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SCIENTIFIC OPINION

Scientific Opinion on the pest categorisation of *Erwinia amylovora* (Burr.) Winsl. et al.[1]

EFSA Panel on Plant Health (PLH)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The European Commission requested the EFSA Panel on Plant Health to perform the pest categorisation for *Erwinia amylovora*, which is the causal agent of fire blight. *E. amylovora* is a plant pathogenic bacterium regulated by the Directive 2000/29/EC (Annexes II-A-II). *E. amylovora* is a single taxonomic entity. This organism can be accurately identified, based on a range of discriminative methods. Detection methods are available for symptomatic and asymptomatic plant material. *E. amylovora* is present in all EU Member States except Estonia, Finland and Malta, where host plants are not widely distributed or are rare. The host plants (mainly pear and apple) are cultivated throughout Europe where environmental conditions are conducive to disease development. Although no recent data are available on losses caused by *E. amylovora* in the EU, fire blight is considered to be the most destructive disease on pear and apple owing to the loss of trees. The analysis of past disease outbreaks previously reported in the EU highlights their considerable potential to have a severe impact on commercial horticulture, especially on apple, pear and quince, as well as on ornamentals and on nursery trade. The disease causes a range of symptoms on the aerial parts of plants, including the fruits, and *E. amylovora* often kills the trees and causes destructive outbreaks. Contaminated rootstocks, cuttings and grafted trees for transplanting, beehive transportation, rain and wind, are responsible for medium- and long-distance dissemination of the pathogen. Existing control is mainly based on prevention and exclusion. The use of chemical or biological products can prevent infection, and sanitation methods applied to infected plants can control the disease to a certain extent. No curative chemical control agents are available that eradicate *E. amylovora* in infected orchards.

KEY WORDS

Erwinia amylovora, fire blight, pest categorisation, quarantine pest, regulated non-quarantine pest

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[1] On request from the European Commission, Question No EFSA-Q-2014-00252, adopted on 27 November 2014.

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The current European Union plant health regime is established by Council Directive 2000/29/EC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community (OJ L 169, 10.7.2000, p. 1).

The Directive lays down, amongst others, the technical phytosanitary provisions to be met by plants and plant products and the control checks to be carried out at the place of origin on plants and plant products destined for the Union or to be moved within the Union, the list of harmful organisms whose introduction into or spread within the Union is prohibited and the control measures to be carried out at the outer border of the Union on arrival of plants and plant products.

The Commission is currently carrying out a revision of the regulatory status of organisms listed in the Annexes of Directive 2000/29/EC. This revision targets mainly organisms which are already locally present in the EU territory and that in many cases are regulated in the EU since a long time. Therefore it is considered to be appropriate to evaluate whether these organisms still deserve to remain regulated under Council Directive 2000/29/EC, or whether, if appropriate, they should be regulated in the context of the marketing of plant propagation material, or be deregulated. The revision of the regulatory status of these organisms is also in line with the outcome of the recent evaluation of the EU Plant Health Regime, which called for a modernisation of the system through more focus on prevention and better risk targeting (prioritisation).

In order to carry out this evaluation, a recent pest risk analysis is needed which takes into account the latest scientific and technical knowledge on these organisms, including data on their agronomic and environmental impact, as well as their present distribution in the EU territory. In this context, EFSA has already been asked to prepare risk assessments for some organisms listed in Annex IIAII. The current request concerns 23 additional organisms listed in Annex II, Part A, Section II as well as five organisms listed in Annex I, Part A, Section I, one listed in Annex I, Part A, Section II and nine organisms listed in Annex II, Part A, Section I of Council Directive 2000/29/EC. The organisms in question are the following:

Organisms listed in Annex II, Part A, Section II:

- *Ditylenchus destructor* Thorne
- *Circulifer haematoceps*
- *Circulifer tenellus*
- *Helicoverpa armigera* (Hübner)
- *Radopholus similis* (Cobb) Thorne (could be addressed together with the IIAI organism *Radopholus citrophilus* Huettel, Dickson and Kaplan)
- *Paysandisia archon* (Burmeister)
- *Clavibacter michiganensis* spp. *insidiosus* (McCulloch) Davis *et al.*
- *Erwinia amylovora* (Burr.) Winsl. *et al.* (also listed in Annex IIB)
- *Pseudomonas syringae* pv. *persicae* (Prunier *et al.*) Young *et al.*
- *Xanthomonas campestris* pv. *phaseoli* (Smith) Dye
- *Xanthomonas campestris* pv. *pruni* (Smith) Dye
- *Xylophilus ampelinus* (Panagopoulos) Willems *et al.*
- *Ceratocystis fimbriata* f. sp. *platani* Walter (also listed in Annex IIB)
- *Cryphonectria parasitica* (Murrill) Barr (also listed in Annex IIB)
- *Phoma tracheiphila* (Petri) Kanchaveli and Gikashvili
- *Verticillium albo-atrum* Reinke and Berthold
- *Verticillium dahliae* Klebahn
- Beet leaf curl virus
- Citrus tristeza virus (European isolates) (also listed in Annex IIB)
- Grapevine flavescence dorée MLO (also listed in Annex IIB)

- Potato stolbur mycoplasma
- *Spiroplasma citri* Saglio *et al.*
- Tomato yellow leaf curl virus

Organisms listed in Annex I, Part A, Section I:

- *Rhagoletis cingulata* (Loew)
- *Rhagoletis ribicola* Doane
- Strawberry vein banding virus
- Strawberry latent C virus
- Elm phloem necrosis mycoplasm

Organisms listed in Annex I, Part A, Section II:

- *Spodoptera littoralis* (Boisd.)

Organisms listed in Annex II, Part A, Section I:

- *Aculops fuchsiae* Keifer
- *Aonidiella citrina* Coquillet
- Prunus necrotic ringspot virus
- Cherry leafroll virus
- *Radopholus citrophilus* Huettel, Dickson and Kaplan (could be addressed together with IIAII organism *Radopholus similis* (Cobb) Thorne
- *Scirtothrips dorsalis* Hendel
- *Atropellis* spp.
- *Eotetranychus lewisi* McGregor
- *Diaporthe vaccinii* Shear.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

EFSA is requested, pursuant to Article 29(1) and Article 22(5) of Regulation (EC) No 178/2002, to provide a pest risk assessment of *Ditylenchus destructor* Thorne, *Circulifer haematoceps, Circulifer tenellus, Helicoverpa armigera* (Hübner), *Radopholus similis* (Cobb) Thorne, *Paysandisia archon* (Burmeister), *Clavibacter michiganensis* spp. *insidiosus* (McCulloch) Davis *et al, Erwinia amylovora* (Burr.) Winsl. *et al, Pseudomonas syringae pv. persicae* (Prunier *et al)* Young *et al. Xanthomonas campestris* pv. *phaseoli* (Smith) Dye, *Xanthomonas campestris* pv. *pruni* (Smith) Dye, *Xyîophilus ampelinus* (Panagopoulos) Willems *et al, Ceratocystis fimbriata* f. sp. *platani* Walter, *Cryphonectria parasitica* (Murrill) Barr, *Phoma tracheiphila* (Petri) Kanchaveli and Gikashvili, *Verticillium alboatrum* Reinke and Berthold, *Verticillium dahliae* Klebahn, Beet leaf curl virus, Citrus tristeza virus (European isolates), Grapevine flavescence dorée MLO, Potato stolbur mycoplasma, *Spiroplasma citri* Saglio *et al,* Tomato yellow leaf curl virus, *Rhagoletis cingulata* (Loew), *Rhagoletis ribicola* Doane, Strawberry vein banding virus, Strawberry latent C virus, Elm phloem necrosis mycoplasma, *Spodoptera littoralis* (Boisd.), *Aculops fuchsiae* Keifer, *Aonidiella citrina* Coquillet, Prunus necrotic ringspot virus, Cherry leafroll virus, *Radopholus citrophilus* Huettel Dickson and Kaplan (to address with the IIAII *Radopholus similis* (Cobb) Thorne), *Scirtothrips dorsalis* Hendel, *Atropellis* spp., *Eotetranychus lewisi* McGregor and *Diaporthe vaccinii* Shear., for the EU territory.

In line with the experience gained with the previous two batches of pest risk assessments of organisms listed in Annex II, Part A, Section II, requested to EFSA, and in order to further streamline the preparation of risk assessments for regulated pests, the work should be split in two stages, each with a specific output. EFSA is requested to prepare and deliver first a pest categorisation for each of these 38 regulated pests (step 1). Upon receipt and analysis of this output, the Commission will inform EFSA for which organisms it is necessary to complete the pest risk assessment, to identify risk reduction options and to provide an assessment of the effectiveness of current EU phytosanitary requirements (step 2). *Clavibacter michiganensis* spp. *michiganensis* (Smith) Davis *et al.* and *Xanthomonas campestris* pv. *vesicatoria* (Doidge) Dye, from the second batch of risk assessment requests for Annex IIAII organisms requested to EFSA (ARES(2012)880155), could be used as pilot cases for this approach, given that the working group for the preparation of their pest risk assessments has been constituted and it is currently dealing with the step 1 "pest categorisation". This proposed modification of previous request would allow a rapid delivery by EFSA by May 2014 of the first two outputs for step 1 "pest categorisation", that could be used as pilot case for this request and obtain a prompt feedback on its fitness for purpose from the risk manager's point of view.

As indicated in previous requests of risk assessments for regulated pests, in order to target its level of detail to the needs of the risk manager, and thereby to rationalise the resources used for their preparation and to speed up their delivery, for the preparation of the pest categorisations EFSA is requested, in order to define the potential for establishment, spread and impact in the risk assessment area, to concentrate in particular on the analysis of the present distribution of the organism in comparison with the distribution of the main hosts and on the analysis of the observed impacts of the organism in the risk assessment area.

ASSESSMENT

1. Introduction

1.1. Purpose

This document presents a pest categorisation prepared by the EFSA Scientific Panel on Plant Health (hereinafter referred to as the Panel) for the species *Erwinia amylovora* in response to a request from the European Commission.

1.2. Scope

The risk assessment area is the territory of the European Union (hereinafter referred to as the EU) with 28 Member States (hereinafter referred to as MSs), restricted to the area of application of Council Directive 2000/29/EC.

2. Methodology and data

2.1. Methodology

The Panel performed the pest categorisation for *E. amylovora* following guiding principles and steps presented in the EFSA Guidance on a harmonised framework for pest risk assessment (EFSA PLH Panel, 2010) and as defined in the International Standards for Phytosanitary Measures (ISPM) No 11 (FAO, 2013) and ISPM No 21 (FAO, 2004).

