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Pest categorisation of *Synchytrium endobioticum*

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Abstract

The Panel on Plant Health performed a pest categorisation of the fungus *Synchytrium endobioticum*, the causal agent of potato wart disease, for the European Union (EU). The identity of the pest is well established and reliable methods exist for its detection and identification. *S. endobioticum* is present in most continents. The pest is listed in Annex IAI of Directive 2000/29/EC and is present with a restricted and fragmentary distribution in the EU. The major host is *Solanum tuberosum* (potato), but in Mexico, the pest also affects wild *Solanum* spp. *S. endobioticum* could potentially enter the EU through multiple pathways associated with soil as substrate for non-host plants, contaminant or commodity. The presence of the pest in 16 EU Member States characterised by different climatic conditions suggests that it could establish in the rest of the EU. The disease induces the formation of warts on potato tubers, stolons and stem bases reducing plant growth and yield and making tubers unmarketable. Additional losses may occur during storage. The only available strategy to control the disease and prevent it from spreading is the application of strict phytosanitary measures and the cultivation of potato varieties resistant to the pathotype(s) present in the infested field(s). Specific phytosanitary measures exist (Council Directive 69/464/EEC) for the control of potato wart disease in the EU. The main uncertainties refer to the distribution and host range of the pest, and the importance of some pathways of entry. *S. endobioticum* meets all the criteria assessed by EFSA for consideration as potential Union quarantine pest. The criteria for considering *S. endobioticum* as a potential Union regulated non-quarantine pest are not met since, in addition to potato seed tubers, soil (as commodity, substrate or contaminant) and ware potato tubers are major means of spread.

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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 packardii</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 morbosa</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> Kugelán	<i>Ips sexdentatus</i> Börner
<i>Gilpinia hercyniae</i> (Hartig)	<i>Ips typographus</i> Heer
<i>Gonipterus scutellatus</i> Gyll.	<i>Sternonchetus 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>Carneiocephala 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> (Fabricius)
<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

Synchytrium endobioticum 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 *S. endobioticum* (Schilb.) Percival was conducted at the beginning of the categorisation in the ISI Web of Science bibliographic database, using the scientific name of the pest as well as its synonyms (*Chrysophlyctis endobiotica* Schilbersky and *Synchytrium solani* Massee) as search terms. 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, online) 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 *S. endobioticum*, following guiding principles and steps presented in the EFSA guidance on the harmonised framework for pest risk assessment (EFSA PLH Panel, 2010) and as defined in the International Standard for Phytosanitary Measures No 11 (FAO, 2013) and 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 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, in agreement with EFSA guidance on a harmonised framework for pest risk assessment (EFSA PLH Panel, 2010).

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.

Synchytrium endobioticum (Schilbersky) Percival 1909 is an obligate fungal pathogen of the family Synchytriaceae. The Index Fungorum database (www.indexfungorum.org) provides the following taxonomical identification:

Current scientific name: *Synchytrium endobioticum* (Schilb.) Percival 1909

Family – Synchytriaceae

Genus – *Synchytrium*

Species – *endobioticum*

Other reported synonyms (EPPO, online): *Chrysophlyctis endobiotica* Schilb.; *Synchytrium solani* Massee

Common name: wart disease of potato

Other common names: potato wart disease, black scab of potato, black wart of potato, wart of potato

3.1.2. Biology of the pest

Synchytrium endobioticum is an obligate biotrophic, soil-borne fungal pathogen (Karling, 1964). It survives in the soil as winter sporangia (resting spores), which remain dormant and infectious for 40–50 years at depths of up to 50 cm (Noble and Glynne, 1970; Hampson, 1975, 1981; McDonnell and Kavanagh, 1980; Rintelen et al., 1983; Laidlaw, 1985; Putnam and Sindermann, 1994; Arora and Khurana, 2004; Franc, 2007; Steinmüller et al., 2012; Przetakiewicz, 2015). Przetakiewicz (2015) showed that, after 43 years, under favourable conditions, disease recurrence may occur even from a single winter sporangium of *S. endobioticum*. Laidlaw (1985) reported that winter sporangia survived in the soil for even 70 years.

In spring, winter sporangia, present in decomposing warts and soil, germinate to produce about 200–300 motile zoospores each, which can move in wet soil up to a distance of 50 mm (Hampson, 1986; Franc, 2007). Under ideal conditions, few winter sporangia are needed for infection of potato plants; infection has been reported at soil inoculum levels of less than one sporangium/gr of soil (Hampson, 1992; Browning, 1995). Zoospores are short-lived and, depending on the temperature, they survive up to 1–2 h after their formation (Percival, 1910; Curtis, 1921; Franc, 2007). Once zoospores reach the epidermal cells of meristematic tissues of growing potato plant parts, such as tuber buds, stolon tips or young leaf primordia, they encyst and infect the host (Curtis, 1921; Stachewicz and Enzian, 1998a,b). Following infection, potato cells enlarge and haploid sori form inside the cells while neighbouring cells begin to proliferate, resulting in the characteristic tumour-like tissues (warts) and the increased presence of meristematic tissue that provides new infection courts for the fungus. Each sorus contains 1–9 short-lived summer sporangia (Curtis, 1921; EPPO, online). Summer sporangia can release several hundred haploid zoospores which can infect new susceptible host tissues (secondary disease cycle). These rapidly repeating secondary disease cycles ultimately result in an extensive invasion of host cells and rapid onset of wart formation (Curtis, 1921). Young warts are a nutrient sink and expand rapidly (their size can increase up to 1,800-fold within 16 days compared with an eightfold increase in tuber volume within 21 days) at the expense of other plant tissues (Weiss, 1925). In the presence of favourable environmental conditions, this process continues throughout the growing season (Hampson, 1993). Under stress (e.g. water shortage) or unfavourable conditions, the zoospores can act as isogametes and fuse to form uninucleate, diploid, biflagellate zygotes, which infect the host tissue in the same way as the zoospores to form winter sporangia (Curtis, 1921; Franc, 2007). Following infection by zygotes, the host cell in which winter sporangia form does not swell but divides to form warts. As these warts mature, they decay and disintegrate releasing the winter sporangia into the soil (Curtis, 1921; Lange and Olson, 1981).

Potato wart disease is favoured by cool and wet soils during tuber development. A soil temperature of at least 8°C and soil water are required for the germination of both winter and summer sporangia and for the dispersal of zoospores (Hampson, 1993). Discrepancies exist in the literature concerning the range of optimal temperatures for infection under field conditions. These discrepancies may be partially due to differences in density, age and viability of inoculum (winter sporangia) in the soil as well as in soil type and temperature. In general, cool summers with average temperatures of 18°C or less, winters of approximately 160 days at or below 5°C, and annual precipitation of 700 mm or more favour the development of the disease (Weiss, 1925; Bojňanský, 1960). Still, new outbreaks have been reported from areas in South-Eastern Europe where summer temperatures are higher (EPPO, online).

According to Weiss (1925), the most favourable conditions for the appearance of the disease are periodic flooding of the potato field, followed by draining and aeration. In general, damp regions offer the most suitable conditions for disease development. Bojňanský (1968) found that peat and well-aerated sandy soils provide conditions favourable for potato wart disease. According to Tarasova (1969), sandy soils favour the decay of warts, and the microelements B, Cu, Zn and Mo stimulate the germination of winter sporangia under field conditions. Soil pH is of less importance, as the disease has been reported in soils with pH ranging from 3.9 to 8.5 (Weiss, 1925).

Winter sporangia are very resistant to high temperatures, microbial antagonism and competition. Wet sporangia were no longer infectious after 60 min at 70°C, whereas dry sporangia could survive at 100°C for 11–12 h (Glynne, 1926; Weiss and Brierley, 1928). They also survived composting for 12 days at 60–65°C and pasteurisation for 90 min at 70°C (Steinmüller et al., 2012). Winter sporangia have also been shown to survive the digestion system of animals fed on infected potato tubers or grazed in infested fields (Hartman and McCubbin, 1924; Weiss and Brierley, 1928). Weiss and Brierley (1928) showed that winter sporangia survived treatment in 1% formaldehyde and 0.1% mercuric chloride (chemicals used at that time as potato seed disinfectants) for 1 h and 3 h (the longest periods tested), respectively.

