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Pest categorisation of *Phyllosticta solitaria*

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Abstract

The Panel on Plant Health performed a pest categorisation of *Phyllosticta solitaria*, the causal agent of blotch of apple, for the EU. The pest is a well-defined fungal species and methods are available for its detection and identification. *P. solitaria* is present in Canada and the continental states of the USA. The pest is not known to occur in the EU and is listed in Annex IAI of Directive 2000/29/EC, meaning its introduction into the EU is prohibited. The major cultivated host is *Malus domestica* (apple), but wild *Malus* and *Crataegus* species may also be affected. All hosts and major pathways of entry of the pest into the EU are currently regulated. The disease is favoured by warm, wet weather during the growing season. Host availability and climate matching suggest that *P. solitaria* could establish in parts of the EU and further spread mainly by human-assisted means. The pest causes premature defoliation, fruit cracking and rot, and twig and branch cankers. At the beginning of the 20th century, disease incidences of 70–90% on fruit of untreated susceptible apple cultivars had been reported and the disease was considered as a limiting factor in the commercial production of those cultivars. Nowadays, the disease is rare in commercial apple orchards, probably due to regular fungicide sprays against other diseases. The pest introduction in the EU would potentially cause impacts to apple production. The main uncertainties concern the host range, the maximum distance of conidial dispersal by wind-driven rain, and the magnitude of potential impacts to the EU. *P. solitaria* meets all the criteria assessed by EFSA for consideration as a potential Union quarantine pest. The criteria for considering *P. solitaria* as a potential Union regulated non-quarantine pest are not met, since the pest is not known to occur in the EU.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

1.1.1. Background

Council Directive 2000/29/EC¹ on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community establishes the present European Union plant health regime. The Directive lays down the phytosanitary provisions 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. In the Directive's 2000/29/EC annexes, the list of harmful organisms (pests) whose introduction into or spread within the Union is prohibited, is detailed together with specific requirements for import or internal movement.

Following the evaluation of the plant health regime, the new basic plant health law, Regulation (EU) 2016/2031² on protective measures against pests of plants, was adopted on 26 October 2016 and will apply from 14 December 2019 onwards, repealing Directive 2000/29/EC. In line with the principles of the above-mentioned legislation and the follow-up work of the secondary legislation for the listing of EU regulated pests, EFSA is requested to provide pest categorizations of the harmful organisms included in the annexes of Directive 2000/29/EC, in the cases where recent pest risk assessment/pest categorisation is not available.

1.1.2. Terms of reference

EFSA is requested, pursuant to Article 22(5.b) and Article 29(1) of Regulation (EC) No 178/2002³, to provide scientific opinion in the field of plant health.

EFSA is requested to prepare and deliver a pest categorisation (step 1 analysis) for each of the regulated pests included in the appendices of the annex to this mandate. The methodology and template of pest categorisation have already been developed in past mandates for the organisms listed in Annex II Part A Section II of Directive 2000/29/EC. The same methodology and outcome is expected for this work as well.

The list of the harmful organisms included in the annex to this mandate comprises 133 harmful organisms or groups. A pest categorisation is expected for these 133 pests or groups and the delivery of the work would be stepwise at regular intervals through the year as detailed below. First priority covers the harmful organisms included in Appendix 1, comprising pests from Annex II Part A Section I and Annex II Part B of Directive 2000/29/EC. The delivery of all pest categorisations for the pests included in Appendix 1 is June 2018. The second priority is the pests included in Appendix 2, comprising the group of *Cicadellidae* (non-EU) known to be vector of Pierce's disease (caused by *Xylella fastidiosa*), the group of *Tephritidae* (non-EU), the group of potato viruses and virus-like organisms, the group of viruses and virus-like organisms of *Cydonia* Mill., *Fragaria* L., *Malus* Mill., *Prunus* L., *Pyrus* L., *Ribes* L., *Rubus* L. and *Vitis* L. and the group of *Margarodes* (non-EU species). The delivery of all pest categorisations for the pests included in Appendix 2 is end 2019. The pests included in Appendix 3 cover pests of Annex I part A section I and all pest categorisations should be delivered by end 2020.

For the above-mentioned groups, each covering a large number of pests, the pest categorisation will be performed for the group and not the individual harmful organisms listed under "such as" notation in the Annexes of the Directive 2000/29/EC. The criteria to be taken particularly under consideration for these cases, is the analysis of host pest combination, investigation of pathways, the damages occurring and the relevant impact.

Finally, as indicated in the text above, all references to 'non-European' should be avoided and replaced by 'non-EU' and refer to all territories with exception of the Union territories as defined in Article 1 point 3 of Regulation (EU) 2016/2031.

¹ Council Directive 2000/29/EC of 8 May 2000 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 169/1, 10.7.2000, p. 1–112.

² Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants. OJ L 317, 23.11.2016, p. 4–104.

³ 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.

1.1.2.1. Terms of Reference: Appendix 1

List of harmful organisms for which pest categorisation is requested. The list below follows the annexes of Directive 2000/29/EC.

Annex IIAI

(a) Insects, mites and nematodes, at all stages of their development

| | |
|---|---|
| <i>Aleurocantus</i> spp. | <i>Numonia pyrivorella</i> (Matsumura) |
| <i>Anthonomus bisignifer</i> (Schenkling) | <i>Oligonychus perditus</i> Pritchard and Baker |
| <i>Anthonomus signatus</i> (Say) | <i>Pissodes</i> spp. (non-EU) |
| <i>Aschistonyx eppoi</i> Inouye | <i>Scirtothrips aurantii</i> Faure |
| <i>Carposina niponensis</i> Walsingham | <i>Scirtothrips citri</i> (Moultex) |
| <i>Enarmonia packardi</i> (Zeller) | <i>Scolytidae</i> spp. (non-EU) |
| <i>Enarmonia prunivora</i> Walsh | <i>Scrobipalopsis solanivora</i> Povolny |
| <i>Grapholita inopinata</i> Heinrich | <i>Tachypterellus quadrigibbus</i> Say |
| <i>Hishomonus phycitis</i> | <i>Toxoptera citricida</i> Kirk. |
| <i>Leucaspis japonica</i> Ckll. | <i>Unaspis citri</i> Comstock |
| <i>Listronotus bonariensis</i> (Kuschel) | |

(b) Bacteria

| | |
|--------------------------------------|--|
| Citrus variegated chlorosis | <i>Xanthomonas campestris</i> pv. <i>oryzae</i> (Ishiyama) |
| <i>Erwinia stewartii</i> (Smith) Dye | Dye and pv. <i>oryzicola</i> (Fang, et al.) Dye |

(c) Fungi

| | |
|---|---|
| <i>Alternaria alternata</i> (Fr.) Keissler (non-EU pathogenic isolates) | <i>Elsinoe</i> spp. Bitanc. and Jenk. Mendes |
| <i>Anisogramma anomala</i> (Peck) E. Müller | <i>Fusarium oxysporum</i> f. sp. <i>albedinis</i> (Kilian and Maire) Gordon |
| <i>Apiosporina morbosus</i> (Schwein.) v. Arx | <i>Guignardia piricola</i> (Nosa) Yamamoto |
| <i>Ceratocystis virescens</i> (Davidson) Moreau | <i>Puccinia pittieriana</i> Hennings |
| <i>Cercoseptoria pini-densiflorae</i> (Hori and Nambu) Deighton | <i>Stegophora ulmea</i> (Schweinitz: Fries) Sydow & Sydow |
| <i>Cercospora angolensis</i> Carv. and Mendes | <i>Venturia nashicola</i> Tanaka and Yamamoto |

(d) Virus and virus-like organisms

| | |
|---|---|
| Beet curly top virus (non-EU isolates) | Little cherry pathogen (non- EU isolates) |
| Black raspberry latent virus | Naturally spreading psorosis |
| Blight and blight-like | Palm lethal yellowing mycoplasma |
| Cadang-Cadang viroid | Satsuma dwarf virus |
| Citrus tristeza virus (non-EU isolates) | Tatter leaf virus |
| Leprosis | Witches' broom (MLO) |