In accordance with the Guidance on a harmonised framework for pest risk assessment in the EU (EFSA PLH Panel, 2010), this work is initiated as a result of the review or revision of phytosanitary policies and priorities. As explained in the background of the European Commission request, the objective of this mandate is to provide updated scientific advice to the European risk managers for their evaluation of whether these organisms listed in the Annexes of the Directive 2000/29/EC still deserve to remain regulated under Council Directive 2000/29/EC, or whether they should be regulated in the context of the marketing of plant propagation material, or be deregulated. Therefore, to facilitate the decision making process, in the conclusions of the pest categorisation, the Panel addresses explicitly each criterion for quarantine pest according to ISPM 11 (FAO, 2013) but also for regulated non-quarantine pest according to ISPM 21 (FAO, 2004) and includes additional information required as per the specific terms of reference received by the EC. In addition, for each conclusion the Panel provides a short description of its associated uncertainty.

The Table 1 below presents the ISPM 11 (FAO, 2013) and ISPM 21 (FAO, 2004) pest categorisation criteria against which the Panel provides its conclusions. It should be noted that the Panel's conclusions are formulated respecting its remit and particularly with regards to the principle of separation between risk assessment and risk management (EFSA founding regulation[4]), therefore, instead of determining whether the pest is likely to have an unacceptable impact, the Panel will present a summary of the observed pest impacts. Economic impacts are expressed in terms of yield and quality losses and not in monetary terms, in agreement with the Guidance on a harmonised framework for pest risk assessment (EFSA PLH Panel, 2010).

[4] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31/1, 1.2.2002, p. 1–24.

Table 1: International Standards for Phytosanitary Measures ISPM 11 (FAO, 2013) and ISPM 21 (FAO, 2004) pest categorisation criteria under evaluation

Pest categorisation criteria	ISPM 11 for being a potential quarantine pest	ISPM 21 for being a potential regulated non-quarantine pest
Identity of the pest	The identity of the pest should be clearly defined to ensure that the assessment is being performed on a distinct organism, and that biological and other information used in the assessment is relevant to the organism in question. If this is not possible because the causal agent of particular symptoms has not yet been fully identified, then it should have been shown to produce consistent symptoms and to be transmissible	The identity of the pest is clearly defined
Presence (ISPM 11) or absence (ISPM 21) in the PRA area	The pest should be **absent from all or a defined part of the PRA area**	The pest is **present** in the PRA area
Regulatory status	If the pest is present but not widely distributed in the PRA area, it should be under official control or expected to be under official control in the near future	The pest is under official control (or being considered for official control) in the PRA area with respect to the specified plants for planting
Potential for establishment and spread in the PRA area	The PRA area should have ecological/climatic conditions including those in protected conditions suitable for the establishment and spread of the pest and, where relevant, host species (or near relatives), alternate hosts and vectors should be present in the PRA area	–
Association of the pest with the plants for planting and the effect on their intended use	–	Plants for planting are a pathway for introduction and spread of this pest
Potential for consequences (including environmental consequences) in the PRA area	There should be clear indications that the pest is likely to have an unacceptable economic impact (including environmental impact) in the PRA area	–
Indication of impact(s) of the pest on the intended use of the plants for planting	–	The pest may cause severe economic impact on the intended use of the plants for planting
Conclusion	If it has been determined that the pest has the potential to be a quarantine pest, the PRA process should continue. If a pest does not fulfil all of the criteria for a quarantine pest, the PRA process for that pest may stop. In the absence of sufficient information, the uncertainties should be identified and the PRA process should continue	If a pest does not fulfil all the criteria for a regulated non-quarantine pest, the PRA process may stop

In addition, in order to reply to the specific questions listed in the terms of reference, three issues are specifically discussed only for pests already present in the EU: the analysis of the present EU distribution of the organism in comparison with the EU distribution of the main hosts; the analysis of the observed impacts of the organism in the EU; and the pest control and cultural measures currently implemented in the EU.

The Panel will not indicate in its conclusions of the pest categorisation whether to continue the risk assessment process as it is clearly stated in the terms of reference that at the end of the pest categorisation the European Commission will indicate if further risk assessment work is required following their analysis of the Panel's scientific opinion.

2.2. Data

2.2.1. Literature search

A literature search on *E. amylovora* was conducted at the beginning of the mandate. The search was conducted for the scientific name of the pest together with the most frequently used common names on the ISI Web of Knowledge database. Further references and information were obtained from experts, from citations within the references as well as from grey literature. The results of the EFSA procurement "Preparatory work for pest categorisation of 3 bacteria listed in the annexes of the Council directive 2000/29/EC, contract number: NP/EFSA/ALPHA/2014/06-CT01" were also used.

2.2.2. Data collection

To complement the information concerning the current situation of the pest provided by the literature and online databases on pest distribution, damage and management, the Panel sent a short questionnaire on the current situation at country level based on the information available in the European and Mediterranean Plant Protection Organization (EPPO) Plant Quarantine Retrieval (PQR) system to the National Plant Protection Organisation (NPPO) contacts of the 28 EU Member States, and of Iceland and Norway. Iceland and Norway are part of the European Free Trade Association (EFTA) and are contributing to EFSA data collection activities, as part of the agreements EFSA has with these two countries. A summary table on the pest status based on the EPPO PQR and MS replies is presented in Table 2.

Information on the distribution of the main host plants was obtained from Hucorne (2012), who retrieved data from the EUROSTAT database.

In its analyses the Panel also considered the pest risk analyses prepared for Australia, (Biosecurity Australia, 2011), Norway (Sletten and Rafoss, 2007), Ireland (Choiseul, 2007) and in general (Roberts et al., 1998; Roberts and Sawyer, 2008).

3. Pest categorisation

3.1. Identity and biology of the pest

3.1.1. Taxonomy

Name:

Erwinia amylovora (Burrill 1882) Winslow et al., 1920

Synonyms:

Micrococcus amylovorus Burrill,
Bacillus amylovorus (Burrill) Trevisan
Bacterium amylovorus (Burrill) Chester,
Erwinia amylovora (Burrill) Winslow et al. f. sp. *rubi* Starr et al.

Taxonomic position:

Kingdom: Procaryota; Domain: Bacteria; Phylum: Proteobacteria; Class: Gamma Proteobacteria; Order: Enterobacteriales; Family: Enterobacteriaceae; Genus: *Erwinia*; Species: *Erwinia amylovora*

Common names:

Fire blight (English), Feu bactérien (French), Feuerbrand (German), Bacterievuur (Dutch), Colpo di fuoco (Italian), Ildsot (Danish), Pærebrann (Norwegian), Bakteriální spála růžovitých (Czech), Fuego bacteriano (Spanish), Fogo bacteriano (Portuguese), Vaktiriako kapsimo (Greek), Zaraga ogniova (Polish).

Gram-negative, non-spore-forming, facultatively anaerobic, rod-shaped bacteria isolated from plant environments have been traditionally classified into the genus *Erwinia* (Winslow et al., 1920. Plant pathologists initially divided *Erwinia* strains into four groups, considering cultural and biochemical characters: the "amylovora" group, the "carotovora" group, the "herbicola" group, and a fourth group comprising "atypical" *Erwinia* spp. (Dye, 1968, 1969a, b, c).

The phylogenetic position of the genus *Erwinia* and other plant-associated enterobacteria has been revised using 16S rDNA gene sequencing (Kwon et al., 1997; Hauben et al., 1998, Mergaert et al., 1999), and new species have been described (Kim et al., 1999; Geider et al. 2009; López et al., 2011; Matsuura et al., 2012). The former *Erwinia* genus is now classified into five different genera: (1) *Erwinia* spp. including *E. amylovora*, *E. mallotivora*, *E. persicinus*, *E. psidii*, *E. rhapontici*, *E. tracheiphila*, *E. pyrifoliae*, *E. piriflorinigrans* and *E. uzenensis*; (2) *Pectobacterium* spp.; (3) *Dickeya* spp.; (4) *Brenneria* spp.; and (5) *Pantoea* spp. Thus, *Erwinia amylovora* forms a compact species, clearly differentiated from other species of the genus *Erwinia*.

3.1.2. Pest biology

Fire blight mainly affects members of the subfamily Maloideae of the family Rosaceae. The symptoms of fire blight of Maloideae plants are similar in all host plants, apart from some specificities. Pear is the host species showing the most characteristic symptoms, with flowers, leaves, shoots and fruits dark coloured or blackish, as if they have been burnt. In apple, loquat and other susceptible rosaceous plants, the colour of the plant foliage may be reddish. Under favourable conditions symptoms progress very rapidly in a few days.

Symptoms of fire blight have been extensively described in several existing reviews and books (van der Zwet and Beer, 1995; Vanneste, 2000; Palacio-Bielsa and Cambra, 2009; van der Zwet et al. 2012). Flowers are considered to be the organ most susceptible to *E. amylovora.* The bacterium can penetrate through all structures, but preferentially through the nectaries. Initially flowers appear wet, later show a brownish discoloration and finally have a blackish necrotic aspect. The infection may progress through the peduncle and affect the whole corymb (flower cluster), including leaves that remain attached to the budding structure. The symptoms in actively growing shoots consist of darkened tips with a loss of turgor that finally become necrotised and curved in the shape of the typical shepherd's stick. Leaves can be infected via the vascular system of the shoot or by direct penetration via stomata or wounds. The typical symptoms on leaves start with initial turgor loss followed by a dark discoloration. Fruits can be affected, especially in the immature stages, when the pathogen penetrates through lenticels or wounds, especially those caused by hail. Fruits become dark and necrotic inside and may remain hanging mummified on the tree. Twigs, branches and the trunk may also be infected, resulting in limited nutrition of subordinate tree branches, which in turns leads to a rapid wilt of the leaves but not defoliation. This stage often ends with formation of cankers, which appear in summer or autumn, thus providing a survival site for the pathogen during winter. Cankers are discoloured or depressed lateral areas in the bark, which upon debarking often exhibit reddish-orange and humid tissues in the cortical parenchyma. Infections of rootstocks and the grafting area are not frequent, but they can kill the tree rapidly. Bacterial exudates may be produced in all affected organs, often in the form of droplets or mucilaginous filaments of a whitish or yellowish colour. They are constituted of large numbers of pathogen cells immersed in an exopolysaccharide matrix (amylovoran). Exudates are frequently observed under high humidity or wet conditions and are an important source of pathogen dissemination by rain, thunderstorms and insects.

Symptoms of fire blight can be confused with other causes, especially at the start of disease development, such as infections by *Pseudomonas syringae* pv. *syringae* and *E. pyrifoliae* described in Korea and Japan (Kim et al., 1999), *E. piriflorinigrans* in Spain (López et al., 2011) and *E. uzenensis* in Japan (Matsuura et al., 2012), or with damage from insects such as *Janus compresus* and *Zeuzera pyrina*, or even with certain physiological disorders. Fungal cankers, i.e. those caused by *Phomopsis mali* or *Sphaeropsis malorum*, might be sometimes confused with fire blight cankers, especially when observed on apple. Thus, confirmation of pest identity requires laboratory analysis following the recommended methods (see sections 3.1.3 and 3.1.4).