The pest develops pathotypes which are defined by their virulence on differential potato varieties (Baayen et al., 2006; EPPO, online). Until 1941, only one pathotype (pathotype 1(D1) – also called 'European pathotype') was known, to which most commercially grown potato varieties are resistant (Hampson and Proudfoot, 1974; Langerfeld, 1984; Hampson, 1993; Busse et al., 2017). Since then, more than 40 pathotypes have been reported in Europe, with pathotypes 2 (G1), 6(O1) and 18(T1) being the most aggressive and widely distributed (Stachewicz, 2002; Baayen et al., 2006; Çakir et al., 2009; Flath et al., 2014; Obidiegwu et al., 2014; Przetakiewicz, 2015; Busse et al., 2017). Each pathotype displays its own pattern of pathogenicity on different potato varieties (Gagnon et al., 2016). Some pathotypes have a considerably wider host range in terms of pathogenicity on different potato varieties than others, and thus, they pose a serious threat for potato production in Europe (Baayen et al., 2005). Occurrence of new pathotypes is attributed to many factors, including the use of resistant potato varieties and the presence of wild solanaceous weeds in potato fields (Melnik, 1998). However, the true number of pathotypes is not known and pathotype identification using differential varieties is hampered by inconsistent nomenclature (pathotype codes developed separately in each country or the same number has been used for different pathotypes), the lack of internationally accepted differential potato varieties, the diversity of test methods and the diverse rating systems used to classify levels of resistance (Baayen et al., 2006; Flath et al., 2014).

S. endobioticum was implicated as a potential vector of Potato Virus X (PVX) (Nienhaus and Stille, 1965). The authors assumed that the virus is transmitted inside the winter sporangia of the pest. However, there has been no further research to confirm these initial observations and Lange (1978) was not successful in transmitting the virus from infected potato plants to tomato using zoospores of *S. endobioticum*.

3.1.3. Detection and identification of the pest

Are detection and identification methods available for the pest?

Yes. *Synchytrium endobioticum* can be detected and identified based on host association, symptomatology, morphology and molecular methods. Molecular methods are also available for distinguishing the common European pathotype, pathotype 1(D1), from the other three most important pathotypes occurring in Europe, i.e. 2 (G1), 6(O1) and 18(T1)

Synchytrium endobioticum can be detected and identified on potato plant material based on symptomatology and morphology of its sporangia formed in warts (EPPO, online). The identity of sporangia can be further confirmed by molecular methods (Gagnon et al., 2016; EPPO, online).

Methods are also available for the detection and identification of *S. endobioticum* winter sporangia in soil (EPPO, online).

Determination of viability of winter sporangia of *S. endobioticum* can be made by microscopic examination or bioassay (EPPO, online). Fresh sporangia generally have homogeneous, granular, greyish contents. Upon germination, they become empty and disintegrate. However, there is considerable dispute about whether the viability can be assessed by microscopic examination of their contents and/or plasmolysis of these contents (EPPO, online). It is generally agreed that winter sporangia with incomplete, heterogeneous contents may be difficult to identify as dead or alive. It is also agreed that the

use of vital staining and UV fluorescence techniques does not overcome this difficulty. Therefore, the distinction between live and dead winter sporangia is recommended to be restricted to cases where the features observed allow for unambiguous discrimination, and to experts with many years of experience with *S. endobioticum*. In case of doubt, winter sporangia should be considered viable.

Bioassays using a set of differential potato varieties have been developed for the identification of the most common pathotypes present in Europe (EU and non-EU countries), i.e. 1(D1), 2 (G1), 6(O1) and 18(T1) and molecular methods are available for distinguishing pathotype 1(D1) from the other three most common pathotypes present in Europe (van de Vossenberg et al., 2017; EPPO, online).

Symptoms

The typical symptoms of the disease are proliferating warts produced mainly on tubers, stolons and, in severely infected plants or very susceptible potato varieties, on stem bases (Hampson, 1981; Franc, 2007; CABI, online; EPPO, online). As symptoms most often appear on below-ground plant parts (stolons, tubers), the disease is often not noticed before harvest. Warts vary markedly in shape but are mostly spherical, with their diameter ranging from less than 1 cm to more than 8 cm (Hampson, 1981). They also vary in size from < 1 g to > 50 g fresh weight, the latter with a potential to release approximately 200,000 winter sporangia in soil (Hampson and Coombes, 1985; Hampson, 1996). Infection of tubers originates in eye tissue, but the warts may expand to engulf the whole tuber. Early infection of young developing tubers results in distortions and sponginess and makes them unrecognisable. In older tubers, the infected eyes develop into characteristic, warty, cauliflower-like protuberances. Similar warts occur on stolons while roots are not affected. Occasionally, warts also form on the lower leaves and the aerial buds located at the stem bases. These warts look pulpy to touch and are softer than those formed on tubers. Morphologically they consist of distorted, proliferated branches and leaves mixed together in a mass of hyperplastic tissue (Hampson, 1981; Obidiegwu et al., 2014).

Warts formed above ground are green, because of their exposure to light, while subterranean warts are white to brown (Hampson, 1981). At maturity, wart tissue becomes dark brown to black. All warts eventually rot and disintegrate, sometimes prior to harvest (Putnam and Sindermann, 1994).

Potato wart has an incubation period of several weeks (Spieckermann and Kotthof, 1924). According to EPPO (online), small warts appear on artificially inoculated potato tubers after 4–5 weeks incubation in the dark, at temperatures 16–18°C and high relative humidity (at least 85–90%).

As the disease may continue developing after harvest, small warts hardly noticed at harvest may become evident during prolonged storage of tubers. Although the disease does not kill the host, the meristematic tissue of sprouts may be so severely infected that plants fail to emerge from seed tubers early in the growing season. Infected plants occasionally show general symptoms of reduced vigour, especially when warts are formed at the stem base (Obidiegwu et al., 2014).

Symptoms associated with potato wart may appear similar to those caused by powdery scab (*Spongospora subterranea* f. sp. *subterranea*), common scab (*Actinomyces scabies*), potato smut (*Thecaphora solani*) or a non-parasitic disease named 'proliferation of eyes' or 'pseudo-wart'. Therefore, detection and identification of *S. endobioticum* on potato plant material is only possible by laboratory examination (Franc, 2007; EPPO, online).

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Morphology

S. endobioticum does not produce hyphae (Franc, 2007; Obidiegwu et al., 2014; EPPO, online) but sporangia of two types: winter and summer sporangia.

Winter sporangia are aseptate, golden brown to dark brown, mostly spherical to ovoid in shape, thick-walled (triple wall), with the outer wall furrowed, prominently ridged and irregularly thickened, 25–75 µm (mean 50 µm) in diameter. When warts decay, winter sporangia have a characteristic angular appearance in median view (Obidiegwu et al., 2014; EPPO, online). These morphological characters distinguish the winter sporangia of the pest from those of other terrestrial *Synchytrium* species present in potato fields. Hampson et al. (1996) found that winter sporangia contain allomelanin, which protects the sporangia from degradation due to irradiation, enzymatic lysis, high temperatures, etc. and may contribute to their longevity in soil (see Section 3.1.2).

Summer sporangia are thin-walled, transparent and of similar size to winter sporangia (EPPO, online). Numerous zoospores may be visible within the summer sporangia (EPPO, online).

Zoospores are approximately 3 µm in diameter, spherical to elongate in shape, and have a single flagellum 17 µm long with a whiplash portion of ca. 2.5 µm in length (Obidiegwu et al., 2014; EPPO, online).

3.2. Pest distribution

3.2.1. Pest distribution outside the EU

Synchytrium endobioticum originates in South America (Andean region) (EPPO, online). It was introduced into Europe in the 1880s and into North America in the 1900s. Since then, the pest has been reported in all continents (Figure 1 and Table 2). However, the distribution of the pest in most of the infested countries is fragmentary due to strict statutory measures for preventing its spread (Kunkel 1919; EPPO, online). These measures combined with the limited dispersal potential of the pest via natural means (e.g. water, wind, etc) have greatly contributed to its confinement mainly to the site(s) where it was initially detected (Franc, 2007).

S. endobioticum occurs in many European countries neighbouring the EU28, such as Belarus, Faroe Islands, Norway, Russia, Switzerland, Ukraine, Montenegro and Turkey (EPPO, online).