Annex IIB

(a) Insect mites and nematodes, at all stages of their development

| | |
|-------------------------------------|--|
| <i>Anthonomus grandis</i> (Boh.) | <i>Ips cembrae</i> Heer |
| <i>Cephalcia lariciphila</i> (Klug) | <i>Ips duplicatus</i> Sahlberg |
| <i>Dendroctonus micans</i> Kugelan | <i>Ips sexdentatus</i> Börner |
| <i>Gilpinia hercyniae</i> (Hartig) | <i>Ips typographus</i> Heer |
| <i>Gonipterus scutellatus</i> Gyll. | <i>Sternochetus mangiferae</i> Fabricius |
| <i>Ips amitinus</i> Eichhof | |

(b) Bacteria

Curtobacterium flaccumfaciens pv. *flaccumfaciens*
(Hedges) Collins and Jones

(c) Fungi

Glomerella gossypii Edgerton

Hypoxyton mammatum (Wahl.) J. Miller

Gremmeniella abietina (Lag.) Morelet

1.1.2.2. Terms of Reference: Appendix 2

List of harmful organisms for which pest categorisation is requested per group. The list below follows the categorisation included in the annexes of Directive 2000/29/EC.

Annex IAI**(a) Insects, mites and nematodes, at all stages of their development**

Group of Cicadellidae (non-EU) known to be vector of Pierce's disease (caused by *Xylella fastidiosa*), such as:

- | | |
|--|---|
| 1) <i>Carneocephala fulgida</i> Nottingham | 3) <i>Graphocephala atropunctata</i> (Signoret) |
| 2) <i>Draeculacephala minerva</i> Ball | |

Group of Tephritidae (non-EU) such as:

- | | |
|--|---|
| 1) <i>Anastrepha fraterculus</i> (Wiedemann) | 12) <i>Pardalaspis cyanescens</i> Bezzi |
| 2) <i>Anastrepha ludens</i> (Loew) | 13) <i>Pardalaspis quinaria</i> Bezzi |
| 3) <i>Anastrepha obliqua</i> Macquart | 14) <i>Pterandrus rosa</i> (Karsch) |
| 4) <i>Anastrepha suspensa</i> (Loew) | 15) <i>Rhacochlaena japonica</i> Ito |
| 5) <i>Dacus ciliatus</i> Loew | 16) <i>Rhagoletis completa</i> Cresson |
| 6) <i>Dacus curcurbitae</i> Coquillett | 17) <i>Rhagoletis fausta</i> (Osten-Sacken) |
| 7) <i>Dacus dorsalis</i> Hendel | 18) <i>Rhagoletis indifferens</i> Curran |
| 8) <i>Dacus tryoni</i> (Froggatt) | 19) <i>Rhagoletis mendax</i> Curran |
| 9) <i>Dacus tsuneonis</i> Miyake | 20) <i>Rhagoletis pomonella</i> Walsh |
| 10) <i>Dacus zonatus</i> Saund. | 21) <i>Rhagoletis suavis</i> (Loew) |
| 11) <i>Epochra canadensis</i> (Loew) | |

(c) Viruses and virus-like organisms

Group of potato viruses and virus-like organisms such as:

- | | |
|----------------------------------|--|
| 1) Andean potato latent virus | 4) Potato black ringspot virus |
| 2) Andean potato mottle virus | 5) Potato virus T |
| 3) Arracacha virus B, oca strain | 6) non-EU isolates of potato viruses A, M, S, V, X and Y (including Yo, Yn and Yc) and Potato leafroll virus |

Group of viruses and virus-like organisms of *Cydonia* Mill., *Fragaria* L., *Malus* Mill., *Prunus* L., *Pyrus* L., *Ribes* L., *Rubus* L. and *Vitis* L., such as:

- | | |
|--------------------------------------|--|
| 1) Blueberry leaf mottle virus | 8) Peach yellows mycoplasma |
| 2) Cherry rasp leaf virus (American) | 9) Plum line pattern virus (American) |
| 3) Peach mosaic virus (American) | 10) Raspberry leaf curl virus (American) |
| 4) Peach phony rickettsia | 11) Strawberry witches' broom mycoplasma |
| 5) Peach rosette mosaic virus | 12) Non-EU viruses and virus-like organisms of <i>Cydonia</i> Mill., <i>Fragaria</i> L., <i>Malus</i> Mill., <i>Prunus</i> L., <i>Pyrus</i> L., <i>Ribes</i> L., <i>Rubus</i> L. and <i>Vitis</i> L. |
| 6) Peach rosette mycoplasma | |
| 7) Peach X-disease mycoplasma | |

Annex IIAI

(a) Insects, mites and nematodes, at all stages of their development

Group of *Margarodes* (non-EU species) such as:

- 1) *Margarodes vitis* (Phillipi)
- 2) *Margarodes vredendalensis* de Klerk
- 3) *Margarodes prieskaensis* Jakubski

1.1.2.3. Terms of Reference: Appendix 3

List of harmful organisms for which pest categorisation is requested. The list below follows the annexes of Directive 2000/29/EC.

Annex IAI

(a) Insects, mites and nematodes, at all stages of their development

| | |
|---|--|
| <i>Acleris</i> spp. (non-EU) | <i>Longidorus diadecturus</i> Eveleigh and Allen |
| <i>Amauromyza maculosa</i> (Malloch) | <i>Monochamus</i> spp. (non-EU) |
| <i>Anomala orientalis</i> Waterhouse | <i>Myndus crudus</i> Van Duzee |
| <i>Arrhenodes minutus</i> Drury | <i>Nacobbus aberrans</i> (Thorne) Thorne and Allen |
| <i>Choristoneura</i> spp. (non-EU) | <i>Naupactus leucoloma</i> Boheman |
| <i>Conotrachelus nenuphar</i> (Herbst) | <i>Premnotrypes</i> spp. (non-EU) |
| <i>Dendrolimus sibiricus</i> Tschetverikov | <i>Pseudopityophthorus minutissimus</i> (Zimmermann) |
| <i>Diabrotica barberi</i> Smith and Lawrence | <i>Pseudopityophthorus pruinus</i> (Eichhoff) |
| <i>Diabrotica undecimpunctata howardi</i> Barber | <i>Scaphoideus luteolus</i> (Van Duzee) |
| <i>Diabrotica undecimpunctata undecimpunctata</i> Mannerheim | <i>Spodoptera eridania</i> (Cramer) |
| <i>Diabrotica virgifera zea</i> Krysan & Smith | <i>Spodoptera frugiperda</i> (Smith) |
| <i>Diaphorina citri</i> Kuway | <i>Spodoptera litura</i> (Fabricus) |
| <i>Heliothis zea</i> (Boddie) | <i>Thrips palmi</i> Karny |
| <i>Hirschmanniella</i> spp., other than <i>Hirschmanniella</i> <i>gracilis</i> (de Man) Luc and Goodey | <i>Xiphinema americanum</i> Cobb <i>sensu lato</i> (non-EU populations) |
| <i>Liriomyza sativae</i> Blanchard | <i>Xiphinema californicum</i> Lamberti and Bleve-Zacheo |