The biological cycle of *E. amylovora* is relatively well known. The primary infections occur in spring, generally from inoculum of the preceding year from the same orchard or from surrounding areas. Sources of primary inoculum might be found in buds, where bacterial cells may easily overwinter (Bonn, 1978). *E. amylovora* enters its host plants through natural openings such as nectaries or stomata, and, after multiplication in these organs, bacteria can invade peduncles, shoots, leaves and immature fruits. The most receptive stages of the host are the flowering and active vegetative growth periods. Secondary flowers that may be produced in late spring or summer are more prone to infections than the flowers produced during the main bloom, because warm temperatures favour pathogen multiplication. The most favourable environmental conditions for fire blight infection are temperatures from 18 to 29 °C, high relative humidity (90–95 %) and wet plant surfaces, e.g. following rain (van der Zwet and Beer, 1995). During the bloom period, temperatures as low as 12 °C, are also favourable for infection (van der Zwet and Beer, 1995; van der Zwet et al., 2012).

Exudates can be transported by insects, rain or wind and contribute to late infections during the vegetative period. In summer, secondary infections are favoured by a combination of wounds produced by hail or strong thunderstorms and the presence of contaminated pollen and insect pollinators such as bees. Summer pruning may provide additional penetration sites on trees, and contaminated pruning tools may facilitate both pathogen dissemination and plant infection. In autumn, plant tissues are less susceptible to infections, and generally the progression of infections slows down or stops. In winter, the pathogen survives in buds, lignified tissues and cankers, thus providing the inoculum for the following season.

The main sources of inoculum (primary and secondary) for infection are propagating plant material, contaminated pollen, pollinating insects, lesions and exudates on plant surfaces and tools for pruning. The role of birds in disseminating viable *E. amylovora* cells has been suspected but never proven unambiguously.

Local environmental conditions favouring the formation of inoculum and host phenological stages at the time of inoculum dissemination in the orchards may explain changes in disease severity and incidence from year to year, whereas differences from area to area during the same season might be explained by differing degrees of aggressiveness of the local strain. Finally, cultivar susceptibility plays a major role in the amount of disease caused by same inoculum pressure.

3.1.3. Intraspecific diversity

In general, there is a genetic homogeneity among the strains of *E. amylovora* (Paulin, 2000). Nonetheless, isolates from *Rubus* species form a distinct genetic clade (Starr et al., 1951; Rezzonico et al., 2012). Strains from fruit trees and ornamental rosaceous plants show widely variable aggressiveness (Norelli et al., 1986; Cabrefiga and Montesinos, 2005). Molecular fingerprinting analysis has shown minor differences among strains by means of pulsed-field gel electrophoresis (PFGE), enterobacterial repetitive intergenic consensus polymerase chain reaction (ERIC-PCR), BOX-based repetitive extragenic palindromic PCR (BOX-PCR), repetitive sequence-based PCR

(REP-PCR), amplified fragment length polymorphism (AFLP) and random amplified polymorphic DNA (RAPD) (Zhang and Geider, 1997; Rico et al., 2004; Donat et al., 2007), plasmid profile (Llop et al., 2006, 2011, 2012) and repetitive sequences variable number tandem repeat (VNTR) and cluttered regularly spaced short palindromic repeats (CRISPR) (McGee and Sundin, 2012). However, this degree of variability is considered moderate and no subspecies or pathovar structure within *E. amylovora* can be distinguished.

The first strains of *E. amylovora* that were sequenced were Ea 273 (ATCC 49946) and CFBP 1430. There are currently several bacteria strains obtained from different host plants and geographical origins, that have been sequenced which show a high degree of genetic homogeneity and have been globally described as a pangenome with a large conserved core (Mann et al., 2013). The genome of *E. amylovora* (3.8 Mb) is organised as a main circular chromosome with none to several plasmids. Genomic analysis of several strains has shown that they contain several genomic islands, they have a lower capacity for anaerobic metabolism than other enterobacteria and they are adapted to rosaceous plant hosts by means of virulence factors and sorbitol metabolism. Sorbitol is frequently present in Rosaceae.

Plasmids contribute to the diversity between strains and may play a role in fitness and virulence. A total of 12 plasmids has been described (size from 1.7 to 71.4 kb), and the most studied are pEA29 and pEI70, which have a role in virulence, and pEA34 and pEA8.7, which are involved in streptomycin resistance (Llop et al., 2011, 2012).

3.1.4. Detection and identification of the pest

Fire blight diagnostics requires symptom recognition and isolation and identification of *E. amylovora* from plant material. Laboratory confirmation is needed because symptoms may be confused with other diseases or disorders.

The EPPO PM7/20 protocol (EPPO, 2013) recommends isolation of *E. amylovora* followed by confirmation by serology and/or a nucleic acid-based method, with or without culture enrichment (EPPO 2013). The recommended growth media are the non-selective media, such as King’s medium B (KB) or nutrient sucrose agar medium (NSA) and the semi-selective medium CCT (Ishimaru and Klos, 1984). Isolation may sometimes fail, if the pathogen is present in a viable but non-culturable (VBNC) state (Ordax et al., 2006, 2009). For immunological detection and identification purposes there are different methods, but the most often recommended is the double-antibody sandwich indirect enzyme-linked immunosorbent assay (DASI-ELISA) method, based on monoclonal antibodies (Gorris et al. 1996). Nucleic acid-based methods can be used for conventional or real-time PCR, with specific primers targeted to the chromosome or to the plasmids (Bereswill et al., 1992, 1995; McManus and Jones, 1995; Maes et al., 1996; Llop et al., 2000; Salm and Geider, 2004). However, some strains lack plasmids and may give false-negative reactions with plasmid-based assays (Llop et al. 2006). There are also protocols adapted to detection using loop-mediated isothermal amplification (LAMP)-based methods (Temple and Johnson, 2011; Bühlmann et al., 2013).

Upon isolation of pure cultures of the putative *E. amylovora*, several complementary tests are recommended, such as the tobacco hypersensitivity reaction, the immature fruit inoculation (Beer and Rundle, 1983) or the inoculation of shoots of host species (Ruz et al., 2008) to demonstrate pathogenicity of the isolated cultures (EPPO, 2013).

Owing to the phytosanitary risk posed by latent infections, protocols for analysis of asymptomatic material have been developed, especially for nursery material to prevent spread of the disease (EPPO, 2013).

3.2. Current distribution of the pest

3.2.1. Global distribution of the pest

E. amylovora is widely distributed, being reported from Europe, Asia, Northern Africa, Eastern Mediterranean countries, Northern and Central America and New Zealand (Figure 1). The pathogen has not been reported in countries from South America or most parts of Africa and Asia, where the host plants are grown and climatic conditions are suitable for fire blight (Vanneste, 2000; van der Zwet et al., 2012; CABI, 2014).

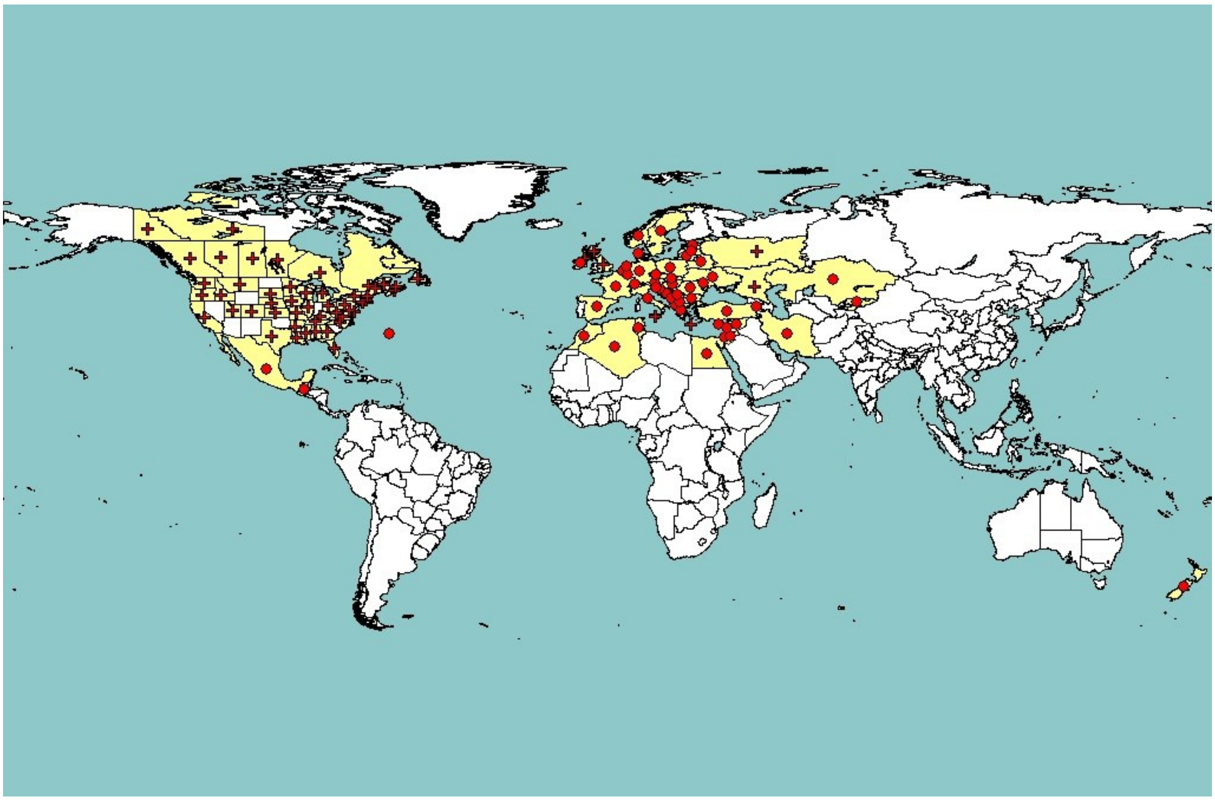

Figure 1: Global distribution of *Erwinia amylovora* (extracted from EPPO PQR (2014, version 5.3.1), accessed 16 June 2014). Red circles represent pest presence as national records and red crosses pest presence as subnational records

3.2.2. Pest distribution in the EU

As indicated by the answers to a questionnaire sent by EFSA to EU MSs, the presence of *E. amylovora* is reported in all EU MSs with the exception of Estonia, Finland and Malta (see Table 2).