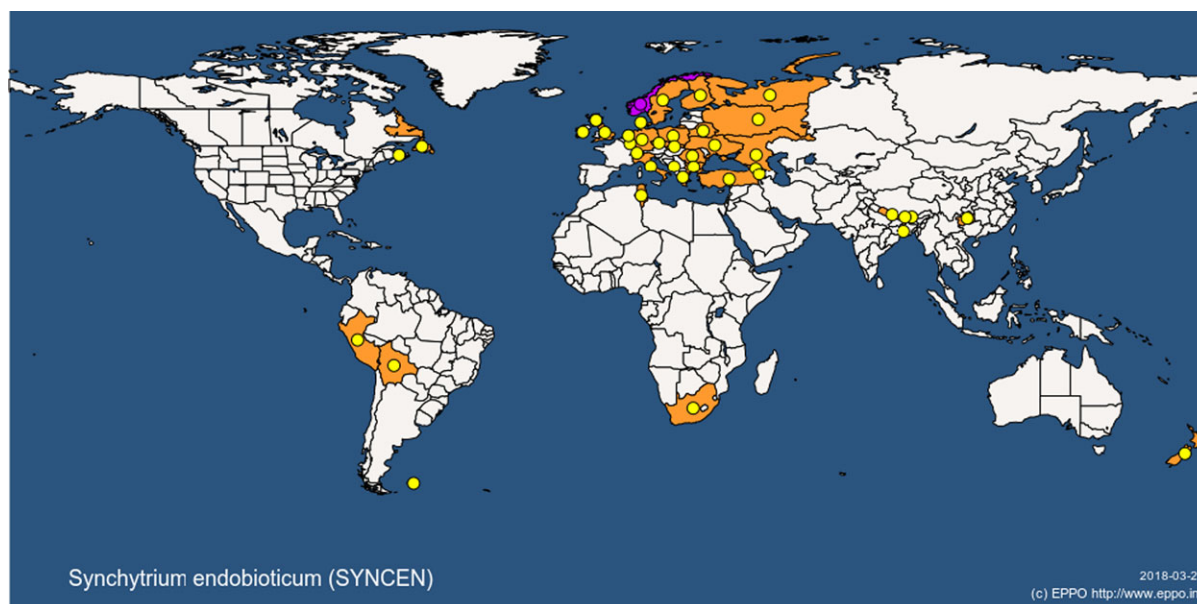


Figure 1: Global distribution map for *Synchytrium endobioticum* (extracted from the EPPO Global Database accessed on 2/5/2018) ● Present; ● Transient

Table 2: Global distribution of *Synchytrium endobioticum* based on information extracted from the EPPO Global Database (last updated: 6/4/2018; last accessed: 28/5/2018)

Continent	Country	Status
Africa	South Africa	Present, restricted distribution
	Tunisia	Present, few occurrences
America	Bolivia	Present, no details
	Canada	Present, restricted distribution
	Falkland Islands (UK)	Present, no details
	Peru	Present, no details
Asia	Bhutan	Present, no details
	China	Present, no details
	India	Present, restricted distribution
	Nepal	Present, no details
Europe (non-EU)	Armenia	Present, few occurrences
	Belarus	Present, restricted distribution
	Faroe Islands (Denmark)	Present, no details
	Georgia	Present, restricted distribution
	Montenegro	Present, restricted distribution
	Norway	Transient, under eradication
	Russia	Present, restricted distribution
	Switzerland	Present, few occurrences
	Turkey	Present, restricted distribution
	Ukraine	Present, restricted distribution
Oceania	New Zealand	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?

YES. *Synchytrium endobioticum* is present in 16 EU Member States, with a restricted and fragmentary distribution.

Potato wart disease was first described in England in 1886, and soon thereafter in Czech Republic and Slovakia, Hungary and Ireland. It was discovered in Germany, the Netherlands, Poland, and Finland in the beginning of the 20th century (Franc, 2007; Obidiegwu et al., 2014). Over time, potato wart disease occurred sporadically in most other EU MSs. According to the EPPO Global Database, *S. endobioticum* is currently present in 16 EU MSs (Table 3). Its distribution in each of those countries is reported as restricted and fragmentary resulting from many years of statutory control (EPPO, online).

Table 3: Current distribution of *Synchytrium endobioticum* in the 28 EU Member States based on information from the EPPO Global Database (last updated: 6/4/2018; last accessed: 28/5/2018)

EU Member State	Status
Bulgaria	Present, restricted distribution
Czech Republic	Present, restricted distribution
Denmark	Present, few occurrences
Estonia	Present, restricted distribution
Finland	Present, few occurrences
Germany	Present, restricted distribution
Greece	Present, few occurrences
Ireland	Present, restricted distribution
Italy	Present, restricted distribution
Luxembourg	Present, restricted distribution
Netherlands	Present, few occurrences
Poland	Present, few occurrences
Romania	Present, restricted distribution
Slovakia	Present, restricted distribution
Sweden	Present, restricted distribution
United Kingdom	Present, restricted distribution

Uncertainties on the pest distribution worldwide

Because of the very long persistence of winter sporangia in the soil, the EPPO Standard PM 3/59(3) recommends that a field previously infested with *S. endobioticum* can be de-scheduled after a minimum of 20 years since the last detection, provided that it is sampled, tested and found free from viable winter sporangia (EPPO, online). This combined with (i) the resistance of winter sporangia to high temperatures, microbial antagonism and competition, (ii) the lack of effective chemical or physical control measures to eliminate the inoculum in the soil, (iii) the uneven distribution of winter sporangia in the soil, (iv) the difficulty in distinguishing live and dead winter sporangia, and (v) the fact that the sensitivity of the available molecular methods is not high enough for the detection of low inoculum levels in the soil, result in some uncertainties with regards to the status of *S. endobioticum* in countries worldwide where the pest is reported as 'absent, unreliable record' or 'no longer present' or 'eradicated' (Table 4). It is worth noting that by 1970, the pest was considered no longer present in the Netherlands (Baayen et al., 2006). In 1973, however, it was rediscovered in a field in the province of Groningen. *Synchytrium endobioticum* was also considered eradicated in Denmark until it was detected again in 2014 and 2016 (IPPC, 2014; Molet et al., 2016; EPPO, online).

Uncertainty also exists about the status of *S. endobioticum* in countries where the absence of the pest was either not confirmed by surveys or confirmed by surveys which were conducted more than 20 years ago (Table 4). Also, the pest status in Cyprus, Malta and Spain is uncertain because there is no information available in the EPPO Global Database.

Table 4: Countries where the status of *Synchytrium endobioticum* is considered as uncertain

Continent	Country	Status	Detailed information provided by EPPO Global Database
Africa	Egypt	Absent, unreliable record	Doubtful record
	Zimbabwe	Absent, unreliable record	Doubtful record
America	Ecuador	Absent, unreliable record	This record from the Caribbean Plant Protection Commission (CPPC) is not confirmed by the Ecuador Plant Protection Service, surprisingly since the pest is of Andean origin
	United States of America	Absent, pest eradicated	Discovered in 1918 in Pennsylvania, later found in Maryland and West Virginia. Thought to have been eradicated by 1974, but it was found again in one garden in Maryland in 1987. Finally, it was considered eradicated in Maryland in 1994
	Uruguay	Absent, confirmed by survey	First reported in 1933 (national record). Between 1980 and 1986 a national prevention campaign against <i>Pseudomonas solanacearum</i> was undertaken and commercial potato crops were thoroughly inspected; <i>S. endobioticum</i> was never found. From 1988 onwards, the Plant Protection Services have been analysing the seed potato consignments from the national certification programme and have not found the pest The Panel notes that only potato seed tubers produced under the certification scheme were tested; there is no information whether tests were conducted for the presence of the pest on ware potatoes
Asia	Iran	Absent, unreliable record	Doubtful record
	Japan	Absent, confirmed by survey	Based on NPPO declaration dated 1992
	Korea Dem. People's Republic	Absent, unreliable record	Doubtful record
	Korea, Republic	Absent, unreliable record	Doubtful record
	Lebanon	Absent, unreliable record	Doubtful record
Europe (EU 28)	Croatia	Absent, pest no longer present	The pest was eradicated in 1960. 206 tests on potato samples collected in 2003 growing season were negative The Panel questions the size of the sampling
	Cyprus	—	
	Hungary	Absent, pest eradicated	First recorded in 1971. Eradicated in 1971 The Panel questions the reliability of this information Australian data sheet: first described in Hungary in 1896. However, this could well be in what is now Slovakia, so in the absence of any other proper report in Hungary, unconfirmed
	Malta	—	
	Portugal	Absent, pest eradicated	From NPPO (1992): absent, pest eradicated. No details are provided
	Spain	—	

—: pest status unknown because there is no information available.

3.3. Regulatory status

3.3.1. Council Directive 2000/29/EC

Synchytrium endobioticum is listed in Council Directive 2000/29/EC. Details are presented in Tables 5 and 6.