(b) Fungi

| | |
|--|--|
| <i>Ceratocystis fagacearum</i> (Bretz) Hunt | <i>Mycosphaerella larici-leptolepis</i> Ito et al. |
| <i>Chrysomyxa arctostaphyli</i> Dietel | <i>Mycosphaerella populorum</i> G. E. Thompson |
| <i>Cronartium</i> spp. (non-EU) | <i>Phoma andina</i> Turkensteen |
| <i>Endocronartium</i> spp. (non-EU) | <i>Phyllosticta solitaria</i> Ell. and Ev. |
| <i>Guignardia laricina</i> (Saw.) Yamamoto and Ito | <i>Septoria lycopersici</i> Speg. var. <i>malagutii</i> Ciccarone and Boerema |
| <i>Gymnosporangium</i> spp. (non-EU) | <i>Thecaphora solani</i> Barrus |
| <i>Inonotus weirii</i> (Murril) Kotlaba and Pouzar | <i>Trechispora brinkmannii</i> (Bresad.) Rogers |
| <i>Melampsora farlowii</i> (Arthur) Davis | |

(c) Viruses and virus-like organisms

| | |
|----------------------------------|-------------------------|
| Tobacco ringspot virus | Pepper mild tigré virus |
| Tomato ringspot virus | Squash leaf curl virus |
| Bean golden mosaic virus | Euphorbia mosaic virus |
| Cowpea mild mottle virus | Florida tomato virus |
| Lettuce infectious yellows virus | |

(d) Parasitic plants

Arceuthobium spp. (non-EU)

Annex I A I I

(a) Insects, mites and nematodes, at all stages of their development

Meloidogyne fallax Karssen

Rhizoecus hibisci Kawai and Takagi

Popillia japonica Newman

(b) Bacteria

Clavibacter michiganensis (Smith) Davis et al. ssp. *sepedonicus* (Spieckermann and Kotthoff) Davis et al.

Ralstonia solanacearum (Smith) Yabuuchi et al.

(c) Fungi

Melampsora medusae Thümen

Synchytrium endobioticum (Schilbersky) Percival

Annex I B

(a) Insects, mites and nematodes, at all stages of their development

Leptinotarsa decemlineata Say

Liriomyza bryoniae (Kaltenbach)

(b) Viruses and virus-like organisms

Beet necrotic yellow vein virus

1.2. Interpretation of the Terms of Reference

Phyllosticta solitaria is one of a number of pests listed in the Appendices to the Terms of Reference (ToR) to be subject to pest categorisation to determine whether it fulfils the criteria of a quarantine pest or those of a regulated non-quarantine pest for the area of the EU excluding Ceuta, Melilla and the outermost regions of Member States (MS) referred to in Article 355(1) of the Treaty on the Functioning of the European Union (TFEU), other than Madeira and the Azores.

2. Data and methodologies

2.1. Data

2.1.1. Literature search

A literature search on *P. solitaria* 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. Relevant papers 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 European and Mediterranean Plant Protection Organization (EPPO) Global Database (EPPO, 2018) and relevant publications.

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 database was 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 and is a subproject of PHYSAN (Phyto-Sanitary Controls) specifically concerned with plant health information. The Europhyt database manages 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 MS and the phytosanitary measures taken to eradicate or avoid their spread.

2.2. Methodologies

The Panel performed the pest categorisation for *P. solitaria*, following guiding principles and steps presented in the EFSA guidance on quantitative pest risk assessment (EFSA PLH Panel, 2018) and in the International Standard for Phytosanitary Measures No 11 (FAO, 2013) and No 21 (FAO, 2004).

This work was initiated following an evaluation of the EU plant health regime. Therefore, to facilitate the decision-making process, in the conclusions of the pest categorisation, the Panel addresses explicitly each criterion for a Union quarantine pest and for a Union regulated non-quarantine pest in accordance with Regulation (EU) 2016/2031 on protective measures against pests of plants, and includes additional information required in accordance with the specific terms of reference received by the European Commission. In addition, for each conclusion, the Panel provides a short description of its associated uncertainty.

Table 1 presents the Regulation (EU) 2016/2031 pest categorisation criteria on which the Panel bases its conclusions. All relevant criteria have to be met for the pest to potentially qualify either as a quarantine pest or as a regulated non-quarantine pest. If one of the criteria is not met, the pest will not qualify. A pest that does not qualify as a quarantine pest may still qualify as a regulated non-quarantine pest that needs to be addressed in the opinion. For the pests regulated in the protected zones only, the scope of the categorisation is the territory of the protected zone; thus, the criteria refer to the protected zone instead of the EU territory.

It should be noted that 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, 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, whereas addressing social impacts is outside the remit of the Panel.

Table 1: Pest categorisation criteria under evaluation, as 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 | Criterion in Regulation (EU) 2016/2031 regarding Union quarantine pest | Criterion in Regulation (EU) 2016/2031 regarding protected zone quarantine pest (articles 32–35) | Criterion in Regulation (EU) 2016/2031 regarding Union regulated non-quarantine pest |
|---|--|--|--|
| Identity of the pest (Section 3.1) | Is the identity of the pest established, or has it been shown to produce consistent symptoms and to be transmissible? | Is the identity of the pest established, or has it been shown to produce consistent symptoms and to be transmissible? | Is the identity of the pest established, 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 widely distributed within the EU? Describe the pest distribution briefly! | Is the pest present in the EU territory? If not, it cannot be a protected zone quarantine organism | Is the pest present in the EU territory? If not, it cannot be a regulated non-quarantine pest. (A regulated non-quarantine pest must be present in the risk assessment area) |
| Regulatory status (Section 3.3) | If the pest is present in the EU but not widely distributed in the risk assessment area, it should be under official control or expected to be under official control in the near future | The protected zone system aligns with the pest free area system under the International Plant Protection Convention (IPPC). The pest satisfies the IPPC definition of a quarantine pest that is not present in the risk assessment area (i.e. protected zone) | Is the pest regulated as a quarantine pest? If currently regulated as a quarantine pest, are there grounds to consider its status could be revoked? |

| Criterion of pest categorisation | Criterion in Regulation (EU) 2016/2031 regarding Union quarantine pest | Criterion in Regulation (EU) 2016/2031 regarding protected zone quarantine pest (articles 32–35) | Criterion in Regulation (EU) 2016/2031 regarding Union regulated non-quarantine pest |
|---|---|---|--|
| 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! | Is the pest able to enter into, become established in, and spread within, the protected zone areas? Is entry by natural spread from EU areas where the pest is present possible? | Is spread mainly via specific plants for planting, rather than via natural spread or via movement of plant products or other objects? Clearly state if plants for planting is the main pathway! |
| Potential for consequences in the EU territory (Section 3.5) | Would the pests' introduction have an economic or environmental impact on the EU territory? | Would the pests' introduction have an economic or environmental impact on the protected zone areas? | Does the presence of the pest on plants for planting have an economic impact, as regards the intended use of those plants for planting? |
| Available measures (Section 3.6) | Are there measures available to prevent the entry into, establishment within or spread of the pest within the EU such that the risk becomes mitigated? | Are there measures available to prevent the entry into, establishment within or spread of the pest within the protected zone areas such that the risk becomes mitigated? Is it possible to eradicate the pest in a restricted area within 24 months (or a period longer than 24 months where the biology of the organism so justifies) after the presence of the pest was confirmed in the protected zone? | Are there measures available to prevent pest presence on plants for planting such that the risk becomes mitigated? |
| 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 | A statement as to whether (1) all criteria assessed by EFSA above for consideration as potential protected zone quarantine pest were met, and (2) if not, which one(s) were not met | A statement as to whether (1) all criteria assessed by EFSA above for consideration as a potential regulated non-quarantine pest were met, and (2) if not, which one(s) were not met |

The Panel will not indicate in its conclusions of the pest categorisation whether to continue the risk assessment process, but following the agreed two-step approach, will continue only if requested by the risk managers. However, during the categorisation process, experts may identify key elements and knowledge gaps that could contribute significant uncertainty to a future assessment of risk. It would be useful to identify and highlight such gaps so that potential future requests can specifically target the major elements of uncertainty, perhaps suggesting specific scenarios to examine.

3. Pest categorisation

3.1. Identity and biology of the pest

3.1.1. Identity and taxonomy

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

YES. The identity of the pest is well-established.