Table 2: Current distribution of *Erwinia amylovora* in the 28 EU MSs, Iceland and Norway, based on the answers received via email from the NPPOs or, in the absence of a reply, on information from EPPO PQR

Country	NPPO answer
Austria	**Present,** subject to official control
Belgium	**Present,** in all parts of the area, except in specified pest-free areas (buffer zones) and subject to official control
Bulgaria	**Present,** widespread
Croatia	**Present,** only in some areas
Cyprus	**Present,** widespread
Czech Republic	**Present,** restricted distribution

Country	NPPO answer
Denmark	**Present,** restricted distribution
Estonia [(b)]	**Absent,** pest eradicated
Finland [(b)]	**Absent,** confirmed by survey
France [(b)]	**Present,** restricted distribution
Germany	**Present,** restricted distribution
Greece [(a)]	**Present,** widespread; restricted distribution in Kriti
Hungary	**Present,** restricted distribution
Ireland [(b)]	**Present,** few occurrences
Italy [(b)]	**Present,** restricted distribution
Latvia [(a) (b)]	**Present,** few occurrences
Lithuania [(a) (b)]	**Present,** restricted distribution
Luxembourg [(a)]	**Present,** restricted distribution
Malta	**Absent,** no pest records, confirmed by survey
Poland	**Present,** restricted distribution
Portugal [(b)]	Few outbreaks under eradication, confirmed by survey
Romania [(a)]	**Present,** widespread
Slovak Republic [(b)]	**Present,** except in specified pest-free areas
Slovenia [(b)]	**Present,** only in some areas
Spain [(b)]	**Present,** restricted distribution
Sweden	**Present,** restricted distribution
The Netherlands	**Present,** low prevalence in specified areas (buffer zones)
UK [(b)]	**Present,** in all parts of England, only in some areas in Northern Ireland and Scotland. Eradicated in Channel Islands
Iceland [(a)]	–
Norway [(a)]	**Present,** restricted distribution

(a): When no information was made available to EFSA, the pest status in the EPPO PQR (2012) was used.
(b): According to the Directive 2000/29/EC protected zones were established
—: no information available
EPPO PQR, European and Mediterranean Plant Protection Organization Plant Quarantine Data Retrieval System; NPPO, National Plant Protection Organisation.

E. amylovora is widespread (except in 'buffer zones' as defined by Annex IV, Part B, point 21 of Council Directive 2000/29/EC) in Austria, Belgium, Bulgaria, Cyprus, Greece, Romania, and The Netherlands; present with restricted distribution (except in 'Protected Zones' designated in Annex IV, Part B, point 21 of Council Directive 2000/29/EC, and defined by Article 2, paragraph 1(h) of Council Directive 2000/29/EC) in Croatia, Czech Republic, Denmark, France, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, Luxemburg, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden and United Kingdom, and absent in Estonia, Finland and Malta.

In Norway, according to Sletten and Rafoss (2007), *E. amylovora* is present in a few coastal locations, but it has not reached commercial fruit-growing areas.

Overall, coordinated efforts to restrict the spread of *E. amylovora*, conducted either at the MS level or regionally within the MSs, have succeeded in restricting the distribution or at least delaying the spread of the pathogen. In view of the data on the current distribution of the pathogen and further evidences given below (sections 3.4 and 3.5), it can be concluded that *E. amylovora* has some potential for future spread within the EU territory.

3.2.3. Vectors and their distribution in the EU

Insects, mainly pollinators, are probably the most efficient carriers at short and medium distance and the ability to transmit the bacterium. *E. amylovora* can survive for several days in bees (Alexandrova et al., 2002), and several weeks in pollen, nectar and honey (Vanneste 1996), and up to four weeks in *Ceratitis capitata* (Ordax et al., 2010). Other insects or even migratory birds may potentially transport inoculum, but there are no scientific evidences to support this hypothesis (Seidel et al., 1994).

3.3. Regulatory status

E. amylovora is considered as a quarantine pest by the Comite Regional de Sanidad Vegetal del Cono Sur (COSAVE) in South America, the Interafrican Phytosanitary Council (IAPSC) and several countries around the world (e.g. Australia, New Zealand, Norway).

3.3.1. Council Directive 2000/29/EC

3.3.1.1. *Erwinia amylovora*

E. amylovora is a regulated harmful organism in the EU and listed in Council Directive 2000/29/EC in Annex II, Part A, Section II, point 3, and in Annex II, Part B, point 2 (see Table 3).

Table 3: *Erwinia amylovora* in Council Directive 2000/29/EC

Annex II, Part A	Harmful organisms whose introduction into, and spread within, all Member States shall be banned if they are present on certain plants or plant products		
Section II	Harmful organisms known to occur in the Community and relevant for the entire Community		
(b)	Bacteria		
	Species	Subject of contamination	
3	*Erwinia amylovora* (Burr.) Winsl. et al.	Plants of *Amelanchier* Med., *Chaenomeles* Lindl., *Cotoneaster* Ehrh., *Crataegus* L., *Cydonia* Mill., *Eriobotrya* Lindl., *Malus* Mill., *Mespilus* L., *Photinia davidiana* (Dcne.) Cardot, *Pyracantha* Roem., *Pyrus* L. and *Sorbus* L., intended for planting, other than seeds	
Annex II, Part B	Harmful organisms whose shall be banned if they are present on certain plants or plant introduction into, and whose spread within, certain protected zones products		
	Species	Subject of contamination	Protected zone(s)
2	*Erwinia amylovora* (Burr.) Winsl. et al.	Parts of plants, other than fruit, seeds and plants intended for planting, but including live pollen for pollination of *Amelanchier* Med., *Chaenomeles* Lindl., *Cotoneaster* Ehrh., *Crataegus* L., *Cydonia* Mill., *Eriobotrya* Lindl., *Malus* Mill., *Mespilus* L., *Photinia davidiana* (Dcne.) Cardot, *Pyracantha* Roem., *Pyrus* L. and *Sorbus* L.	E (except the autonomous communities of Aragon, Castilla la Mancha, Castilla y León, Extremadura, Murcia, Navarra and La Rioja, and the province of Guipuzcoa (Basque Country), the Comarcas de L'Alt Vinalopó and El Vinalopó Mitjà in the province of Alicante and the municipalities of Alborache and Turís in the province of Valencia (Comunidad Valenciana)), EE, F (Corsica), IRL (except Galway City), I (Abruzzo, Apulia, Basilicata, Calabria, Campania, Emilia-Romagna (the provinces of Parma and Piacenza), Lazio, Liguria, Lombardy (except the provinces of Mantua and Sondrio), Marche, Molise, Piedmont, Sardinia, Sicily, Tuscany, Umbria, Valle d'Aosta, Veneto (except the provinces of Rovigo and Venice, the communes Barbona, Boara Pisani, Castelbaldo, Masi, Piacenza d'Adige, S. Urbano, Vescovana in the province of Padova and the area situated to the south of highway A4 in the province of Verona)), LV, LT (except the municipalities of Babtai and Kėdainiai (region of Kaunas)), P, SI (except the regions Gorenjska, Koroška, Maribor and Notranjska, and the communes of Lendava and Renče-Vogrsko (south from the highway H4)), SK (except the communes of Blahová, Čenkovce, Horné

	Mýto, Okoč, Topoľníky and Trhová Hradská (Dunajská Streda County), Hronovce and Hronské Kľačany (Levice County), Dvory nad Žitavou (Nové Zámky County), Málinec (Poltár County), Hrhov (Rožňava County), Veľké Ripňany (Topoľčany County), Kazimír, Luhyňa, Malý Horeš, Svätuše and Zatín (Trebišov County)), FI, UK (Northern Ireland, Isle of Man and Channel Islands)

3.3.1.2. Carriers of *Erwinia amylovora*

Beehives are regulated in Council Directive 2000/29/EC in Annex IV, Part B, point 21.3 (see Table 4).

Table 4: *Erwinia amylovora* carriers in Council Directive 2000/29/EC

Annex IV, Part B	Special requirements which must be laid down by all Member States for the introduction and movement of plants, plant products and other objects into and within certain protected zones		
	Plants, plant products and other objects	Special requirements	Protected zone(s)
21.3	From 15 March to 30 June, beehives	There shall be documented evidence that the beehives: (a) originate in third countries recognised as being free from *Erwinia amylovora* (Burr.) Winsl. et al. in accordance with the procedure laid down in Article 18(2), or (b) originate in the Canton of Valais in Switzerland, or (c) originate in the protected zones listed in the right-hand column, or (d) have undergone an appropriate quarantine measure before being moved	E (except the autonomous communities of Aragon, Castilla la Mancha, Castilla y León, Extremadura, Murcia, Navarra and La Rioja, and the province of Guipuzcoa (Basque Country), the Comarcas de L'Alt Vinalopó and El Vinalopó Mitjà in the province of Alicante and the municipalities of Alborache and Turís in the province of Valencia (Comunidad Valenciana)), EE, F (Corsica), IRL (except Galway City), I (Abruzzo, Apulia, Basilicata, Calabria, Campania, Emilia-Romagna (the provinces of Parma and Piacenza), Lazio, Liguria, Lombardy (except the provinces of Mantua and Sondrio), Marche, Molise, Piedmont, Sardinia, Sicily, Tuscany, Umbria, Valle d'Aosta, Veneto (except the provinces of Rovigo and Venice, the communes Barbona, Boara Pisani, Castelbaldo, Masi, Piacenza d'Adige, S. Urbano, Vescovana in the province of Padova and the area situated to the south of highway A4 in the province of Verona)), LV, LT (except the municipalities of Babtai and Kėdainiai (region of Kaunas)), P, SI (except the regions Gorenjska, Koroška, Maribor and Notranjska, and the communes of Lendava and Renče-Vogrsko (south from the highway H4)), SK (except the communes of Blahová, Čenkovce, Horné Mýto, Okoč, Topoľníky and Trhová Hradská (Dunajská Streda County), Hronovce and Hronské Kľačany (Levice County), Dvory nad Žitavou (Nové Zámky County), Málinec (Poltár County), Hrhov (Rožňava County), Veľké Ripňany (Topoľčany County), Kazimír, Luhyňa, Malý Horeš, Svätuše and Zatín (Trebišov County)), FI, UK (Northern Ireland, Isle of Man and Channel Islands)

3.3.1.3. Regulated hosts of *Erwinia amylovora*

E. amylovora affects plant species belonging to the subfamily Maloideae of the family Rosaceae. They are all regulated. Other incidental hosts have been described as *Rubus* sp. (Starr et al., 1951), but isolates from *Rubus* appear to be distinct on the basis of cross-infection studies (Ries and Otterbacher, 1977). *E. amylovora* was reported to cause a disease on plum (Mohan and Thomson, 1996; Vanneste et al., 2002), on apricot (Korba and Šillerová, 2010) and on ornamental Rosaceae species: *Rosa rugosa* (Vanneste et al., 2002), *R. canina* (Bastas et al., 2013) and *Spiraea prunifolia* (Bastas and Sahin, 2014). These findings support the fact that *E. amylovora* has possible additional or incidental hosts outside the subfamily Maloideae. Annex IIAII (see section 3.4.1) lists the major and minor hosts of *E. amylovora*.