Table 5: *Synchytrium endobioticum* 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 II	Harmful organisms known to occur in the community and relevant for the entire community
(c)	Fungi
2.	<i>Synchytrium endobioticum</i> (Schilbersky) Percival

3.3.2. Legislation addressing the hosts of *Synchytrium endobioticum*

Table 6: Regulated hosts and commodities that may involve *Synchytrium endobioticum* 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
10.	Tubers of <i>Solanum tuberosum</i> L., seed potatoes	Third countries other than Switzerland
11.	Plants of stolon- or tuber-forming species of <i>Solanum</i> L. or their hybrids, intended for planting, other than those tubers of <i>Solanum tuberosum</i> L. as specified under Annex III A (10)	Third countries
13.	Plants of Solanaceae intended for planting, other than seeds and those items covered by Annex III A (10), (11) or (12)	Third countries, other than European and Mediterranean 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
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
25.1	Tubers of <i>Solanum tuberosum</i> L., originating in countries where <i>Synchytrium endobioticum</i> (Schilbersky) Percival is known to occur	Without prejudice to the prohibitions applicable to the tubers listed in Annex III(A)(10), (11) and (12), official statement that: (a) the tubers originate in areas known to be free from <i>Synchytrium endobioticum</i> (Schilbersky) Percival (all races other than Race 1, the common European race), and no symptoms of <i>Synchytrium endobioticum</i> (Schilbersky) Percival have been observed either at the place of production or in its immediate vicinity since the beginning of an adequate period; or

		(b) provisions recognised as equivalent to the Community provisions on combating <i>Synchytrium endobioticum</i> (Schilbersky) Percival in accordance with the procedure referred to in Article 18(2) have been complied with, in the country of origin
33.	Plants with roots, planted or intended for planting, grown in the open air	Official statement that: (a) the place of production is known to be free from <i>Clavibacter michiganensis</i> ssp. <i>sepedonicus</i> (Spieckermann and Kotthoff) Davis et al. and <i>Synchytrium endobioticum</i> (Schilbersky) Percival.
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 two 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).
Section II Plants, plant products and other objects originating in the Community		
	Plants, plant products and other objects	Special requirements
18.1	Tubers of <i>Solanum tuberosum</i> L., intended for planting	Official statement that: (a) the Union provisions to combat <i>Synchytrium endobioticum</i> (Schilbersky) Percival have been complied with;
18.2	Tubers of <i>Solanum tuberosum</i> L., intended for planting, other than tubers of those varieties officially accepted in one or more Member States pursuant to Council Directive 70/457/EEC of 29 September 1970 on the common catalogue of varieties of agricultural plant species (1)	Without prejudice to the special requirements applicable to the tubers listed in Annex IV(A)(II) (18.1), official statement that the tubers: — belong to advanced selections such a statement being indicated in an appropriate way on the document accompanying the relevant tubers, — have been produced within the Community, and — have been derived in direct line from material which has been maintained under appropriate conditions and has been subjected within the Community to official quarantine testing in accordance with appropriate methods and has been found, in these tests, free from harmful organisms
18.3	Plants of stolon or tuber-forming species of <i>Solanum</i> L., or their hybrids, intended for planting,	(a) The plants shall have been held under quarantine conditions and shall have been found free of any harmful organisms in quarantine testing;

	other than those tubers of <i>Solanum tuberosum</i> L. specified in Annex IV(A)(II) (18.1) or (18.2), and other than culture maintenance material being stored in gene banks or genetic stock collections	<p>(b) the quarantine testing referred to in (a) shall:</p> <p>(aa) be supervised by the official plant protection organisation of the Member State concerned and executed by scientifically trained staff of that organisation or of any officially approved body;</p> <p>(bb) be executed at a site provided with appropriate facilities sufficient to contain harmful organisms and maintain the material including indicator plants in such a way as to eliminate any risk of spreading harmful organisms;</p> <p>(cc) be executed on each unit of the material,</p> <p>— by visual examination at regular intervals during the full length of at least one vegetative cycle, having regard to the type of material and its stage of development during the testing programme, for symptoms caused by any harmful organisms,</p> <p>— by testing, in accordance with appropriate methods to be submitted to the Committee referred to in Article 18:</p> <p>— in the case of all potato material at least for</p> <ul style="list-style-type: none"> — Andean potato latent virus, — Arracacha virus B. oca strain, — Potato black ringspot virus, — Potato spindle tuber viroid, — Potato virus T, — Andean potato mottle virus, — common potato viruses A, M, S, V, X and Y (including Y^o, Yⁿ and Y^c) and Potato leaf roll virus, — <i>Clavibacter michiganensis</i> ssp. <i>sepedonicus</i> (Spieckermann and Kotthoff) Davis et al., — <i>Ralstonia solanacearum</i> (Smith) Yabuuchi et al., <p>— in the case of true seed potato of least for the viruses and viroid listed above;</p> <p>(dd) by appropriate testing on any other symptom observed in the visual examination in order to identify the harmful organisms having caused such symptoms;</p> <p>(c) any material, which has not been found free, under the testing specified under (b) from harmful organisms as specified under (b) shall be immediately destroyed or subjected to procedures which eliminate the harmful organism(s);</p> <p>(d) each organisation or research body holding this material shall inform their official Member State plant protection service of the material held.</p>
18.4	Plants of stolon, or tuber-forming species of <i>Solanum</i> L., or their hybrids, intended for planting, being stored in gene banks or genetic stock collections	Each organisation or research body holding such material shall inform their official Member State plant protection service of the material held.
18.5	Tubers of <i>Solanum tuberosum</i> L., other than those mentioned in Annex IV(A)(II) (18.1), (18.1.1), (18.2), (18.3) or (18.4)	There shall be evidence by a registration number put on the packaging, or in the case of loose-loaded potatoes transported in bulk, on the vehicle transporting the potatoes, that the potatoes have been grown by an officially registered producer, or originate from officially registered collective storage or dispatching centres located in the area of production, indicating that the tubers are free from <i>Ralstonia solanacearum</i> (Smith) Yabuuchi et al. and that

		(a) the Union provisions to combat <i>Synchytrium endobioticum</i> (Schilbersky) Percival, [...] are complied with
24.	Plants with roots, planted or intended for planting, grown in the open air	There shall be evidence that the place of production is known to be free from <i>Clavibacter michiganensis</i> ssp. <i>sepedonicus</i> (Spieckermann and Kotthoff) Davis et al. and <i>Synchytrium endobioticum</i> (Schilbersky) Percival
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	
1.3.	Plants of stolon- or tuber-forming species of <i>Solanum</i> L. or their hybrids, intended for planting.	
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	
4.	Tubers of <i>Solanum tuberosum</i> L.	
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.	

In addition to Council Directive 2000/29/EC on protective measures against the introduction into and spread within the EU territory of *S. endobioticum*, and given that:

- potato production occupies an important place in the EU agriculture,
- *S. endobioticum* is considered one of the most harmful organisms to potatoes,
- the disease has occurred in several MSs and some limited sources of infection exist in the EU, and
- there is a permanent risk to potato cultivation throughout the EU territory if effective measures are not taken to control the disease and prevent it from spreading.

Measures to be taken within the 28 EU MSs to control potato wart disease and to prevent it from spreading are set in Council Directive 69/464/EEC.⁴ These measures mainly concern:

- the demarcation of the contaminated plot and a safety zone around it large enough to ensure the protection of surrounding areas,
- the prohibition of growing or storing in the contaminated plots potato plants or other plants intended for transplanting
- the cultivation of the safety zone only with potato varieties resistant to the *S. endobioticum* pathotype(s) present in the contaminated plot
- each MS will communicate to the Commission before 1 January each year a list of all the potato varieties accepted by them for marketing and which they have found, by official investigation, to be resistant to *S. endobioticum* and they will state the 'races' (pathotypes) to which the varieties are resistant, and
- the MSs will revoke the measures taken to control potato wart or to prevent its spreading only if *S. endobioticum* is no longer found to be present.

⁴ Council Directive 69/464/EEC of 8 December 1969 on control of potato wart disease. Official Journal of the European Communities L323, 561-562. Available on line: <https://publications.europa.eu/en/publication-detail/-/publication/f98a2365-6b81-49b2-a7d8-25ad6ec6297c/language-en>

According to Article 9 of the above-mentioned Directive, MSs may adopt additional or stricter provisions as may be required to control potato wart disease or to prevent it from spreading.

3.4. Entry, establishment and spread in the EU

3.4.1. Host range

The major natural host of *Synchytrium endobioticum* is *Solanum tuberosum* (cultivated potato), but in Mexico, the pest has also been reported to affect wild species of the genus *Solanum* (Obidiegwu et al., 2014; EPPO, online).