Phyllosticta solitaria is a fungus of the family Phyllostictaceae. The Index Fungorum database (www.indexfungorum.org) provides the following taxonomical identification:

Current scientific name: *Phyllosticta solitaria* Ellis & Everhart

Family – Phyllostictaceae

Genus – *Phyllosticta*

Species – *solitaria*

Common name (EPPO, 2018): blotch of apple

Other common names (EPPO, 2018): apple blotch, fruit blotch of pome fruits, leaf spot of pome fruits, canker of apple

3.1.2. Biology of the pest

P. solitaria overwinters as dormant mycelia in branch and twig cankers or dormant buds and as pycnosclerotia in cankers (Yoder, 2014). Primary inoculum infecting leaves and fruits in the spring (from petal fall to about 4 weeks later) are conidia (pycnidiospores) originating from overwintering pycnosclerotia formed on the surface of the central (older) area of the cankers. In spring, pycnidia are formed in the edges of the cankers and serve as inoculum sources for repeated infections throughout the spring and summer (Sheldon, 1907; Guba, 1925; Yoder, 2014). The fungus grows out of the original canker on the branch and forms pycnidia in successive years indicating that the canker is perennial (Sheldon, 1907). New cankers are primarily formed by infections of the bark through the petioles (Gardner, 1922). According to Guba (1925), the primary infections on leaves and fruits are always seen in close proximity to cankers on the branches indicating that these are the main source of primary inoculum. The conidia formed on leaf and fruit lesions serve as a secondary inoculum from spring to early fall (Sheldon, 1907; Guba, 1925). In autumn, production of conidia ceases and pycnosclerotia are formed in cankers and lesions on fruits and leaves. The importance of overwintering pycnosclerotia on fruit mummies and fallen leaves as sources of primary inoculum is uncertain (Guba, 1925).

Conidia are dispersed by rain-splash and wind-driven rain, and disease incidence and severity are strongly correlated with rainfall (Guba, 1925). Varying results for minimum, maximum and optimal temperature for conidia germination *in vitro* have been reported depending on the age of the conidia. The optimum temperature for germination is 20–25°C (Guba, 1925; Burgert, 1933). Minimum temperature for germination is 5°C (Guba, 1925; Burgert, 1933). The maximum temperature for germination is 39°C (Burgert, 1933). For *in vitro* sporulation and mycelium growth, the optimum temperature is 22–29°C (Mix, 1933). Sporulation and germination are independent of light (Guba, 1925; Mix, 1933). The fungus can survive cold storage down to 1–2°C for at least 9 months (McClintock, 1930). No teleomorph has been reported.

3.1.3. Detection and identification of the pest

Are detection and identification methods available for the pest?

Yes. As symptoms caused by *P. solitaria* on apples are similar to those of other diseases, the pest can only be detected and identified based on host association and symptomatology combined with cultural and morphological characteristics. There are no molecular methods available for the detection and identification of the pest.

P. solitaria is difficult to be reliably detected and identified based only on symptomatology and host association, as similar symptoms on apples are also caused by other diseases (e.g. Marssonina leaf blotch, sooty blotch, flyspeck, apple scab, star crack viral disease). As there are no molecular diagnostic methods available, for a reliable detection and identification of *P. solitaria*, cultural and morphological characteristics should also be considered in addition to host association and symptomatology.

Symptoms

The disease affects leaves, petioles, buds, twigs, small branches and fruits of apple trees (Guba, 1925; Yoder, 2014; CABI, online).

Symptoms on leaves and petioles develop 2–3 weeks after infection (Guba, 1925). Two types of lesions occur; the most severe type appears on the veins of the lower leaf surface and on petioles as

elongated, sunken, light tan or buff lesions (Yoder, 2014). The second type of symptoms consists of pinhead-sized, yellowish-green spots in the interveinal areas (Yoder, 2014). Pycnidia appear on leaf lesions early in the season, whereas pycnosclerotia are formed late in the season (Guba, 1925). Pycnosclerotia are more common in the lesions formed on the petioles than on the leaves. Lesions on the petioles may cause early defoliation (Guba, 1925).

First symptoms on twigs and small branches appear at the nodes and sometimes at the internodes on current-season growth in late summer (August) (Guba, 1925; Yoder, 2014). They are very common on the water sprouts (Guba, 1925). During the first year, roughly circular, slightly raised or blister-like, dark purplish or black cankers appear (Guba, 1925; Yoder, 2014). Pycnosclerotia are formed in the centre of the cankers and remain dormant till next spring (Guba, 1925). During the second year, the cankers enlarge and become light tan or orange (Yoder, 2014). Conidia are produced from the pycnosclerotia and the pycnidia, the latter being formed on the margin of the cankers. In the following seasons, new boundary zones form around each canker (Guba, 1925). The cankers may coalesce resulting in girdling of twigs and small branches (Yoder, 2014).

Early symptoms on fruits are small (up to 3 mm in diameter), raised and blister-like dark-coloured spots (Yoder, 2014). As the spots enlarge, they appear with irregular lobed edges, a star-like shape and they can turn into shiny blotches (up to 1.3 cm in diameter) as they coalesce. The lesions may crack when the fruit enlarges (Gloyer, 1911; Guba, 1925; Yoder, 2014). Pycnidia are usually present when the first blotches appear; they are initially sparse but soon they increase in number (Guba, 1925). In early fall, the formation of pycnidia on fruit lesions ceases and only pycnosclerotia are formed.

Morphology

Pycnidia vary in form and size depending on the plant organ they are originating from (Guba, 1925). Those formed on leaf spots are globose with a thin wall and smaller (60–95 μm in diameter) than those on the petioles. The ostiole is 9–12 \times 7–12 μm . On the fruit, pycnidia are depressed (elliptical), 57–95 μm \times 107–166 μm , black, punctiform and prominent with a slightly larger ostiole. The pycnidia formed on the bark are generally larger than those on the fruit.

Pycnosclerotia are globose or subglobose, 115–274 \times 107–238 μm , with thick walls enclosing hyaline parenchymatic tissue.

Conidia are pyriform with a truncate base, unicellular, hyaline with thin smooth walls (size 7–11 \times 6–8.5 μm). They are surrounded by a slime layer containing guttules and have long apical gelatinous appendages, which are very broad at the base and may cover half of the spore wall (Guba, 1925).

In culture, the mycelium is septate, pale green with irregular branching (Guba, 1925). Pycnosclerotia and pycnidia-like structures are formed on almost all types of growth media but conidia are rarely formed (Guba, 1925). Pycnidia with conidia can be produced on agar media containing apple bark (Guba, 1925).

