel's conclusions on the pest categorisation criteria defined in Regulation (EU) 2016/2031 on protective measures against pests of plants (the number of the relevant sections of the pest categorisation is shown in brackets in the first column)

Criterion of pest categorisation	Panel's conclusions against criterion in Regulation (EU) 2016/2031 regarding Union quarantine pest	Key uncertainties
Identity of the pest (Section 3.1)	The identity of the pest is clearly defined	None
Absence/presence of the pest in the EU (Section 3.2)	The pest is not present in the EU territory	None
Pest potential for entry, establishment and spread in the EU (Section 3.4)	The pest is able to enter, establish and spread in the EU territory	Uncertainty on the identity of the potential insect vector(s) of *X. taiwanensis*. Uncertainty on the host status of *Pyrus* spp. other than *P. pyrifolia* grown in the EU

Criterion of pest categorisation	Panel's conclusions against criterion in Regulation (EU) 2016/2031 regarding Union quarantine pest	Key uncertainties
Potential for consequences in the EU (Section 3.5)	The pest may have a severe economic impact in the EU	Uncertainty on the impact of *X. taiwanensis* on pear production in the EU since there is no information on the susceptibility of *Pyrus communis* and other *Pyrus* species grown in the EU.
Available measures (Section 3.6)	Yes, there are measures available to prevent the entry, establishment, spread and impact of the pest.	None
Conclusion (Section 4)	All criteria assessed by EFSA are met to consider *X. taiwanensis* as a potential quarantine pest	
Aspects of assessment to focus on/scenarios to address in future if appropriate:	Two aspects urge to be assessed in the near future: 1) The susceptibility of *P. communis* and other *Pyrus* spp. grown in the EU to the pest. 2) The identification of the putative insect vector(s), including the determination whether known *Xylella* vectors widely present in the EU territory (*Philaenus spumarius*) might be a suitable vector for *X. taiwanensis* as well. Given that the present categorisation has explored most if not all of the available data on these points, a complete pest risk assessment is unlikely to provide much clearer conclusions, until the key knowledge gaps and uncertainties identified in this opinion are reduced by research. The same risk mitigation measures as for *X. fastidiosa* could be applied.	

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Abbreviations

EPPO	European and Mediterranean Plant Protection Organisation
FAO	Food and Agriculture Organisation

IPPC	International Plant Protection Convention
ISPM	International Standards for Phytosanitary Measures
MS	Member State
PLH	EFSA Panel on Plant Health
PZ	Protected Zone
TFEU	Treaty on the Functioning of the European Union
ToR	Terms of Reference

Glossary

Containment (of a pest)	Application of phytosanitary measures in and around an infested area to prevent spread of a pest (FAO, 2018)
Control (of a pest)	Suppression, containment or eradication of a pest population (FAO, 2018)
Entry (of a pest)	Movement of a pest into an area where it is not yet present, or present but not widely distributed and being officially controlled (FAO, 2018)
Eradication (of a pest)	Application of phytosanitary measures to eliminate a pest from an area (FAO, 2018)
Establishment (of a pest)	Perpetuation, for the foreseeable future, of a pest within an area after entry (FAO, 2018)
Greenhouse	A walk-in, static, closed place of crop production with a usually translucent outer shell, which allows controlled exchange of material and energy with the surroundings and prevents release of plant protection products (PPPs) into the environment.
Hitchhiker	An organism sheltering or transported accidentally via inanimate pathways including with machinery, shipping containers and vehicles; such organisms are also known as contaminating pests or stowaways (Toy and Newfield, 2010).
Impact (of a pest)	The impact of the pest on the crop output and quality and on the environment in the occupied spatial units
Introduction (of a pest)	The entry of a pest resulting in its establishment (FAO, 2018)
Pathway	Any means that allows the entry or spread of a pest (FAO, 2018)
Phytosanitary measures	Any legislation, regulation or official procedure having the purpose to prevent the introduction or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests (FAO, 2018)
Quarantine pest	A pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled (FAO, 2018)
Risk reduction option (RRO)	A measure acting on pest introduction and/or pest spread and/or the magnitude of the biological impact of the pest should the pest be present. A RRO may become a phytosanitary measure, action or procedure according to the decision of the risk manager
Spread (of a pest)	Expansion of the geographical distribution of a pest within an area (FAO, 2018)

Appendix A – *Xylella taiwanensis* host plants/species affected

Source: EPPO Global Database (EPPO, 2022, online)

Host status	Host name	Plant family	Common name	Reference
Cultivated hosts	*Pyrus pyrifolia*	*Rosaceae*	Asian pear, Japanese pear, Chinese pear, Apple-pear, Nashi	Leu and Su (1993)
Wild weed hosts	Not known			
Artificial/experimental host	Not known			

Appendix B – Distribution of *Xylella taiwanensis*

Distribution records based on EPPO Global Database (EPPO, 2022, online) and literature survey.

Region	Country	Sub-national (province, district, county, municipality)	Status
Asia	Taiwan	Taichung municipality (districts of: Houli, Heping, Dongshi, Xinshe) (Leu and Su, 1993; Su and Leu, 1995)	Present
		County of Miaoli (district of Cholan) (Su and Leu, 1995)	
		County of Chiayi (municipality of Chuchi) (Su and Leu, 1995)	
		County of Changhua (Leu and Su, 1993)	
		County of Hsinchu (municipality of Hsinpu) (Su and Leu, 1995)	
		City of Taitung (Su and Leu, 1995)	

Appendix C – EU 27 and Member State cultivation/harvested/production area of pears (in 1,000 ha)

Source EUROSTAT (accessed 14/10/2022).

Pear (*Pyrus communis*)	**2017**	**2018**	**2019**	**2020**	**2021**
EU 27	113.81	113.54	110.66	107.76	107.66
Belgium	10.02	10.15	10.37	10.66	10.45
Bulgaria	0.45	0.57	0.70	0.50	0.55
Czechia	0.71	0.75	0.80	0.83	0.80
Denmark	0.30	0.29	0.30	0.30	0.30
Germany	2.14	2.14	2.14	2.14	2.14
Estonia	0.00	0.00	0.00	0.00	0.00
Ireland	0.00	0.00	0.00	0.00	0.00
Greece	4.07	4.41	4.34	5.42	5.09
Spain	21.89	21.33	20.62	20.22	20.02
France	5.25	5.24	5.25	5.38	5.87
Croatia	0.71	0.80	0.86	0.73	0.75
Italy	31.73	31.34	28.71	26.60	26.79
Cyprus	0.07	0.06	0.06	0.06	0.07
Latvia	0.20	0.20	0.20	0.20	0.20
Lithuania	0.82	0.82	0.82	0.85	0.85
Luxembourg	0.02	0.02	0.02	0.01	0.01
Hungary	2.90	2.84	2.81	2.62	2.74
Malta	0.00	0.00	0.00	0.00	0.00
Netherlands	9.70	10.00	10.09	10.00	10.07
Austria	0.46	0.49	0.50	0.54	0.55
Poland	7.26	7.30	7.22	5.80	5.60
Portugal	11.54	11.21	11.33	11.33	11.16
Romania	3.12	3.10	3.08	3.09	3.17
Slovenia	0.20	0.21	0.21	0.22	0.23
Slovakia	0.11	0.12	0.11	0.10	0.09
Finland	0.04	0.05	0.04	0.05	0.05
Sweden	0.12	0.11	0.10	0.11	0.11