Under experimental conditions, *S. endobioticum* can infect the roots of *Solanum lycopersicum* (tomato) and other species of the Family Solanaceae, such as *Capsicastrum nanum*, *Datura* sp., *Duboisia* sp., *Hyoscyamus* sp., *Lycium* sp., *Nicandria* sp., *Nicotiana* sp., *Schizanthus* sp., *Physalis franchetii*, and *Solanum dulcamara* without inducing wart formation (Hampson, 1976; Hampson, 1979; Hampson and Haard, 1980; Hampson, 1986; CABl, online; EPPO, online).

Solanum tuberosum is the only major host (EPPO, online) and is regulated in the EU. Therefore, the Panel decided to focus this pest categorisation on *Solanum tuberosum*. Nevertheless, uncertainty exists on the host status of wild species of *Solanum* present in the EU territory.

3.4.2. Entry

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

YES. Under the current EU legislation, the pest could potentially enter the EU through the following pathways: (i) soil and growing media consisting of soil or organic substances attached to or associated with plants with roots, planted or intended for planting, grown in greenhouses established in infested areas in Tunisia and infested European non-EU28 countries, other than Turkey, Belarus, Georgia, Moldova, Russia and Ukraine, (ii) soil and growing media consisting of soil or organic substances not attached to or associated with plants originating in Tunisia and infested continental European non-EU28 countries, other than Turkey, Belarus, Moldova, Russia and Ukraine, (iii) soil and growing media consisting of soil or organic substances attached to or associated with below ground plant parts (bulbs, tubers, corms, etc), other than potato tubers and roots originating in Tunisia and infested European non-EU28 countries, other than Turkey, Belarus, Georgia, Moldova, Russia and Ukraine, (iv) soil adhering to agricultural machinery and implements, footwear, vehicles, etc. that have been used in infested areas in third countries, (v) manure of livestock fed on infected potato tubers or having grazed in infested fields in third countries, and (vi) waste of potato processing industries originating in infested third countries and intended to be used as fertiliser.

The PLH Panel identified the following pathways for the entry of *S. endobioticum* into the EU territory, in the absence of the current EU legislation:

- 1) Potato tubers intended for planting (seed tubers), particularly those with inconspicuous warts.
- 2) Potato tubers intended for consumption or processing (ware potatoes), particularly those with inconspicuous warts, that may be planted (especially in small holdings and private gardens), discarded (whole potatoes or peels) or used for livestock feed
- 3) Soil adhering to potato tubers (seed and ware potatoes) of resistant varieties
- 4) Soil adhering to below ground parts (tubers, bulbs, roots, etc.) of non-host plants intended for planting
- 5) Soil and growing media containing soil or organic substances not associated with plants
- 6) Soil adhering to agricultural machinery and implements, footwear, vehicles, etc.
- 7) Manure derived from animals fed on infected potato tubers (whole tubers or peels) or having grazed in infested fields
- 8) Waste (plant material and water) of potato processing industries used as fertiliser or for irrigation.

S. endobioticum is not known to infect the true seeds of potato plants. The pest is unlikely to enter the EU territory by natural means (wind, water) as it has a limited capacity for natural spread.

The following pathways of entry of *S. endobioticum* into the EU territory are regulated by the current EU legislation (Table 3, Annexes III & IV):

- potato tubers intended for planting (seed tubers) originating in third countries,
- tubers of *Solanum tuberosum* (ware potatoes) originating in infested third countries,
- stolon- or tuber-forming plants for planting of *Solanum* spp., or their hybrids, other than *Solanum tuberosum* seed tubers, originating in third countries,
- plants for planting of the family Solanaceae, other than *Solanum tuberosum* seed tubers and stolon- or tuber-forming *Solanum* species, originating in third countries other than European non-EU28 countries and Mediterranean countries,
- plants with roots, planted or intended for planting, grown in the open air,
- 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 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.

Based on the above, under the current EU legislation, the pest could potentially enter the risk assessment area through the following pathways:

- soil and growing media consisting of soil or organic substances attached to or associated with plants with roots, planted or intended for planting, grown in greenhouses established in infested areas in Tunisia and infested European non-EU28 countries, other than Turkey, Belarus, Georgia, Moldova, Russia and Ukraine.
- soil and growing media consisting of soil or organic substances not attached to or associated with plants originating in Tunisia and infested continental European non-EU28 countries, other than Turkey, Belarus, Moldavia, Russia and Ukraine.
- soil and growing media consisting of soil or organic substances attached to or associated with below ground plant parts (bulbs, tubers, corms, etc), other than potato tubers and roots originating in Tunisia and infested European non-EU28 countries, other than Turkey, Belarus, Georgia, Moldova, Russia and Ukraine.
- soil adhering to agricultural machinery and implements, footwear, vehicles, etc. that have been used in infested areas in third countries.
- manure of livestock fed on infected potato tubers or having grazed in infested fields in third countries.
- waste of potato processing industries originating in infested third countries and intended to be used as fertiliser.

Uncertainty exists on whether the pest could enter the EU territory through the last three of the above-mentioned pathways, because there are no import data available in the Eurostat database (accessed on 2/5/2018).

According to Eurostat, during the period 2011–2015, an average of 360,000 tonnes of potato tubers was imported into the EU territory from third countries yearly, with 4.17% of them originating in infested countries (Table 7).

Table 7: Volume (in tonnes) of potato tubers imported during the period 2011–2015 into the 28 EU Member States from third countries (Source: Eurostat, extracted on 3/5/2018)

EU28 potato tuber importation (in tons)	2011	2012	2013	2014	2015
From non-EU countries	402,036	349,711	455, 497	288,063	306,179
From non-EU infested countries	13,397	10,491	37, 416	8,620	5,109
% from infested countries	3	3	8	3	2

Between 1998 and 2017, there were 16 extra- and intra-EU interceptions of *S. endobioticum* on potato tubers in the Europhyt database (search done on 03/05/2018) (Table 8).

Table 8: Interceptions of *Synchytrium endobioticum* on tubers of *Solanum tuberosum* imported into or traded within the 28 EU Member States during the period 1998–2017 (Source: Europhyt, extracted on 3/5/2018)

Year	Intercepted in	Origin	Number of interceptions
1999	France	Germany	1
2004	Netherlands	Germany	2
2009	Bulgaria	Turkey	11
2012	Bulgaria	Greece	1
2017	Netherlands	Peru ^(a)	1

(a): Intercepted in the luggage of a traveller.

3.4.3. Establishment

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

YES. The pest is currently present in 16 EU MSs, which indicates that the biotic (host availability) and abiotic (climate suitability) factors occurring in the risk assessment area are favourable for its establishment.

3.4.3.1. EU distribution of main host plants

Potatoes are widely grown in the EU territory (Table 9; Source: Eurostat, data extracted on 3/5/2018).

Table 9: Area (in 1,000 ha) cultivated with *Solanum tuberosum* in the 28 EU Member States between 2011 and 2015 (Source: Eurostat, extracted on 3/5/2018)

Countries	2011	2012	2013	2014	2015	Mean of EU area grown with <i>Solanum tuberosum</i> (in 1,000 ha) during the period 2011–2015
European Union (EU28)	1,922	1,798	1,741	1,663	1,656	1,756
Poland	393	373	337	267	293	333
Germany	259	238	243	245	237	244
Romania	248	229	208	203	196	217
France	159	154	161	168	167	162
Netherlands	159	150	156	156	156	155
United Kingdom	146	149	139	141	129	141
Belgium	82	67	75	80	79	77
Spain	80	72	72	76	72	74
Italy	62	59	50	52	50	55
Denmark	42	40	40	20	42	36
Lithuania	37	32	28	27	23	29
Portugal	27	25	27	27	25	26
Sweden	28	25	24	24	23	25
Greece	28	24	25	24	21	24
Czech Republic	26	24	23	24	23	24
Finland	24	21	22	22	22	22
Austria	23	22	21	21	20	22
Hungary	21	25	21	21	19	21
Bulgaria	16	15	13	10	11	13
Latvia	14	12	12	11	10	12
Croatia	11	10	10	10	10	10
Ireland	10	9	11	9	9	10
Slovakia	10	9	9	9	8	9

Countries	2011	2012	2013	2014	2015	Mean of EU area grown with <i>Solanum tuberosum</i> (in 1,000 ha) during the period 2011–2015
Estonia	6	6	5	4	4	5
Cyprus	5	5	5	5	5	5
Slovenia	4	3	3	4	3	3
Malta	1	1	1	1	1	1
Luxembourg	1	1	1	1	1	1

3.4.3.2. Climatic conditions affecting establishment

Currently, *S. endobioticum* is known to occur in 16 EU MSs (Table 3). These MSs are characterised by a range of the Köppen-Geiger climate types (Peel et al., 2007) (Figure 2), which also occur in those EU MSs where potatoes are grown, and the pest is reported as no 'longer present' or 'eradicated' (EPPO, online). The only exception is the BSk (Arid, steppe, cold) climate type, which is only present in some areas of Spain, but there is no information on the pest status in that MS. The BSk climate is also present in parts of Turkey (Figure 2), which are known to be infested by *S. endobioticum* (Anonymous, 2009). Although the disease had been observed previously in cooler areas, its presence in Turkey shows that the pest is also well adapted to continental climates (Çakir et al., 2009).