Below, the specific requirements of Annex III, Annex IV and Annex V of Council Directive 2000/29/EC are presented only for the host plants and commodities regulated for *E. amylovora* in Annex IIAII.

Table 5: *Erwinia amylovora* host plants in Council Directive 2000/29/EC

Annex III, Part A	Plants, plant products and other objects the introduction of which shall be prohibited in all Member States	
	Description	Country of origin
9	Plants of *Chaenomeles* Lindl., *Cydonia* Mill., *Crateagus* L., *Malus* Mill., [...], *Pyrus* L., [...] intended for planting, other than dormant plants free from leaves, flowers and fruit	Non-European countries
18	Plants of *Cydonia* Mill., *Malus* Mill., [...] and *Pyrus* L. and their hybrids, and [...], intended for planting, other than seeds	Without prejudice to the prohibitions applicable to the plants listed in Annex IIIA(9), where appropriate, non-European countries, other than Mediterranean countries, Australia, New Zealand, Canada, the continental states of the USA
Annex III, Part B	Plants, plant products and other objects the introduction of which shall be prohibited in certain protected zones	
	Description	Protected zone(s)
1	Without prejudice to the prohibitions applicable to the plants listed in Annex IIIA(9), (9.1), (18), where appropriate, plants and live pollen for pollination of: *Amelanchier* Med., *Chaenomeles* Lindl., *Crataegus* L., *Cydonia* Mill., *Eriobotrya* Lindl., *Malus* Mill., *Mespilus* L., *Pyracantha* Roem., *Pyrus* L. and *Sorbus* L., other than fruit and seeds, originating in third countries other than Switzerland and other than those recognised as being free from *Erwinia amylovora* (Burr.) Winsl. et al. in accordance with the procedure laid down in Article 18(2), or in which pest-free areas have been established in relation to *Erwinia amylovora* (Burr.) Winsl.	E (except the autonomous communities of Aragon, Castilla la Mancha, Castilla y León, Extremadura, Murcia, Navarra and La Rioja, and the province of Guipuzcoa (Basque Country), the Comarcas de L'Alt Vinalopó and El Vinalopó Mitjà in the province of Alicante and the municipalities of Alborache and Turís in the province of Valencia (Comunidad Valenciana)), EE, F (Corsica), IRL (except Galway City), I (Abruzzo, Apulia, Basilicata, Calabria, Campania, Emilia-Romagna (the provinces of Parma and Piacenza), Lazio, Liguria, Lombardy (except the provinces of Mantua and Sondrio), Marche, Molise, Piedmont, Sardinia, Sicily, Tuscany, Umbria, Valle d'Aosta, Veneto (except the provinces of Rovigo and Venice, the communes Barbona, Boara Pisani, Castelbaldo, Masi, Piacenza d'Adige, S. Urbano, Vescovana in the province of Padova and the area situated to the south of highway A4 in the province of Verona)), LV, LT (except the municipalities of Babtai and Kėdainiai (region of Kaunas)), P, SI (except the regions Gorenjska, Koroška, Maribor and Notranjska, and the communes of Lendava and Renče-Vogrsko (south from

	et al. in accordance with the relevant International Standard for Phytosanitary Measures and recognised as such in accordance with the procedure laid down in Article 18(2)	highway H4)), SK (except the communes of Blahová, Čenkovce, Horné Mýto, Okoč, Topoľníky and Trhová Hradská (Dunajská Streda County), Hronovce and Hronské Kľačany (Levice County), Dvory nad Žitavou (Nové Zámky County), Málinec (Poltár County), Hrhov (Rožňava County), Veľké Ripňany (Topoľčany County), Kazimír, Luhyňa, Malý Horeš, Svätuše and Zatín (Trebišov County)), FI, UK (Northern Ireland, Isle of Man and Channel Islands)
2	Without prejudice to the prohibitions applicable to the plants listed in Annex IIIA(9), (9.1), (18), where appropriate, plants and live pollen for pollination of: *Cotoneaster* Ehrh. and *Photinia davidiana* (Dcne.) Cardot, other than fruit and seeds, originating in third countries other than those recognised as being free from *Erwinia amylovora* (Burr.) Winsl. et al. in accordance with the procedure laid down in Article 18(2), or in which pest-free areas have been established in relation to *Erwinia amylovora* (Burr.) Winsl. et al. in accordance with the relevant International Standard for Phytosanitary Measures and recognised as such in accordance with the procedure laid down in Article 18(2)	E (except the autonomous communities of Aragon, Castilla la Mancha, Castilla y León, Extremadura, Murcia, Navarra and La Rioja, and the province of Guipuzcoa (Basque Country), the Comarcas de L'Alt Vinalopó and El Vinalopó Mitjà in the province of Alicante and the municipalities of Alborache and Turís in the province of Valencia (Comunidad Valenciana)), EE, F (Corsica), IRL (except Galway City), I (Abruzzo, Apulia, Basilicata, Calabria, Campania, Emilia-Romagna (the provinces of Parma and Piacenza), Lazio, Liguria, Lombardy (except the provinces of Mantua and Sondrio), Marche, Molise, Piedmont, Sardinia, Sicily, Tuscany, Umbria, Valle d'Aosta, Veneto (except the provinces of Rovigo and Venice, the communes Barbona, Boara Pisani, Castelbaldo, Masi, Piacenza d'Adige, S. Urbano, Vescovana in the province of Padova and the area situated to the south of highway A4 in the province of Verona)), LV, LT (except the municipalities of Babtai and Kėdainiai (region of Kaunas)), P, SI (except the regions Gorenjska, Koroška, Maribor and Notranjska, and the communes of Lendava and Renče-Vogrsko (south from the highway H4)), SK (except the communes of Blahová, Čenkovce, Horné Mýto, Okoč, Topoľníky and Trhová Hradská (Dunajská Streda County), Hronovce and Hronské Kľačany (Levice County), Dvory nad Žitavou (Nové Zámky County), Málinec (Poltár County), Hrhov (Rožňava County), Veľké Ripňany (Topoľčany County), Kazimír, Luhyňa, Malý Horeš, Svätuše and Zatín (Trebišov County)), FI, UK (Northern Ireland, Isle of Man and Channel Islands).
Annex IV, Part A	Special requirements which must be laid down by all Member States for the introduction and movement of plants, plant products and other objects into and within all Member States	
Section I	Plants, plant products and other objects originating outside the Community	
	Plants, plant products and other objects	Special requirements
17	Plants of *Amelanchier* Med., *Chaenomeles* Lindl., *Cotoneaster* Ehrh., *Crataegus* L., *Cydonia* Mill., *Eriobotrya* Lindl., *Malus* Mill., *Mespilus* L., *Photinia davidiana* (Dcne.) Cardot, *Pyracantha* Roem., *Pyrus* L. and *Sorbus* L., intended for planting, other than seeds	Without prejudice to the provisions applicable to the plants listed in Annex III(A)(9), (9.1), (18), Annex III(B)(1) or Annex IV(A)(I)(15), where appropriate, official statement: (a) that the plants originate in countries recognised as being free from *Erwinia amylovora* (Burr.) Winsl. *et al.* in accordance with the procedure laid down in Article 18(2), or (b) that the plants originate in pest-free areas which have been established in relation to *Erwinia amylovora* (Burr.) Winsl. *et al.* in accordance with the relevant International Standard for Phytosanitary Measures and recognised as such in accordance with the procedure laid down in Article 18(2), or (c) that the plants in the field of production and in its immediate vicinity, which have shown symptoms of *Erwinia amylovora* (Burr.) Winsl. *et al.*, have been removed
Section II	Plants, plant products and other objects originating in the Community	

	Plants, plant products and other objects	Special requirements	
9	Plants of *Amelanchier* Med., *Chaenomeles* Lindl., *Cotoneaster* Ehrh., *Crataegus* L., *Cydonia* Mill., *Eriobotrya* Lindl., *Malus* Mill., Mespilus L., *Photinia davidiana* (Dcne.) Cardot, *Pyracantha* Roem., *Pyrus* L. and *Sorbus* L., intended for planting, other than seeds	Official statement: (a) the plants originate in zones recognised as being free from *Erwinia amylovora* (Burr.) Winsl. *et al*. in accordance with the procedure referred to in Article 18(2), or (b) that the plants in the field of production and its immediate vicinity, which have shown symptoms of *Erwinia amylovora* (Burr.) Winsl. *et al*., have been rogued out	
Annex IV, Part B	Special requirements which must be laid down by all Member States for the introduction and movement of plants, plant products and other objects into and within certain protected zones		
	Plants, plant products and other objects	Special requirements	Protected zone(s)
21	Plants and live pollen for pollination of: *Amelanchier* Med., *Chaenomeles* Lindl., *Cotoneaster* Ehrh., *Crataegus* L., *Cydonia* Mill., *Eriobotrya* Lindl., *Malus* Mill., *Mespilus* L., *Photinia davidiana* (Dcne.) Cardot, *Pyracantha* Roem., *Pyrus* L. and *Sorbus* L., other than fruit and seeds	Without prejudice to the prohibitions applicable to the plants listed in Annex IIIA(9), (9.1), (18) and IIIB(1), where appropriate, official statement that: (a) the plants originate in third countries recognised as being free from *Erwinia amylovora* (Burr.) Winsl. et al. in accordance with the procedure laid down in Article 18(2), or (b) the plants originate in pest-free areas in third countries which have been established in relation to *Erwinia amylovora* (Burr.) Winsl. et al. in accordance with the relevant International Standard for Phytosanitary Measures and recognised as such in accordance with the procedure laid down in Article 18(2), or (c) the plants originate in the Canton of Valais in Switzerland, or (d) the plants originate in the protected zones listed in the right-hand column, or (e) the plants have been produced, or, if moved into a 'buffer zone', kept and maintained for a period of at least seven months including the period 1 April to 31 October of the last complete cycle of vegetation, on a field: (aa) located at least 1 km inside the border of an officially designated 'buffer zone' of at least 50 km^2 where host plants are subject to an officially approved and supervised control regime established at the latest before the beginning of the complete cycle of vegetation preceding the last complete cycle of vegetation, with the object of minimising the risk of *Erwinia amylovora* (Burr.) Winsl. et al. being spread from the plants grown there. Details of the description of this "buffer zone" shall be kept available to the Commission and to other Member States. Once the "buffer zone" is	E (except the autonomous communities of Aragon, Castilla la Mancha, Castilla y León, Extremadura, Murcia, Navarra and La Rioja, and the province of Guipuzcoa (Basque Country), the Comarcas de L'Alt Vinalopó and El Vinalopó Mitjà in the province of Alicante and the municipalities of Alborache and Turís in the province of Valencia (Comunidad Valenciana)), EE, F (Corsica), IRL (except Galway City), I (Abruzzo, Apulia, Basilicata, Calabria, Campania, Emilia-Romagna (the provinces of Parma and Piacenza), Lazio, Liguria, Lombardy (except the provinces of Mantua and Sondrio), Marche, Molise, Piedmont, Sardinia, Sicily, Tuscany, Umbria, Valle d'Aosta, Veneto (except the provinces of Rovigo and Venice, the communes Barbona,