3.2. Pest distribution

3.2.1. Pest distribution outside the EU

P. solitaria is known to be present in the USA and Canada (EPPO, 2018; Figure 1 and Table 2).

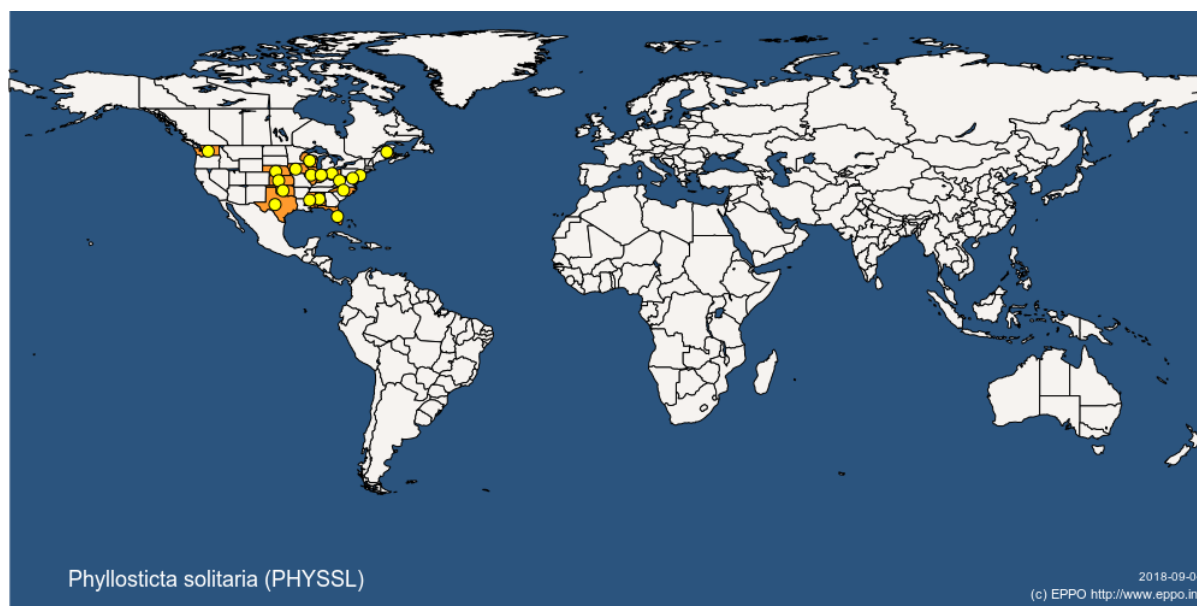


Figure 1: Global distribution map for *Phyllosticta solitaria* (extracted from the EPPO Global Database accessed on 4/9/2018)

Table 2: Global distribution of *Phyllosticta solitaria* based on information extracted from the EPPO Global Database (last updated: 29/5/2018; last accessed: 4/9/2018)

| Continent | Country | Status |
|-----------|--------------------------|----------------------------------|
| America | Canada | Present, restricted distribution |
| | United States of America | Present, restricted distribution |

3.2.2. Pest distribution in the EU

Is the pest present in the EU territory? If present, is the pest widely distributed within the EU?

No. The pest is not known to be present in the EU territory.

According to EPPO Global Database, *P. solitaria* was reported from Denmark in 1948, but it never became established (EPPO, 2018). The pest is not known to be present in the risk assessment area (EPPO, 2018).

3.3. Regulatory status

3.3.1. Council Directive 2000/29/EC

P. solitaria is listed in Council Directive 2000/29/EC. Details are presented in Tables 3 and 4.

Table 3: *Phyllosticta solitaria* in Council Directive 2000/29/EC

| | |
|------------------------|--|
| Annex I, Part A | Harmful organisms whose introduction into, and spread within, all member states shall be banned |
| Section I | Harmful organisms not known to occur in any part of the community and relevant for the entire community |
| (c) | Fungi |
| 13. | <i>Phyllosticta solitaria</i> Ellis & Everhart |

3.3.2. Legislation addressing the hosts of *Phyllosticta solitaria*

Table 4: Regulated hosts and commodities that may involve *Phyllosticta solitaria* in Annexes III, IV and V of 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 <i>Chaenomeles</i> Ldl., <i>Cydonia</i> Mill., <i>Crataegus</i> L., <i>Malus</i> Mill., <i>Prunus</i> L., <i>Pyrus</i> L., and <i>Rosa</i> L., intended for planting, other than dormant plants free from leaves, flowers and fruit | Non-European countries |
| 14. | Soil and growing medium as such, which consists in whole or in part of soil or solid organic substances such as parts of plants, humus including peat or bark, other than that composed entirely of peat | Turkey, Belarus, Moldavia, Russia, Ukraine and third countries not belonging to continental Europe, other than the following: Egypt, Israel, Libya, Morocco, Tunisia |
| 18. | Plants of <i>Cydonia</i> Mill., <i>Malus</i> Mill., <i>Prunus</i> L. and <i>Pyrus</i> L. and their hybrids, and <i>Fragaria</i> L., intended for planting, other than seeds | Without prejudice to the prohibitions applicable to the plants listed in Annex III A (9), where appropriate, non-European countries, other than Mediterranean countries, Australia, New Zealand, Canada, the continental states of the USA |
| Annex IV, Part A | | |
| Special requirements which shall 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 |
| 19.2 | Plants of <i>Cydonia</i> Mill., <i>Fragaria</i> L., <i>Malus</i> Mill., <i>Prunus</i> L., <i>Pyrus</i> L., <i>Ribes</i> L., <i>Rubus</i> L. intended for planting, other than seeds, originating in countries where the relevant harmful organisms are known to occur on the genera concerned the relevant harmful organisms are [...] — on <i>Malus</i> Mill.: — <i>Phyllosticta solitaria</i> Ell. and Ev.; [...] — on <i>Pyrus</i> L.: — <i>Phyllosticta solitaria</i> Ell. and Ev.; | Without prejudice to the provisions applicable to the plants where appropriate listed in Annex III(A)(9) and (18), and Annex IV(A)(I) (15) and (17), official statement that no symptoms of diseases caused by the relevant harmful organisms have been observed on the plants at the place of production since the beginning of the last complete cycle of vegetation |
| 34. | Soil and growing medium, attached to or associated with plants, consisting in whole or in part of soil or solid organic substances such as parts of plants, humus including peat or bark or consisting in part of any solid inorganic substance, intended to sustain the vitality of the plants, originating in: — Turkey, — Belarus, Georgia, Moldova, Russia, Ukraine, — non-European countries, other than Algeria, Egypt, Israel, Libya, Morocco, Tunisia | Official statement that: (a) the growing medium, at the time of planting, was: — either free from soil, and organic matter, or — found free from insects and harmful nematodes and subjected to appropriate examination or heat treatment or fumigation to ensure that it was free from other harmful organisms, or — subjected to appropriate heat treatment or fumigation to ensure freedom from harmful organisms, and |

| | | |
|------------------|--|---|
| | | (b) since planting: — either appropriate measures have been taken to ensure that the growing medium has been maintained free from harmful organisms, or — within 2 weeks prior to dispatch, the plants were shaken free from the medium leaving the minimum amount necessary to sustain vitality during transport, and, if replanted, the growing medium used for that purpose meets the requirements laid down in (a) |
| 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 B | Plants, plant products and other objects originating in territories, other than those territories referred to in Part A | |
| Section I | Plants, plant products and other objects which are potential carriers of harmful organisms of relevance for the entire Community | |
| 3. | Fruits of: — <i>Annona</i> L., <i>Cydonia</i> Mill., <i>Diospyros</i> L., <i>Malus</i> Mill., <i>Mangifera</i> L., <i>Passiflora</i> L., <i>Prunus</i> L., <i>Psidium</i> L., <i>Pyrus</i> L., <i>Ribes</i> L. <i>Syzygium</i> Gaertn., and <i>Vaccinium</i> L., originating in non-European countries, | |
| 7. | (a) Soil and growing medium as such, which consists in whole or in part of soil or solid organic substances such as parts of plants, humus including peat or bark, other than that composed entirely of peat. (b) Soil and growing medium, attached to or associated with plants, consisting in whole or in part of material specified in (a) or consisting in part of any solid inorganic substance, intended to sustain the vitality of the plants, originating in: —Turkey, — Belarus, Moldova, Russia, Ukraine, — non-European countries, other than Algeria, Egypt, Israel, Libya, Morocco, Tunisia | |

3.4. Entry, establishment and spread in the EU

3.4.1. Host range

The only major cultivated host of *P. solitaria* is *Malus domestica* (apple) (EPPO, 2018). In the infested areas, wild species of the genera *Malus*, such as *M. coronaria*, *M. lancifolia* and *M. angustifolia* (Guba, 1925) and *Crataegus* (Seaver, 1922) also become affected by the pest. The latter is reported as an incidental host by EPPO (2018) and as a wild host by CABI (online).