Therefore, the abiotic factors (climate suitability) suggest that the pest could potentially establish wherever potato is grown in the risk assessment area. The potential for *S. endobioticum* to establish is also related to the fact that the pathogen is soil-borne and that potatoes are commonly irrigated, so that soil moisture may be sufficient for the development of the pathogen.

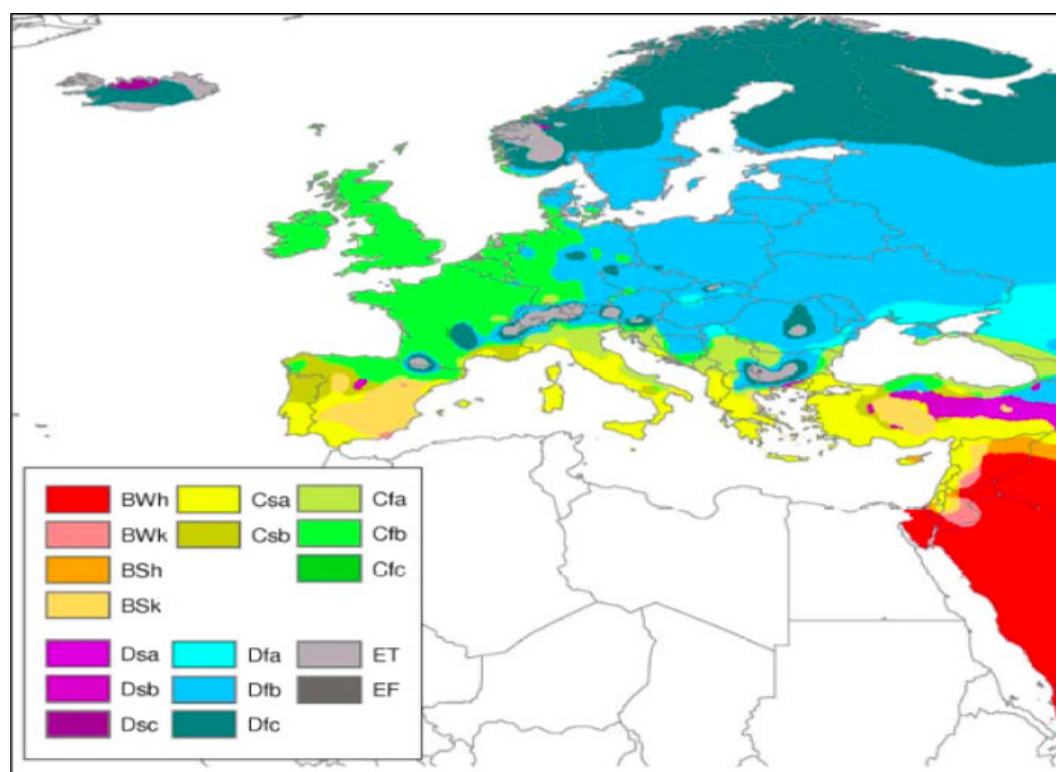


Figure 2: Köppen-Geiger climate type map of Europe, from Peel et al. (2007)

3.4.4. Spread

3.4.4.1. Vectors and their distribution in the EU

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

How? Mainly by 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?

NO. Spread of the pest is mainly via the movement of (i) infected potato seed tubers, (ii) soil as commodity or contaminant, and (iii) infected ware potato tubers

Spread by natural means. *S. endobioticum* has limited capacity for spread by natural means (wind, water, etc.) (Hampson, 1993, 1996; Franc, 2007; Obidiegwu et al., 2014). Nevertheless, winter sporangia can be dispersed within a field or between neighbouring fields by irrigation water runoff, wind and windblown soil particles. Hampson and Coombes (1989) showed that earthworms could also facilitate dissemination of *S. endobioticum* over a distance of 9–25 cm.

Spread by human-assisted means. The pest can spread over long distances through the trade/movement of infected potato tubers and infested soil adhering to potato tubers (especially of resistant potato varieties grown in infested areas) or below ground parts of non-host plants (e.g. roots, bulbs, stolons, etc) or any other object (e.g. farm machinery, implements and footwear used in infested fields, vehicles visiting infested areas, etc) (Hampson, 1981, 1993, 1996; Langerfeld, 1984; Smith et al., 1997; Stachewicz and Langerfeld, 1998; Molet et al., 2016). The pest could also be spread through manure from animals fed on infected potato tubers or having grazed in infested fields (see Section 3.1.2). The pest may easily spread via waste (e.g. discarded potatoes, soil, water) from potato processing industries used as fertiliser, land fill or irrigation water (Efremenko and Yakovleva, 1981; Langerfeld, 1984; Steinmüller et al., 2004). Potato processing is an important industrial sector in many EU MSs, including Germany, where 3 million tonnes of waste are produced of which the major part is used as fertiliser (Steinmüller et al., 2012).

3.5. Impacts

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

YES. The pest is already established in the EU territory causing direct and indirect impacts to potato 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?⁵

YES. The presence of the pest on potato seed tubers has an economic impact.

Potatoes rank fourth on the list of world food crops, after maize, rice and wheat (FAOSTAT, online). The total world potato production was estimated at 381.7 million tonnes in 2014. The EU ranks third in fresh potato production after China and India (FAOSTAT, online). In 2015, the EU produced 53.2 million tonnes of potatoes, with Germany, France and the Netherlands as the largest producers (Table 10). The value of EU potato production, including seed potatoes, at basic prices was EUR 10 billion, representing 2.5% of the total EU agricultural output and 4.7% of the crop output at EU level (de Cicco and Jeanty, 2017). Most potatoes are traded in the internal EU market. The EU is a net potato exporter, but potatoes are imported into its territory in winter and spring from southern and eastern Mediterranean countries, including Egypt, Israel and Turkey, each of which producing 1–5 million tonnes of potatoes annually (de Cicco and Jeanty, 2017).

⁵ See section 2.1 on what falls outside EFSA's remit.

Table 10: Potato production, including potato seed tubers, in the 28 EU Member States in 2015 (Source: Eurostat; extracted on 2/5/2018)

Country	Harvested production (in 1,000 tonnes)	Share of 28 EU MSs harvested production (%)
EU28	53 160	100.00
Germany	10,370	19.51
France	7,114	13.38
Netherlands	6,652	12.51
Poland	6,152	11.57
United Kingdom	5,598	10.53
Belgium	3,665	6.89
Romania	2,625	4.94
Spain	2,284	4.30
Denmark	1,748	3.29
Italy	1,355	2.55
Sweden	803	1.51
Greece	556	1.05
Austria	536	1.01
Finland	532	1.00
Czech Republic	505	0.95
Portugal	487	0.92
Hungary	452	0.85
Lithuania	392	0.74
Ireland	360	0.68
Latvia	204	0.38
Croatia	171	0.32
Bulgaria	165	0.31
Slovakia	145	0.27
Cyprus	96	0.18
Slovenia	91	0.17
Estonia	81	0.15
Luxembourg	13	0.02
Malta	8	0.02

Synchytrium endobioticum is the most important pest in most parts of the world where potatoes are commercially grown (Smith et al., 1997, 2014; Obidiegwu et al., 2014). The disease reduces plant growth and yield and makes potato tubers unmarketable (see Section 3.1.3). Direct yield losses are dependent on soil conditions during tuber development, the susceptibility of the potato variety grown, the aggressiveness of the pathotype(s) present in the infested field(s) and the inoculum (winter sporangia) concentration in the soil (Wale et al., 2011; Molet et al., 2016). Yield losses between 50 and 100% have been reported worldwide (Hampson, 1993; Melnik, 1998; Baker et al., 2007; Franc, 2007). The warts continue to develop during storage of potato tubers resulting in additional losses. The major problem, however, is the contamination of the soil with the persistent winter sporangia of the pest that remain viable and infectious for more than 40 years (see Section 3.1.2). As it is impossible to eliminate the pest in the soil by chemical or physical means (Obidiegwu et al., 2014), infested fields cannot be used for potato production for more than 20 years after the detection of the pest (Baker et al., 2007; Franc, 2007; Molet et al., 2016). The disease is so serious that, for more than 75 years, quarantine and domestic legislations have been in force throughout the world to prevent the pest from spreading (Baker et al., 2007; Obidiegwu et al., 2014; EPPO, online). These measures combined with the limited capacity of *S. endobioticum* for spread by natural means (wind, water, etc.), have mostly contained the pest locally, thus minimising its direct impacts (CABI, online; EPPO, online). However, the pest is still spreading in Europe and new pathotypes arise, which overcome the varietal resistance (Przetakiewicz, 2015; EPPO, online).