		established, official inspections shall be carried out in the zone not comprising the field and its surrounding zone of 500 m width, at least once since the beginning of the last complete cycle of vegetation at the most appropriate time, and all host plants showing symptoms of *Erwinia amylovora* (Burr.) Winsl. et al. should be removed immediately. The results of these inspections shall be supplied by 1 May each year to the Commission and to other Member States, and (bb) which has been officially approved, as well as the “buffer zone”, before the beginning of the complete cycle of vegetation preceding the last complete cycle of vegetation, for the cultivation of plants under the requirements laid down in this point, and (cc) which, as well as the surrounding zone of a width of at least 500 m, has been found free from *Erwinia amylovora* (Burr.) Winsl. et al. since the beginning of the last complete cycle of vegetation, at official inspection carried out at least: — twice in the field at the most appropriate time, i.e. once during June to August and once during August to November; and — once in the said surrounding zone at the most appropriate time, i.e. during August to November, and (dd) from which plants were officially tested for latent infections in accordance with an appropriate laboratory method on samples officially drawn at the most appropriate period. Between 1 April 2004 and 1 April 2005, these provisions shall not apply to plants moved into and within the protected zones listed in the right-hand column which have been produced and maintained on fields located in officially designated “buffer zones”, according to the relevant requirements applicable before 1 April 2004	Boara Pisani, Castelbaldo, Masi, Piacenza d’Adige, S. Urbano, Vescovana in the province of Padova and the area situated to the south of highway A4 in the province of Verona)), LV, LT (except the municipalities of Babtai and Kėdainiai (region of Kaunas)), P, SI (except the regions Gorenjska, Koroška, Maribor and Notranjska, and the communes of Lendava and Renče-Vogrsko (south from the highway H4)), SK (except the communes of Blahová, Čenkovce, Horné Mýto, Okoč, Topoľníky and Trhová Hradská (Dunajská Streda County), Hronovce and Hronské Kľačany (Levice County), Dvory nad Žitavou (Nové Zámky County), Málinec (Poltár County), Hrhov (Rožňava County), Veľké Ripňany (Topoľčany County), Kazimír, Luhyňa, Malý Horeš, Svätuše and Zatín (Trebišov County)), FI, UK (Northern Ireland, Isle of Man and Channel Islands)
Annex V	Plants, plant products and other objects which must be subject to a plant health inspection (at the place of production if originating in the Community, before being moved within the Community—in the country of origin or the consignor country—if originating outside the Community) before being permitted to enter the Community		
Part A	Plants, plant products and other objects originating in the Community		
Section I	Plants, plant products and other objects which are potential carriers of harmful organisms of relevance for the entire Community and which must be accompanied by a plant passport		
1	Plants and plant products		
1.1	Plants, intended for planting, other than seeds, of *Amelanchier* Med., *Chaenomeles* Lindl., *Cotoneaster* Ehrh., *Crataegus* L., *Cydonia* Mill., *Eriobotrya* Lindl., *Malus* Mill., *Mespilus* L., *Photinia davidiana* (Dcne.) Cardot, [...] *Pyracantha* Roem., *Pyrus* L. and *Sorbus* L.		

Section II	Plants, plant products and other objects which are potential carriers of harmful organisms of relevance for certain protected zones, and which must be accompanied by a plant passport valid for the appropriate zone when introduced into or moved within that zone
1	Plants, plant products and other objects
1.3	Plants, other than fruit and seeds, of *Amelanchier* Med., [...], *Chaenomeles* Lindl., *Cotoneaster* Ehrh., *Crataegus* L., *Cydonia* Mill., *Eriobotrya* Lindl., [...] *Malus* Mill., *Mespilus* L., *Photinia davidiana* (Dcne.) Cardot, *Pyracantha* Roem., *Pyrus* L., *Sorbus* L. [...]
1.4	Live pollen for pollination of *Amelanchier* Med., *Chaenomeles* Lindl., *Cotoneaster* Ehrh., *Crataegus* L., *Cydonia* Mill., *Eriobotrya* Lindl., *Malus* Mill., *Mespilus* L., *Photinia davidiana* Cardot, *Pyracantha* Roem., *Pyrus* L. and *Sorbus* L.
Part B	Plants, plant products and other objects originating outside the Community
Section I	Plants, plant products and other objects which are potential carriers of harmful organisms of relevance for the entire Community
1	Plants, intended for planting, other than seeds
Section II	Plants, plant products and other objects which are potential carriers of harmful organisms of relevance for certain protected zones
3	Live pollen for pollination of *Amelanchier* Med., *Chaenomeles* Lindl., *Cotoneaster* Ehrh., *Crataegus* L., *Cydonia* Mill., *Eriobotrya* Lindl., *Malus* Mill., *Mespilus* L., *Photinia davidiana* (Dcne.) Cardot, *Pyracantha* Roem., *Pyrus* L. and *Sorbus* L.
4	Parts of plants, other than fruit and seeds, of *Amelanchier* Med., *Chaenomeles* Lindl., *Cotoneaster* Ehrh., *Crataegus* L., *Cydonia* Mill., *Eriobotrya* Lindl., *Malus* Mill., *Mespilus* L., *Photinia davidiana* (Dcne.) Cardot, *Pyracantha* Roem., *Pyrus* L. and *Sorbus* L.

3.3.2. Marketing directives

The host plants of *E. amylovora* that are regulated in Annex IIAII of Council Directive 2000/29/EC are mentioned in the following Marketing Directives:

- Council Directive 2008/90/EC[5] of 29 September 2008 on the marketing of fruit plant propagating material and fruit plants intended for fruit production;
- Council Directive 98/56/EC[6] of 20 July 1998 on the marketing of propagating material of ornamental plants.

3.4. Elements to assess the potential for establishment and spread in the EU

3.4.1. Host range

Fire blight has been described in nearly 200 plant species, mostly within the family Rosaceae, and within the subfamily Maloideae (van der Zwet and Keil, 1979). The most frequent host genera are *Chaenomeles*, *Cotoneaster*, *Crataegus*, *Cydonia*, *Eriobotrya*, *Malus*, *Mespilus*, *Pyrus*, *Photinia*, *Pyracantha*, *Sorbus* and *Stranvaesia*. However, losses are more important on pear, apple and quince. Fire blight has also been described in raspberry (Starr et al., 1951), Japanese and European plum (Mohan and Thomson, 1996; Vanneste et al., 2002), apricot (Korba and Šillerová, 2010) and *Spirea prunifolia*, *R. canina* and *R. rugosa* (Vanneste et al., 2002; Bastas et al., 2013; Bastas and Sahin, 2014), but these plants seem to get infested only under a very high pressure of inoculum in the field. The last five hosts are not regulated in Directive 2000/29/EC. Susceptibility within a host species is highly dependent on cultivars, and pear cultivars are generally more susceptible than table apples. Cider apple cultivars are generally susceptible, especially those with a late bloom period that coincides

5 Council Directive 2008/90/EC of 29 September 2008 on the marketing of fruit plant propagating material and fruit plants intended for fruit production. OJ L 267, 8.10.2008, p. 8–22.

6 Council Directive 98/56/EC of 20 July 1998 on the marketing of propagating material of ornamental plants. OJ L 226, 13.8.1998, p. 16.

with a high risk of infection (Paulin and Primault, 1993; Martínez-Bilbao et al., 2009; see also Table 6). Loquat cultivars are also highly susceptible (Zilberstaine et al., 1996). Within the ornamental and wild plants, members of the genus *Cotoneaster* are generally very susceptible, as are several species of *Crataegus* and the majority of *Pyracantha* species, and, among *Sorbus* spp., *S. aria* is the most susceptible (van der Zwet and Beer, 1995).

Table 6: Examples of pear, apple and cider apple cultivars susceptible to fire blight. Extracted from Thibault and Le Lezec, 1990; Zeller, 1990; Paulin and Primault, 1993; van der Zwet and Beer, 1995; Martínez-Bilbao et al., 2009; van der Zwet et al., 2012). For some cultivars (e.g. Pinova) the classification in terms of susceptibility varies in the literature

		Pear	
Susceptible to a low degree	**Moderately susceptible**	**Susceptible**	**Highly susceptible**
Ercolini (Coscia)	Bonne Luise des Avranches	Abate Fétel	Alexandrine Douillard
Magallón (Leonardeta)	Beurre Bosc (Kaiser)	Blanquilla	Doyenne du Comice
Rome	Beurre Hardy	Conference	Packham's Triumph
Harrow	Beurre Precoz Morettini	Devoe	Passe Crassane
		General Leclerc	
		Grand Champion	
		Limonera (Dr Jules Guyot)	
		Santa Maria Morettini	
		Williams' (Bartlett)	
		Rocha	
		Table apple	
Susceptible to a low degree	**Moderately susceptible**	**Susceptible**	**Highly susceptible**
Early Red One	Gala	Rome Beauty	Idared
Golden Delicious	Granny Smith	Fuji	Reina de Reinetas
Golden Smoothee	Jonagold	Gloster	
Lysgolden	Reineta Gris	Jonathan	
Mutsu	Pinova	Melrose	
Oregon Spur		Verde Doncella	
Ozak Gold		Pink Lady	
Red Chief		Braeburn	
Reineta Blanca			
Royal Gala			
Starking Delicious			
Starkimson			
Topred			
		Cider apple	
Susceptible to a low degree	**Moderately susceptible**	**Susceptible**	**Highly susceptible**
Rouget de Dol		Douce Coet	Avrolles
Judor		Marie Ménard	Binet Rouge
Reineta de Asturias		Bédan	Clos Renaud
Morro de Liebre		Peau de Chien	Douce Möen
Miguela de Ademuz		Reineta Regil	Locard Vert
			Pero Pardo
			Txalaka

3.4.2. EU distribution of main host plants

Some of the main host plants are widely grown in a wide range of EU MSs for production of table apples and pears and industrial processing (cider and juice apples and quince) (Table 7). In addition, the ornamental host plants have a widespread distribution in the EU, including nurseries and wild plants (Dickoré and Kasperek, 2010).