In EPPO Global Database (EPPO, 2018), *Pyrus* spp. are reported as minor hosts of the pathogen, but no reference is cited. In the available literature, the only documented reports of *Pyrus* spp. being hosts of the pest are those of Sheldon (1907) and Guba (1925), according to which, the original host of *P. solitaria* was probably *Pyrus coronaria* (crab apple), a wild *Pyrus* species. However, based on The Plant List database (<http://www.theplantlist.org/tpl1.1/record/rjp-5767>) and the database of the USDA Natural Resources Conservation Service (<https://plants.usda.gov/core/profile?symbol=MACO5>), *P. coronaria* is a synonym of *M. coronaria*.

Based on the above, *M. domestica* is the only major cultivated host of *P. solitaria* and is regulated in the EU. Therefore, the Panel decided to focus this pest categorisation on *M. domestica*.

3.4.2. Entry

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

Yes, however, all the pathways of entry associated with host plants, and soil and growing media (as commodities or substrates) originating in infested third countries are regulated under the current EU legislation (Council Directive 2000/29/EC).

P. solitaria is not known to be seed-borne. Moreover, the pest is unlikely to enter the EU territory by natural means (wind, water) because of the distance between the infested third countries and the risk assessment area, and the limited capacity of the pest for natural spread.

Therefore, the PLH Panel identified the following pathways for the entry of the pest from infested third countries into the EU territory, in the absence of the current legislation:

- 1) host plants for planting, excluding seeds, but including dormant plants and plant parts for grafting (scions, budwood, rootstocks).
- 2) fresh fruit of host plants; and
- 3) soil and growing media associated or not with plants for planting and carrying infected host plant debris.

The following pathways of entry of *P. solitaria* into the risk assessment area are closed (prohibited) by the current EU legislation (Tables 3 and 4):

- 1) Plants for planting of the genera *Malus* and *Crataegus*, other than dormant plants (free from leaves, flowers and fruit), originating in non-European countries.
- 2) Plants for planting of the genus *Malus*, excluding seeds, originating in non-European countries, other than Mediterranean countries, Australia, New Zealand, Canada, the continental states of the USA.
- 3) Soil and growing media attached to or associated with plants originating in Turkey, Belarus, Georgia, Moldova, Russia, Ukraine and non-European countries, other than Algeria, Egypt, Israel, Libya, Morocco and Tunisia.
- 4) Soil and growing media not attached to or associated with plants originating in Turkey, Belarus, Moldavia, Russia, Ukraine and third countries not belonging to continental Europe other than Egypt, Israel, Libya, Morocco and Tunisia.

Special requirements exist in the EU legislation for the following open pathways of entry of *P. solitaria* into the risk assessment area:

- 1) plants for planting of the genus *Malus* at dormant stage, and
- 2) fresh fruit of the genus *Malus*, originating in third countries, where the pest is known to occur (Table 2).

Based on the above, all the pathways associated with host plants for planting, and soil and growing media, as commodities or substrates, originating in infested third countries are regulated (Council Directive 2000/29/EC).

The Panel identified the following potential pathway of entry of *P. solitaria* into the EU, which is open and not regulated by the EU legislation:

- infected host plant debris in soil adhering to agricultural machinery and implements, footwear, and vehicles originating in infested third countries.

The Panel considers this pathway as uncertain because of the distance between the infested countries and the risk assessment area, and due to the absence of import data in the Eurostat database (accessed on 2/5/2018). Therefore, this pathway is not considered as a major pathway of entry and is not further addressed in the following sections.

There is no record of interception of *P. solitaria* in the Europhyt database (online; search performed on 4/9/2018).

No data exists in Eurostat on imports of dormant host plants for planting from third countries into the EU territory (Source: Eurostat, search done on 5/9/2018). The volume of apple fruits imported into the EU from non-European countries and from countries infested with *P. solitaria* is presented in Table 5.

The ISEFOR database of plants for planting (Eschen et al., 2017), reports shipments of *Malus* spp. plants for planting imported by the EU from the USA and Canada during the period 2000–2003 (up to 10 000 nursery trees per year).

Table 5: Total volume (in tonnes) of apple fruits imported during the period 2013–2017 into the 28 EU Member States from non-EU28 countries as well as from Canada and USA where *Phyllosticta solitaria* is known to be present (Source: Eurostat, extracted on 6/11/2018)

| Total EU 28 apple imports (in tonnes) from | 2013 | 2014 | 2015 | 2016 | 2017 |
|--|---------|---------|---------|---------|---------|
| Non-EU countries | 668,796 | 495,033 | 455,289 | 445,536 | 449,665 |
| Canada | 125 | 198 | 245 | 236 | 137 |
| Canada (%) | 0.02 | 0.04 | 0.05 | 0.05 | 0.03 |
| USA | 12,081 | 9,005 | 6,212 | 4,291 | 2,422 |
| USA (%) | 1.81 | 1.82 | 1.36 | 0.96 | 0.54 |
| USA+Canada (%) | 1.83 | 1.86 | 1.42 | 1.01 | 0.57 |

3.4.3. Establishment

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

Yes. The biotic (host availability) and abiotic (climate suitability) factors occurring in part of the risk assessment area are favourable for the establishment of *P. solitaria*.

3.4.3.1. EU distribution of main host plants

The host of *P. solitaria* (apple) is widely grown in the risk assessment area (Table 6).

Table 6: Area cultivated with apples in the EU between 2013 and 2017 (in 1,000 ha). Source: Eurostat, extracted on 6/11/2018

| EU Member States ^(a) | 2013 | 2014 | 2015 | 2016 | 2017 | Mean of EU apple-growing area (in 1,000 ha) |
|---------------------------------|--------|--------|--------|--------|--------|---|
| EU28 | 536.77 | 524.50 | 538.50 | 523.80 | 522.11 | 529.14 |
| Poland | 162.40 | 163.10 | 180.40 | 164.76 | 162.53 | 166.64 |
| Romania | 60.28 | 56.13 | 55.88 | 55.53 | 55.60 | 56.68 |
| Italy | 53.01 | 52.00 | 52.16 | 56.16 | 57.26 | 54.12 |
| France | 50.68 | 50.17 | 49.65 | 49.65 | 50.31 | 50.09 |
| Hungary | 33.36 | 33.26 | 32.80 | 32.80 | 32.09 | 32.86 |
| Germany | 31.74 | 31.74 | 31.74 | 31.74 | 33.98 | 32.19 |
| Spain | 30.79 | 30.73 | 30.72 | 30.87 | 30.55 | 30.73 |
| United Kingdom | 20.00 | 16.00 | 16.00 | 17.00 | 16.60 | 17.12 |
| Portugal | 13.66 | 13.85 | 14.01 | 14.98 | 14.79 | 14.26 |
| Greece | 12.95 | 12.26 | 11.85 | 10.04 | 9.60 | 11.34 |
| Lithuania | 11.67 | 11.27 | 10.68 | 9.70 | 9.82 | 10.63 |

(a): Only Member States growing more than 10 000 ha are reported.

Apples are also grown, but to a lesser extent, in the Czech Republic, the Netherlands, Belgium, Austria, Croatia, Bulgaria, Slovakia, Latvia, Slovenia, Denmark, Sweden, Estonia, Cyprus, Ireland, Finland and Luxembourg.

3.4.3.2. Climatic conditions affecting establishment

Apple blotch is favoured by warm, wet weather during the growing season (Guba, 1925; Yoder, 2014). Heavy rains and extended wetting periods promote the exudation, dissemination and germination of conidia (see Section 3.1.2).

Considering the areas in North America where *P. solitaria* was reported (EPPO, 2018) (Figure 2), the prevalent climate types are temperate (Cfa: without dry season, hot summer and Cfb: without dry season, warm summer) and cold (Dfa: without dry season, hot summer and Dfb: without dry season, warm summer). Temperate climate types Cfa and Cfb are present in areas of Western Europe, UK and Ireland, around the Adriatic Sea and north of the Iberian Peninsula (Figure 3). Also, cold climates Dfa and Dfb are present in areas of Scandinavia and Eastern Europe. Therefore, the climatic conditions occurring in parts of the EU are suitable for the establishment of *P. solitaria*.