At the EU level, the legislation in force (Council Directive 69/464/EEC) for the control of potato wart (see Section 3.3), among other measures, prohibits the cultivation of the infested field with potatoes

or non-host plants intended for transplanting until the soil is tested free of winter sporangia. In addition, restrictions are in place regarding the crops that can be cultivated in the safety zones, for example only potato varieties found in official tests to be resistant to the pathotype(s) present may be grown. As a result, during the last decades, the infested EU MSs are facing substantial indirect consequences, such as long-term quarantine and regulatory restrictions applied to infested areas, the loss of markets, and restrictions in the export from or movement within the infested areas of plants, plant products and other objects (soil, farm machinery and equipment, vehicles, etc). Indirect economic losses can be especially high when areas grown with potato for seed tuber production become subject to quarantine measures. Changes in production practices and specific research activities, mainly for the identification of pathotypes and determination of resistant varieties to be grown in the safety zone, can result in additional economic losses (Hampson, 1993). For example, the detection of potato wart on Prince Edward Island, Canada, in 2000, followed by strict regulatory actions, resulted in approximately \$30 million loss for the island in that year alone (Franc, 2007).

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. the likelihood of pest entry can be mitigated if potato seed tubers and non-host plants or plant parts (bulbs, roots, tubers, etc.) for planting are sourced from pest-free areas or pest-free places of production and are inspected and lab-tested (including the soil attached to them) both at the place of origin and at the EU entry point. There are no measures that could prevent the establishment of the pest in the EU territory. As chemical control is not effective, in the infested areas strict quarantine and sanitation measures are applied to prevent the pest from spreading.

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

YES. The presence of *Synchytrium endobioticum* on potato seed tubers and below ground parts of non-hosts plants for planting could be prevented by sourcing them in pest-free areas or places of production

Measures for preventing the entry of the pest into the risk assessment area include:

- Import only potato seed tubers from pest free areas or places of production.
- Sourcing ware potato tubers and non-host plants or below ground parts of non-hosts (bulbs, tubers, stolons, roots, etc) intended for planting from pest-free areas or places of production.
- Inspection and laboratory testing prior to export to the EU and at the EU entry point of potato tubers originating in infested third countries.
- Laboratory testing of the soil adhering to potato tubers and non-host plants or below ground parts of non-hosts (bulbs, tubers, stolons, roots, etc) intended for planting, and originating in infested third countries.
- Phytosanitary certificate for the import into the EU of potato tubers, non-host plants and below ground parts of non-hosts (bulbs, tubers, stolons, roots, etc) intended for planting originating in infested third countries.

There are no effective measures to prevent the establishment of the pest in the risk assessment area.

Measures for preventing the spread of the pest in the risk assessment area include:

- Surveys to establish the distribution of the pest in the infested countries and scheduling of infested fields for at least 20 years.
- Destruction of the infected potato crop by deep ploughing (at depths > 50 cm).
- Prohibition of the cultivation of infested fields with potato (particularly for the production of seed tubers) and non-host plants intended for planting or transplanting or livestock feed
- Delimitation of a safety zone around the infested field, where only potato varieties for consumption or processing fully resistant (both in the field and in the laboratory) to the pathotype(s) present in the infested field shall be grown.
- Cleaning and disinfecting the farm machinery and implements, footwear, etc used in the infested field prior to their movement to non-infested fields or areas

- Prohibition of the movement of potato tubers (seed tubers, ware potatoes) and below ground parts of non-host plants from infested areas to pest-free areas
- Prohibition of the movement of tubers (ware potatoes) of resistant varieties grown in the safety zone to pest-free areas
- Proper management of the waste (plant residues, water), derived from the potato processing industry, e.g. burning the plant residues in ovens and disinfecting the water used for washing the potato tubers
- Prohibition of grazing of livestock in the infested areas
- Prohibition of feeding livestock with (i) potato tubers, and (ii) non-host plants, including their below ground parts, grown in infested areas
- Inspection and lab testing of potato tubers (seed and ware potatoes) originating in infested EU MSs prior to their movement within the EU
- Lab testing of the soil adhering to potato tubers and non-host plants and below ground parts of non-hosts (bulbs, tubers, stolons, roots, etc.) intended for planting originating in infested EU MSs, prior to their movement within the EU
- Phytosanitary passport for the movement of potato tubers (seed potatoes, ware potatoes) and non-host plants or below ground plant parts intended for planting within the EU territory

3.6.1. Phytosanitary measures

The current EU legislation (Council Directives 2000/29/EC) covers the host but not all the pathways of entry of *S. endobioticum*. More specifically, the following pathways of entry are not regulated:

- Soil adhering to underground plant parts other than potato tubers,
- Soil attached to non-host plants grown under cover (e.g. plants grown in infested soils in greenhouses),
- Soil adhering to agricultural machinery and implements, footwear, vehicles, etc.,
- Manure of livestock fed on infected potato tubers or having grazed in infested potato fields,
- Waste of potato processing industries.

The following phytosanitary measures are relevant for *S. endobioticum*:

- Pest-free area or pest-free place of production,
- Visual inspection of the potato crop at the place of origin during the growing season and at harvest,
- Soil treatment (e.g. heat treatment, shaking of plants for removing soil),
- Lab testing,
- Plant health inspection,
- Phytosanitary certificate,
- Phytosanitary passport.

These measures can mitigate the risk of entry of *S. endobioticum* into the EU territory, but they are not fully effective in the case of soil treatment as:

- Heat treatment of the soil prior to planting could eliminate the winter sporangia of the pest only if the temperature is high enough and the sterilisation period is long enough (see Section 3.1.2),
- Shaking of the plants requires leaving the minimum amount of soil to sustain the vitality of the plants, which soil could still carry sufficient inoculum (see Section 3.1.2).

Council Directive 69/464/EEC includes the following phytosanitary measures for controlling potato wart disease and preventing it from spreading within the EU territory:

- Destruction of the infected potato crop,
- Scheduling of the infested field,
- Prohibition of growing potatoes or other plants intended for transplanting or stored in the ground of the infested field,
- Delimitation of safety zone around the infested field,
- Official testing for determining potato varieties resistant to the pathotype(s) present in the infested field,
- Cultivation of the safety zone with resistant potato varieties intended only for consumption (ware potatoes).

These measures cannot fully mitigate the risk of disease spreading within the EU, as the pest can potentially be spread through (i) soil attached to farm machinery and implements, footwear, etc. used in the infested areas, (ii) manure of livestock grazing in the infested areas or fed with infected potato tubers, and (iii) waste (including water) derived from potato processing industries. In addition, the Panel suggests that the official testing of potato varieties for resistance to pathotype(s) of the pest present in the infested field(s) shall be conducted by the MSs both in the field and in the laboratory (see Section 3.6.2). In particular, tubers of resistant varieties shall be checked for symptoms and also for the possible formation of winter sporangia on their buds/sprouts (Kritikos et al., 2016).

3.6.1.1. Biological or technical factors limiting the feasibility and effectiveness of measures to prevent the entry, establishment and spread of the pest

The following factors can limit the feasibility and effectiveness of measures to prevent the entry, establishment and spread of *S. endobioticum*:

- The similarity of symptoms caused by *S. endobioticum* on potato tubers with those caused by other potato pathogens (e.g. *Spongospora subterranea* f. sp. *subterranea*, *Thecaphora solani*, *Actinomyces scabies*, etc) or non-parasitic diseases (e.g. proliferation of eyes) makes visual inspection for the detection of the pathogen difficult (see Section 3.1.3).
- Inconspicuous warts present on potato tubers may be overlooked during visual inspection.
- Tubers of resistant potato varieties do not show symptoms, but winter sporangia of the pest might have been formed on their buds/sprouts or the tubers may carry soil contaminated with winter sporangia, thus, reducing the effectiveness of visual inspection.
- The long incubation period and the appearance of symptoms mainly on below ground parts of potato plants (tubers, stolons) reduces the effectiveness of visual inspection during the growing season for the early detection of the pest (see Section 3.1.3).
- The disintegration of warts prior to harvest makes the detection of the pest by visual inspection of the harvested potato tubers even more difficult.
- The aggregated distribution of the winter sporangia in the soil of infested fields (Hampson and Coombes, 1996) makes soil sampling for the detection of the pest difficult, particularly when the inoculum level is very low.
- The difficulty in distinguishing between live and dead winter sporangia makes de-scheduling of infested fields difficult.
- The use by the infested EU MSs of different methods for the identification of pathotypes and the determination of resistant potato varieties to be grown in the safety zone reduces the effectiveness of the phytosanitary measures for the control of the pest set in Council Directive 69/464/EEC (see Section 3.1.2).
- The resistance of the winter sporangia to soil treatments and the high infectivity of low inoculum levels reduce the effectiveness of phytosanitary measures for infested soils (see Section 3.1.2).