Table 7: Area of production in 1 000 ha for apples (including cider apples) (*Malus spp.*), pears (including perry pears) (*Pyrus communis*) and quinces (*Cydonia oblonga*). (Source: Hucorne, 2012. Data on production areas have been retrieved from the Eurostat database. The mean of the years 2006–2010 has been calculated for each crop/country)

Country	Apples (including cider apples) (*Malus spp.*)	Pears (including perry pears) (*Pyrus communis*)	Quinces (*Cydonia oblonga*)
Austria	6.1	0.4	0.0
Belgium	8.2	8.1	0.0
Bulgaria	5.4	0.5	0.3
Croatia	6.3	1.5	0.0
Cyprus	1.1	0.1	0.0
Czech Republic	9.9	0.6	0.0
Denmark	1.6	0.4	0.0
Estonia	1.1	0.0	0.0
Finland	0.7	0.1	0.0
Northern France	23.8	2.3	0.1
Southern France	26.4	5.4	0.1
Germany	31.9	2.1	0.0
Greece	12.2	4.3	0.2
Hungary	42.3	3.1	0.1
Ireland	0.0	0.0	0.0
Italy	59.7	41.0	0.1
Latvia	5.9	0.4	0.1
Lithuania	12.5	0.9	0.1
Luxembourg	0.2	0.0	0.0
Malta	0.0	0.0	0.0
Netherlands	9.2	7.5	0.0
Poland	174.3	13.0	0.0
Portugal	17.7	12.1	0.4
Romania	56.4	4.6	0.9
Slovakia	3.0	0.1	0.0
Slovenia	3.1	0.3	0.0
Spain	35.2	30.8	1.3
Sweden	1.5	0.2	0.0
UK	15.3	1.6	0.0
EU-28	571	141.4	3.7

3.4.3. Analysis of the potential pest distribution in the EU

Fire blight has been reported in most important pome fruit-growing areas of the EU, and it is already established in many of them. Eradication campaigns are ongoing in most of the areas where *E. amylovora* is established. There are still regions without fire blight within the EU MSs where the susceptible hosts are grown, and the presence/absence may change from year to year. Currently, fire blight has the potential to reach its maximum possible distribution in the EU, because in the past 50 years the disease has spread across most MSs, following a pattern closely related to the areas where susceptible host plants are cultivated (apple, pear, quince and susceptible ornamentals). All fruit tree-growing areas of the EU are predicted to be at risk of fire blight (Llorente et al., 2002; Palacio-Bielsa and Cambra, 2009; van der Zwet et al., 2012): this is according to model outputs from agro-climatic forecasting systems for fire blight, e.g. Maryblyt (Lightner and Steiner, 1990; Steiner and Lightner, 1996), which confirm that environmental conditions are favourable for fire blight in such European pome fruit-cultivating areas.

3.4.4. Spread capacity

The main risk of introduction and spread of fire blight over medium and long distances is through plant material contaminated with *E. amylovora*, and mainly through plant nursery materials, because the pathogen can live as an epiphyte or an endophyte in buds and shoots (Calzolari et al., 1982; López et al., 1999). The survival of *E. amylovora* at very low population levels in calyxes of apple fruit discarded in an orchard has been demonstrated, but the potential inoculum was not transferred to susceptible hosts, even when the apples were placed in close proximity to hosts that were in the receptive stage of flowering (Taylor et al., 2003; Ordax et al., 2009).

Fingerprinting techniques can be used as tools for tracing the spread from an outbreak of fire blight and making comparisons between outbreaks and assessments of the source of the introduction (forensic epidemiology). For example, the spread of fire blight in different parts of Europe was followed by PFGE (Jock et al., 2002). In another study, the analysis of a collection of strains from Spain by means of molecular techniques provided evidence of multiple introductions in several affected areas. It also showed that imported plant material from a nursery was the source of an initial outbreak (Donat et al., 2007; Jock et al., 2002; Llop et al., 2011).

Once infections have taken place, rain and wind (especially thunderstorms) play an important role in the transport of inoculum (e.g. bacterial exudates containing protecting mucopolysaccharides) over short distances and probably also over medium to long distances (aero currents).

Insect pollinators are efficient carriers over short and medium distances. For example *E. amylovora* can survive for several days in bees (Alexandrova et al., 2002), for several weeks in pollen, nectar and honey (Vanneste, 1996), and for up to four weeks in *C. capitata* (Ordax et al., 2010). Other insects and birds (Seidel et al., 1994) may potentially transport inoculum.

Workers in orchards can serve as an efficient system of disseminating *E. amylovora*, especially over short to medium distances, by means of hands, clothing, pruning and spraying tools that can be contaminated after manipulating infected plant material (van der Zwet and Keil, 1979; Ceroni et al., 2004; Mazzucchi et al., 2006).

3.5. Elements to assess the potential for consequences in the EU

3.5.1. Potential pest effects

E. amylovora poses a risk to the pear and apple production sector as well as to the nursery trade, since several ornamental species are susceptible hosts that can develop fire blight disease if infected. The often rapid spread of fire blight in certain conditions and the progressive death of affected trees of susceptible cultivars and species, especially pear, have had a strong impact in areas of the USA and the EU where these crops have been abandoned or deeply restructured (van der Zwet and Keil, 1979; van der Zwet et al., 2012).

Both direct losses of fruit trees from fire blight disease and indirect losses arising from the need for removal of infected material can have a considerable impact on productivity. The additional efforts needed for specific measures required to manage fire blight (treatments, inspections, laboratory analysis, eradication), and the effect on the structure of the pome fruit sector (cultivar changes, difficulties for integrated pest management) are also important pest effects (van der Zwet and Beer, 1995; Vanneste, 2000). In terms of the export trade in plant material of susceptible hosts, the presence of fire blight in a country is a major constraint.

Where cultivation of host plants for fruit production occurs under cold environmental conditions, early-blooming varieties are used in order to guarantee that the fruits will ripen during the growing season. In addition, the cold winters in such areas contribute to a narrow synchronised blooming period. These two factors mean that the period of bloom only rarely coincides with periods with weather conditions favourable for infection (Sletten and Rafoss, 2007), thereby reducing the risk of infection. However, the presence of other host species with longer blooming periods, such as some *Cotoneaster*, *Crateagus and Pyracantha* cultivars, can maintain epidemics between periods of disease attack on fruit production host plants. Thus, removal of susceptible ornamental or spontaneous plants has been included in control programmes (Provinz Südtirol, 2005), but it has the effect of reducing biodiversity in landscapes.

3.5.2. Observed pest impact in the EU

The impact caused by fire blight in the countries where it has occurred is very severe, especially with the first outbreaks in pathogen-free areas. Generally, pear has been more affected than apple: in particular, most of the susceptible cultivars (Passe Crassane, Durondeau, General Leclerc, Santa Maria, Williams' and some local cultivars) have suffered important losses and have disappeared or are tending to be replaced by other cultivars.

This impact is illustrated by the spread of the disease since the first detection in the UK in 1958 in Kent (Crosse et al., 1958). Thereafter, *E. amylovora* was first identified in 1966 in the Netherlands and Poland and, years later, in Denmark, and in the early1970s it was identified in Germany, Belgium and France. In the1980s, the disease was reported in Luxembourg, Ireland, Norway, Sweden, the Czech Republic and Switzerland, as well as in Cyprus and Greece. In the 1990s, fire blight was reported in Austria, Moldova, Italy, Spain, Bulgaria, Romania, Hungary, Albania and the former Yugoslavia. More recently, in the past decade, *E. amylovora* has been detected in Slovakia, and in some non-EU countries, such as Ukraine (Vanneste, 2000; van der Zwet et al., 2012).

Losses of nursery material, losses of orchard acreage and losses of production have been documented. For instance, in the Emilia Romagna region (one of the most important pear production areas of the EU, where approximately 65 % of Italian pear production is concentrated), over one million trees were destroyed between 1994 and 2004 (Regione Emilia Romagna, 2005).

The pattern of spread of fire blight has been similar in most MSs. After an initial outbreak consisting of a single focus or multiple foci, the disease generally spreads rapidly within or towards large orchard areas. Frequently during this stage, especially if highly susceptible pear or apple cultivars are present, the disease may advance 100–300 km from the original outbreak in five to six years, having considerable impact on the fruit production sector, killing thousands of trees or causing uprooting or destruction of trees because of the eradication measures needed to manage disease spread. After this period of expansion, it is reported that coexistence with fire blight is possible through different management measures. The pattern of spread depends on the density and distribution of the susceptible hosts in a given area. Additional details on the evolution of fire blight can be found for the UK, France, the Netherlands, Belgium, Poland, Germany and Greece (Vanneste, 2000), Norway (Sletten and Rafoss 2007; Melbøe et al., 2014), Spain (Palacio-Bielsa and Cambra, 2009) and Italy (Finelli et al. 1996; Regione Emilia Romagna, 2005).

3.6. Currently applied control methods in the EU

Mandatory certification of propagation material is in place to guarantee the phytosanitary quality of host plants in trade. In addition to the regulatory tools, the management strategy of fire blight aims to interfere with key stages of the disease cycle, attending to the biology and ecology of *E. amylovora* and taking into account the sources of inoculum, spread mechanisms and the dynamics of progression of the disease (Johnson and Stockwell, 1998). Sanitation methods target the removal of infected tissue by pruning during dormancy and during the growing season, to reduce sources of infection. In addition, removal by up-rooting of infected fruit trees, as well as wild hosts in the vicinity of the orchard, is carried out (van Teylingen, 2002).

The use of host resistant material is only a restrictedly reliable strategy to control fire blight. Unfortunately, there is no plant material completely resistant to fire blight and the most resistant varieties currently available still have moderate to low susceptibility to fire blight (Thibault and Le Lezec, 1990; van der Zwet and Beer, 1995). All materials obtained by Mendelian crossing are moderately resistant, such as Harrow and Harvest pears (Agriculture and Agro-food Canada), or cider apple (Paulin and Primault, 1993; Martínez-Bilbao et al., 2009). However, transgenic apple varieties with a high level of resistance to fire blight have been developed, e.g. a transgenic derivative from Royal Gala (Norelli et al., 2003; Malnoy et al., 2004) and a cisgenic Gala derivative (Broggini et al., 2014). Transgenic apple plants are not allowed to be planted in the EU.

There are no known curative agents that can remove *E. amylovora* from infected plants. Unfortunately, methods for decreasing pathogen inoculum in propagative plant material have limitations: thermotherapy needs high temperatures to kill *E. amylovora*, thus affecting survival of the buds, and disinfectant treatments (e.g. quaternary ammonia, chlorine) do not affect endophytic inoculum (Keck et al., 1995; Ruz et al., 2008). Therefore, the control methods currently applied target prevention of infection.