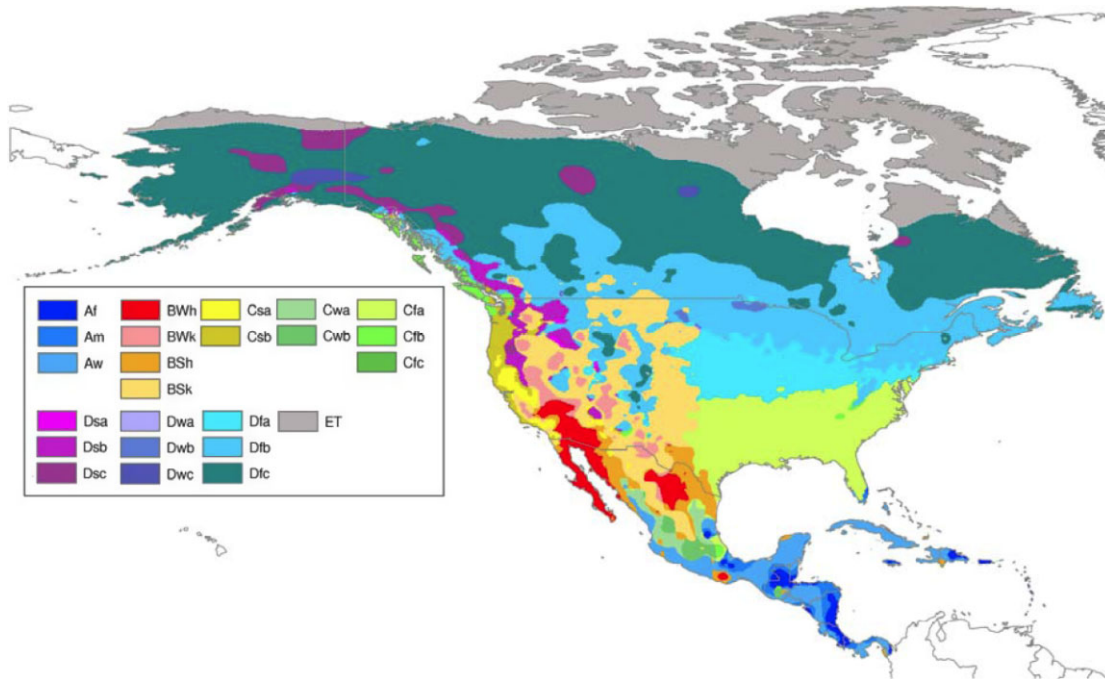


Figure 2: Köppen–Geiger climate type map of North America, from Peel et al. (2007)

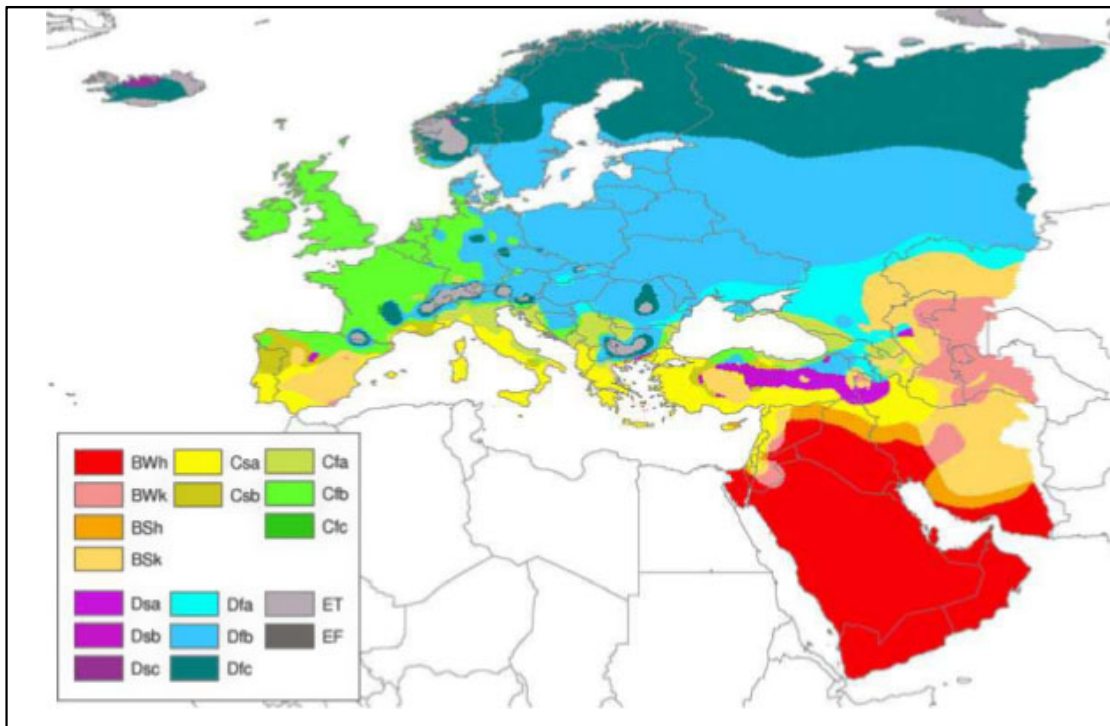


Figure 3: Köppen–Geiger climate type map of Europe, from Peel et al. (2007)

3.4.4. Spread

3.4.4.1. Vectors and their distribution in the EU (if applicable)

Is the pest able to spread within the EU territory following establishment? Yes

How? By natural and human-assisted means

RNQPs: Is spread mainly via specific plants for planting, rather than via natural spread or via movement of plant products or other objects?

Yes. The pest is mainly spread via the movement/trade of host plants for planting, including plants at the dormant stage

Following its establishment in the EU territory, the pest could potentially spread by both natural and human-assisted means.

Spread by natural means. The pest could potentially spread over relatively short distances by rain-splashed and/or washed-off conidia (Guba, 1925). No information exists in the available literature with regards to the maximum distance over which conidia of *P. solitaria* could be dispersed by wind-driven rain.

Spread by human assistance. The pest could potentially spread over long distances via the movement of (i) infected host plants for planting, including dormant plants, and (ii) fresh fruit of host plants.

On average between 2011 and 2015, 2.5 million tonnes of apple fresh fruit have been traded within the EU28 (Eurostat, online). There are no Eurostat data regarding intra-EU28 movement of *Malus* spp. plants for planting.

The Panel considers the movement of infected host plants for planting as the major means of spread.

3.5. Impacts

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

Yes. The introduction of the pest in the EU territory would potentially cause direct and indirect impacts to apple production.

RNQPs: Does the presence of the pest on plants for planting have an economic impact, as regards the intended use of those plants for planting?⁴

Yes. The presence of the pest on host plants for planting (other than seeds) would have an economic impact.

Early reports of *P. solitaria* in the USA (Gloyer, 1911) indicated that the disease was quite prevalent, causing a lot of damage in apple orchards. Trees of susceptible cultivars, which were not systematically sprayed, were often killed by repeated infections on twigs and leaves (Roberts and Pierce, 1926). Surveys in Ohio reported by Gloyer (1911) showed a disease incidence of about 60% of the fruit affected in the local apple cultivar 'Butter Apple', while other cultivars under similar conditions were not affected. Gloyer (1911) also indicated that affected fruit kept in storage soon decayed, because of other fungi that entered through the injured epidermis. In Illinois, Guba (1925) reported disease incidences of 70–90% of fruit in unsprayed susceptible apple cultivars. At that time, *P. solitaria* was considered as a limiting factor in the commercial production of susceptible cultivars of apple, second after scab (Guba, 1925). Nowadays, the disease is rare in commercial apple orchards, probably due to regular fungicide sprays against other diseases (EPPO, 1997; Yoder, 2014).