Chemical control methods have not advanced significantly in the last 50 years. There are a limited number of products available, generally with moderate efficacy, such as copper compounds and certain antibiotics that are applied preventatively (Johnson and Stockwell, 1998; Adaskaveg et al., 2011; Ngugi et al., 2011). Conventional antibiotics, such as streptomycin, tetracycline or kasugamicin, that are authorised for use against fire blight in several countries (e.g. the USA) are not authorised in the EU (only under derogation in some MSs), in spite of the fact that they are the most effective compounds. Nonetheless, resistance to streptomycin has been reported in various cases in the USA (Schroth et al., 1979) where it has been used, linked to the presence of transmissible plasmids that were responsible for a reduced level of control or failure to control the disease in the field (Chiou and Jones, 1995). Copper compounds are the only chemical plant protection products authorised in the EU (EU Pesticide database, online). Copper compounds are sprayed outside the blooming period because they are highly phytotoxic to flowers. Other copper compounds, not listed as phytosanitary products, and not well regulated in the EU, contain copper at low concentrations at high solubility and are commercially available as plant strengtheners or fertilisers (in the form of gluconates, salicylates, alginates). They display a certain ability to control fire blight infection.

Several biocontrol agents have been developed against fire blight and consist of strains of bacteria, such as *Pantoea agglomerans*, *P. vagans*, *Pseudomonas fluorescens*, *Bacillus subtilis/ amyloliquefaciens* and *Lactobacillus plantarum*, or fungi, such as *Aureobasidium pullulans*, and recently specific bacteriophages (reviewed in Bonaterra et al., 2012). The efficacy of several microbial products available on the market for control of fire blight was evaluated in the eastern USA, and they have been shown to have a moderate efficacy (Sundin et al., 2009). In the EU, biocontrol agents and corresponding products have been authorised according to Directive 128/2009 and Regulation 1107/2009, consisting of *B. amyloliquefaciens* QST713, and *A. pullulans* strains DSM14190 and DSM14191 (EU Pesticide database, online).

During the post-bloom stages, the use of plant defence stimulation or resistance-inducing products is recommended, but these products are less efficient than chemical and biological products acting directly against *E. amylovora* (Ngugi et al., 2011). In addition to chemical control methods, several agronomic measures are recommended, such as using lower levels of nitrogen fertiliser to prevent excess plant vigour and prevent secondary flowering, avoiding overhead irrigation systems that favour wetness and inoculum dissemination, performing pruning during winter time to eliminate cankers and infected material and disinfecting tools (Van der Zwet et al., 2012).

Fire blight forecasting systems to predict risk and evolution of the disease have proved useful as tools for timing of treatments (Billing, 1980), especially during the bloom period, and to manage prospections and sampling. They are based on measurement of agro-climatic conditions (temperature, rain, wetness, tree phenology) and there are computer-based tools. A description of existing models is available (University of California, online). One of the most widely used systems is Maryblyt (Steiner and Lightner, 1996), and it has been evaluated in the south of Europe under Mediterranean conditions (Llorente et al., 2002; Palacio-Bielsa et al., 2012). Surveillance programmes are also a key preventative control measure in order to coordinate and prioritise control efforts either at the MS level or at regional levels within a MS (Finelli et al., 2014).

3.7. Uncertainty

- There are a few sources of uncertainty affecting the pest categorisation conclusions to a minor extent.
- There is some uncertainty associated with the absence/presence status of *E. amylovora* in the different MSs, as the Panel has limited information about the survey methods in use.
- There are some uncertainties on the role of contaminated ripened fruits as carriers of inoculum.
- There are some uncertainties on the role of birds in pathogen dissemination; there are only circumstantial indications related to unexpected outbreaks.
- Uncertainty is also related to possible new hosts outside the *Maloideae* subfamily.

CONCLUSIONS

In Table 8 below the Panel summarises its conclusions on the key elements addressed in this scientific opinion in consideration of the pest categorisation criteria defined in ISPM 11 and ISPM 21 and of the additional questions formulated in the terms of reference.

Table 8: The Panel's conclusions on the pest categorisation criteria defined in the International Standards for Phytosanitary Measures (ISPM) No 11 and No 21 and on the additional questions formulated in the terms of reference (ToRs)

Criterion of pest categorisation	Panel's conclusions on ISPM 11 criterion	Panel's conclusions on ISPM 21 criterion	List of main uncertainties
Identity of the pest	*Is the identity of the pest clearly defined? Do clearly discriminative detection methods exist for the pest?*		–
	The identity of the pest is clearly defined. *E. amylovora* is unambiguously detected and identified by microbiological, serological and nucleic acid-based methods		

Criterion of pest categorisation	Panel's conclusions on ISPM 11 criterion	Panel's conclusions on ISPM 21 criterion	List of main uncertainties
Absence/presence of the pest in the risk assessment area	*Is the pest absent from all or a defined part of the risk assessment area?* The pathogen is absent in a few MSs (Estonia, Finland, Malta) and present with restricted distribution in many MSs	*Is the pest present in the risk assessment area?* The pathogen is present in most MSs where important host plants (apple, pear, quince) are cropped or produced in nurseries	Uncertainties are associated with the efficacy of the surveys
Regulatory status	*Mention in which annexes of 2000/29/EC and the marketing directives the pest and associated hosts are listed without further analysis Indicate also whether the hosts and/or commodities for which the pest is regulated in AIIAI or II are comprehensive of the host range* *E. amylovora* and the main associated hosts are under official control and regulated by Directive 2000/29/EC (Annexes IIAII, IIB, IIIA, IIIB, IVAI, IVAII, IVB, VAI, VAII and VBII) and by Directive 2008/90/EC and Council Directive 98/56/EC There are five possible additional hosts (apricot, plum, *Rosa canina*, *R. rugosa* and *Spirea prunifolia*) which are currently not regulated		–
Potential for establishment and spread	*Does the risk assessment area have ecological conditions (including climate and those in protected conditions) suitable for the establishment and spread of the pest?* *Indicate whether the host plants are also grown in areas of the EU where the pest is absent* *And, where relevant, are host species (or near relatives), alternative hosts and vectors present in the risk assessment area?* The susceptible hosts are grown in all MSs. Ecological and climatic conditions suitable for fire blight are present in several areas and regions around the Mediterranean and Central Europe, where summers are warm and humid, with several rain showers and hail storms. This is in accordance with predictions made by disease forecasting models. In northern Europe, although a sporadic disease on fruit trees, it is regularly present in other ornamental and wild host plants Storms, insects (bees), contaminated pollen and susceptible plant propagation material are the main sources of spread of the disease	*Are plants for planting a pathway for introduction and spread of the pest?* Propagating plant material is the main source of introduction of fire blight in pathogen-free areas. Plants for planting, especially grafted rootstocks, might be latently infected by the pathogen and are the most important pathway for its introduction and spread, since they may harbour the pathogen both endophytically and in buds	There are some uncertainties on the role of contaminated ripened fruits as carriers of inoculum There are some uncertainties on the role of birds for the dissemination, and there are only circumstantial indications related to unexpected outbreaks

Criterion of pest categorisation	Panel's conclusions on ISPM 11 criterion	Panel's conclusions on ISPM 21 criterion	List of main uncertainties
Potential for consequences in the risk assessment area	*What are the potential for consequences in the risk assessment area?* *Provide a summary of impact in terms of yield and quality losses and environmental consequences*	*If applicable, is there an indication of the impact(s) of the pest as a result of the intended use of the plants for planting?*	–
	The impact is high in terms of yield and quality losses to the pear and apple production sector owing to the progressive death of affected trees, either plant parts or whole individuals. It is also a major constraint to the nursery trade. However, the impact of the disease varies considerably from year to year in affected areas	One of the main sources of disease introduction in new areas is contaminated host plant material (mainly apple and pear), and there have been several examples of this since the first introduction of fire blight into the EU. The intended use of infected plant material may lead to outbreaks and losses in horticulture	
	Regarding the direct losses caused during production, there is a negative impact on crop management of the specific measures required to coexist with fire blight (treatments, inspections, laboratory analysis, eradication, cultivar changes)		
Conclusion on pest categorisation	*E. amylovora* is present in many areas of the EU, where its host plants are widely distributed; nonetheless, mandatory control measures are in place. It has a severe direct impact on crops (in terms of both losses of trees and plants and losses in yield and quality), causing an increase in indirect costs for growers owing to the management measures needed (e.g. an increased number of chemical treatments, active eradication), which often are not effective enough to control the disease	The pathogen is present in most MSs where important host plants (apple, pear, quince) are cropped or produced in nurseries Propagating plant material is the main source of introduction of fire blight in pathogen-free areas and the intended use of infected plant material may lead to outbreaks and losses in horticulture	–

Criterion of pest categorisation	Panel's conclusions on ISPM 11 criterion	Panel's conclusions on ISPM 21 criterion	List of main uncertainties
Conclusion on specific ToR questions	*If the pest is already present in the EU, provide a brief summary of:* – *the analysis of the present distribution of the organism in comparison with the distribution of the main hosts, and the distribution of hardiness/climate zones, indicating in particular if, in the risk assessment area, the pest is absent from areas where host plants are present and where the ecological conditions (including climate and those in protected conditions) are suitable for its establishment;* *E. amylovora* is widespread (except in buffer and protected zones) in Austria, Belgium, Bulgaria, Cyprus, Greece, Romania and the Netherlands; it is present in restricted areas (in several of them under eradication) in Croatia, the Czech Republic, Denmark, France, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden and the UK; and it is absent in Estonia, Finland and Malta Its main host plants (apple, pear, quince and several ornamental plants such as *Pyracantha*, *Cotoneaster*, *Crataegus*) are widely cultivated throughout the risk assessment area or present in gardens or in the wild. Host genotype (species and cultivars) has an important role in disease epidemics. Ecological and climatic conditions suitable for fire blight are present in the main apple and pear production areas. Therefore, there is great potential for the pathogen to spread and establish into new areas where pome fruits are cultivated *and* – *the analysis of the observed impacts of the organism in the risk assessment area* The analysis of past disease outbreaks previously reported in the EU and in other parts of the world highlights the great potential for the disease to have a severe impact on commercial horticulture, especially on apple, pear and quince, as well as on the nursery trade		There is some uncertainty associated with the absence/ presence status of *E. amylovora* in the different Member States, as the Panel has limited information about the survey methods in use

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ABBREVIATIONS

EFSA	European Food Safety Authority
EPPO	European and Mediterranean Plant Protection Organization
EPPO-PQR	European and Mediterranean Plant Protection Organization Plant Quarantine Retrieval System
ISPM	International Standards for Phytosanitary Measures
MS	Member State
NPPO	national plant protection organisation
PFGE	pulsed-field gel electrophoresis
PLH Panel	Plant Health Panel
PRA	pest risk analysis
RNQP	regulated non-quarantine pest