The introduction of the pest in the EU territory would potentially cause direct and indirect impacts to apple production. However, uncertainty exists whether the agricultural practices (e.g. apple cultivars) and chemical control methods currently applied in the EU would reduce the impact of pest introduction.

⁴ See Section 2.1 on what falls outside EFSA's remit.

3.6. Availability and limits of mitigation measures

Are there measures available to prevent the entry into, establishment within or spread of the pest within the EU such that the risk becomes mitigated?

Yes. Please, see Section 3.3.

RNQPs: Are there measures available to prevent pest presence on plants for planting such that the risk becomes mitigated?

Yes. The presence of the pest on host plants for planting could be prevented by sourcing them in pest-free areas or places of production

3.6.1. Identification of additional measures

Phytosanitary measures (sourcing from pest-free areas or pest-free places of production, inspection and lab testing both at the place of origin and at the EU entry point) are currently applied to the major host and pathways of entry, which are all regulated (Council Directive 2000/29/EC) (See Section 3.3). There are no additional major hosts or pathways of entry.

There are no measures that could prevent the establishment of the pest in the EU territory.

3.7. Uncertainty

- 1) **Host range:** It is not known whether wild species of the genus *Malus* and *Crataegus* in the EU territory are hosts of the pest.
- 2) **Entry:** The absence of data on the quantity of host plants for planting (excluding seeds) and plant parts (bud wood, scions, cuttings) imported from infested third countries into the EU28.
- 3) **Entry:** Uncertainty exists on whether the pest could enter the EU territory on infected host plant debris in soil adhering to agricultural machinery and implements, footwear and vehicles, because of the distance between the infested countries and the risk assessment area, and due to the absence of import data in the Eurostat database.
- 4) **Spread:** The absence of data on the quantity of host plants for planting (excluding seeds) and plant parts for grafting (bud wood, scions, cuttings) moved within the EU28
- 5) **Spread:** Uncertainty exists on the maximum distance over which conidia of the pathogen could be dispersed by wind-blown rain.
- 6) **Impact:** Uncertainty exists whether the agricultural practices (e.g. apple cultivars) and chemical control methods currently applied in the EU would reduce the impact of pest introduction.

4. Conclusions

P. solitaria meets all the criteria assessed by EFSA for consideration as a potential Union quarantine pest (Table 7). The criteria for considering *P. solitaria* as a potential Union regulated non-quarantine pest are not met since the pest is not known to be present in the EU.

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 | Panel's conclusions against criterion in Regulation (EU) 2016/2031 regarding Union regulated non-quarantine pest | Key uncertainties |
|---|--|--|-------------------|
| Identity of the pest (Section 3.1) | The identity of the pest (<i>Phyllosticta solitaria</i>) is clearly defined and there are methods for its detection and identification | The identity of the pest (<i>Phyllosticta solitaria</i>) is clearly defined and there are methods for its detection and identification | None |

| Criterion of pest categorisation | Panel's conclusions against criterion in Regulation (EU) 2016/2031 regarding Union quarantine pest | Panel's conclusions against criterion in Regulation (EU) 2016/2031 regarding Union regulated non-quarantine pest | Key uncertainties |
|---|---|--|--|
| Absence/ presence of the pest in the EU territory (Section 3.2) | The pest is not known to be present in the EU territory | The pest is not known to be present in the EU territory | None |
| Regulatory status (Section 3.3) | The pest is currently officially regulated in the EU as a quarantine pest (Council Directive 2000/29/EC). | The pest is currently officially regulated in the EU as a quarantine pest (Council Directive 2000/29/EC). There are no grounds to consider its status could be revoked | None |
| Pest potential for entry, establishment and spread in the EU territory (Section 3.4) | <p><u>Entry:</u> All major pathways of entry of the pest into the risk assessment area are regulated (Council Directive 2000/29/EC).</p> <p><u>Establishment:</u> The host availability and climate factors occurring in part of the risk assessment area are favourable for the establishment of the pest.</p> <p><u>Spread:</u> Following introduction, the pest could potentially spread by natural and human-assisted means</p> | The pest is mainly spread via host plants for planting, including scions, rootstocks, and budwood | <p><u>Host range:</u> It is not known whether wild species of the genus <i>Malus</i> and <i>Crataegus</i> in the EU territory are hosts of the pest. (Uncertainty 1)</p> <p><u>Entry:</u> absence of data on the quantity of host plants for planting and plant parts imported from infested third countries. (Uncertainty 2)</p> <p><u>Entry.</u> Uncertainty exists on whether the pest could enter the EU territory on infected host plant debris in soil adhering to agricultural machinery and implements, footwear and vehicles. (Uncertainty 3)</p> <p><u>Spread:</u> absence of data on the quantity of host plants for planting and plant parts moved within the EU28. (Uncertainty 4)</p> <p><u>Spread.</u> Uncertainty exists on the maximum distance over which conidia of the pathogen could be dispersed by wind-blown rain. (Uncertainty 5)</p> |
| Potential for consequences in the EU territory (Section 3.5) | The introduction of the pest in the EU territory would potentially cause direct and indirect impacts to apple production | The presence of the pest on host plants for planting would have an economic impact | Uncertainty exists whether the agricultural practices and chemical control methods currently applied in the EU would reduce the impact of pest introduction (Uncertainty 6) |
| Available measures (Section 3.6) | There are measures available to prevent the introduction into and spread within the EU of the pest such that the risk becomes mitigated. These measures are described in Council Directive 2000/29/EC | The presence of the pest on host plants for planting could be prevented by sourcing them in pest-free areas or places of production | None |

| Criterion of pest categorisation | Panel's conclusions against criterion in Regulation (EU) 2016/2031 regarding Union quarantine pest | Panel's conclusions against criterion in Regulation (EU) 2016/2031 regarding Union regulated non-quarantine pest | Key uncertainties |
|---|--|---|-------------------|
| Conclusion on pest categorisation (Section 4) | <i>Phyllosticta solitaria</i> meets all the criteria assessed by EFSA for consideration as potential Union quarantine pest | The criteria for considering <i>Phyllosticta solitaria</i> as a potential Union regulated non-quarantine pest are not met since the pest is not known to be present in the EU | None |
| Aspects of assessment to focus on/ scenarios to address in future if appropriate | None | | |

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Glossary

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| Containment (of a pest) | Application of phytosanitary measures in and around an infested area to prevent spread of a pest (FAO, 1995, 2017) |
| Control (of a pest) | Suppression, containment or eradication of a pest population (FAO, 1995, 2017) |
| 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, 2017) |
| Eradication (of a pest) | Application of phytosanitary measures to eliminate a pest from an area (FAO, 2017) |
| Establishment (of a pest) | Perpetuation, for the foreseeable future, of a pest within an area after entry (FAO, 2017) |
| 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, 2017) |
| Measures | Control (of a pest) is defined in ISPM 5 (FAO, 2017) as "Suppression, containment or eradication of a pest population" (FAO, 1995). Control measures are measures that have a direct effect on pest abundance. Supporting measures are organisational measures or procedures supporting the choice of appropriate Risk Reduction Options that do not directly affect pest abundance. |
| Pathway | Any means that allows the entry or spread of a pest (FAO, 2017) |
| 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, 2017) |
| Protected zones (PZ) | A Protected zone is an area recognised at EU level to be free from a harmful organism, which is established in one or more other parts of the Union. |
| 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, 2017) |
| Regulated non-quarantine pest | A non-quarantine pest whose presence in plants for planting affects the intended use of those plants with an economically unacceptable impact and which is therefore regulated within the territory of the importing contracting party (FAO, 2017) |
| 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, 2017) |

Abbreviations

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| DG SANTÉ | Directorate General for Health and Food Safety |
| EPPO | European and Mediterranean Plant Protection Organization |
| FAO | Food and Agriculture Organization |
| 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 |