3.6.2. Pest control methods

Management of potato wart disease with chemical methods has been explored worldwide for over 70 years (Obidiegwu et al., 2014). However, till today, chemical control of potato wart is unreliable, toxic to the environment and not able to eliminate the pest in the soil. Therefore, so far, the only available strategy to confine the disease and prevent its further spread is the application of strict phytosanitary measures combined with the cultivation of potato varieties resistant to the pathotype(s) present in the infested fields, although the pest can develop new pathotypes that can overcome this resistance. According to Council Directive 69/464/EEC on control of potato wart, a potato variety is regarded as being resistant to a pathotype of *S. endobioticum* when it reacts to infection by the pathogenic agent in such a way that there is no danger of secondary infection. The above-mentioned Directive also sets the minimum measures to be taken by the MSs to prevent potato wart disease from spreading (see Section 3.3), whereas infested MSs may take restrictive measures in addition to those laid down in the Directive.

The effectiveness of varietal resistance depends on the pathotypes of *S. endobioticum* present in the soil (Osterbauer, 2010; Molet et al., 2016). Originally, only one pathotype of the pathogen occurred in Europe [pathotype 1(D1)], and a good level of control was achieved using resistant potato varieties. Since 1941, however, new and more aggressive pathotypes have appeared (Blattný, 1942; Braun, 1942), which proved to be more difficult to control and eradicate than the original pathotype 1(D1) (Baayen et al., 2006). Breeding for resistance to those pathotypes is hampered by the lack of dominant major genes for resistance and the complexity of resistance screening with several

pathotypes (Maris, 1961). As a result, only a few potato varieties are resistant to all three most important pathotypes widespread in Europe, i.e. 2(G1), 6(O1) and 18(T1) (Langerfeld et al., 1994; Melnik, 1998; Baayen and Stachewicz, 2004; Ballvora et al., 2011). For example, in 2013 in the Netherlands, only eight varieties were listed as being resistant to pathotypes 2(G1) and 6(O1) and only one of them was also resistant to pathotype 18(T1) (Anonymous, 2013). In Germany, in 2011, only 12 of the 246 registered potato varieties showed resistance to all three pathotypes (Anonymous, 2011).

Eradication of the pest has been achieved in some EU MSs through statutory means, including strict phytosanitary control and prohibition of cultivation of susceptible varieties (Langerfeld et al., 1994), maintained over decades because of the longevity of winter sporangia in infested fields (Baayen et al., 2006). However, uncertainty exists whether effective eradication of the pest can be achieved, as in some EU MSs (e.g. the Netherlands, Denmark) the pest was considered either no longer present or eradicated, but new outbreaks were detected recently (see Section 3.2.2).

Despite the strict phytosanitary measures applied by the infested EU MSs, the reports on new outbreaks indicate that the pest is still spreading within the EU territory (EPPO, online).

3.7. Uncertainty

- 1) Pest distribution. Uncertainty exists about the distribution of *S. endobioticum* in the EU and worldwide (see Section 3.2).
- 2) Host range. It is not known whether wild species of the genus *Solanum* present in the EU territory are hosts of the pest (see Section 3.4.1).
- 3) Entry. Uncertainty exists about the import volume of (i) soil adhering to agricultural machinery and implements, footwear, vehicles, etc., (ii) manure of livestock fed on infected potato tubers or having grazed in infested potato fields, and (iii) waste of potato processing industries.

4. Conclusions

Synchytrium endobioticum meets all the criteria assessed by EFSA for consideration as potential Union quarantine pest (Table 11). The criteria for considering *S. endobioticum* as a potential Union regulated non-quarantine pest are not met since, in addition to potato seed tubers, soil (as commodity, substrate or contaminant) and ware potato tubers are also major means of spread.

Table 11: 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>Synchytrium endobioticum</i>) is clearly defined and there are reliable methods for its detection and identification	The identity of the pest (<i>Synchytrium endobioticum</i>) is clearly defined and there are reliable methods for its detection and identification	None
Absence/presence of the pest in the EU territory (Section 3.2)	The pest is present in 16 EU Member States with a restricted and fragmentary distribution	The pest is present in 16 EU Member States with a restricted and fragmentary distribution	The distribution of the pest might be wider than that reported in the EPPO Global Database (Uncertainty 1)
Regulatory status (Section 3.3)	The pest is currently officially regulated in the EU as a quarantine pest (Council Directive 2000/29/EC). Measures for the control of potato wart disease and its prevention from spreading within the EU territory also exist (Council Directive 69/464/EEC).	The pest is currently officially regulated in the EU as a quarantine pest (Council Directive 2000/29/EC). Measures for the control of potato wart disease and its prevention from spreading within the EU territory also exist (Council Directive 69/464/EEC). There are no grounds to consider its status could be revoked.	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
Pest potential for entry, establishment and spread in the EU territory (Section 3.4)	<p>The pest could potentially enter into, become established in and spread within the EU.</p> <p>Pathways of entry:</p> <ol style="list-style-type: none"> 1. soil and growing media consisting of soil or organic substances attached to or associated with plants with roots, planted or intended for planting, grown in greenhouses established in infested areas in Tunisia and infested European non-EU28 countries, other than Turkey, Belarus, Georgia, Moldova, Russia and Ukraine, 2. soil and growing media consisting of soil or organic substances not attached to or associated with plants originating in Tunisia and infested continental European non-EU28 countries, other than Turkey, Belarus, Moldavia, Russia and Ukraine, 3. soil and growing media consisting of soil or organic substances attached to or associated with below ground plant parts (bulbs, tubers, corms, etc), other than potato tubers and roots originating in Tunisia and infested European non-EU28 countries, other than Turkey, Belarus, Georgia, Moldova, Russia and Ukraine 4. soil adhering to agricultural machinery and implements, footwear, vehicles, etc. that have been used in infested areas in third countries 5. manure of livestock fed on infected potato tubers or having grazed in infested fields in third countries 6. waste of potato processing industries originating in infested third countries and intended to be used as fertiliser 	<p>The pest can spread in the EU territory through the movement of potato tubers (seed tubers) and soil as commodity, substrate or contaminant [attached to potato tubers, or below ground parts of non-host plants, or other objects (e.g. farm machinery and implements, footwear, etc)].</p> <p>Therefore, potato seed tubers are not the only major means of spread.</p>	<ol style="list-style-type: none"> 1. The distribution of the pest might be wider than that reported in the EPPO Global Database (Uncertainty 1) 2. The host status of wild <i>Solanum</i> plant species present in the EU territory is not known (Uncertainty 2). 3. The import volume of (i) soil adhering to agricultural machinery and implements, footwear, vehicles, etc., (ii) manure of livestock fed on infected potato tubers or having grazed in infested potato fields, and (iii) waste of potato processing industries is unknown (Uncertainty 3).
Potential for consequences in the EU territory (Section 3.5)	<p>The pest is already present in the EU causing direct and indirect impacts to potato production. Further introduction of the pest would increase the magnitude of this impact</p>	<p>The presence of the pest on potato seed tubers has an economic impact, as regards the intended use of that plant material</p>	<p>None</p>

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
Available measures (Section 3.6)	There are measures available to prevent the entry into, establishment and spread of the pest within the EU. These include pest-free areas or places of production, inspection and lab testing of imported potato tubers and soil adhering to them or to below ground parts of non-host plants, cultivation of resistant potato varieties, waste management, cleaning and disinfecting farm machinery, implements, etc. Nevertheless, the currently applied phytosanitary measures (Council Directives 2000/29/EC and 69/464/EEC) are not fully effective in preventing the introduction and spread of the pest in the EU	The presence of the pest on potato seed tubers and below ground parts of non-hosts plant for planting could be prevented by sourcing them in pest-free areas or places of production. Nevertheless, the currently applied phytosanitary measures (Council Directives 2000/29/EC and 69/464/EEC) are not fully effective in preventing the spread of the pest in the EU	None
Conclusion on pest categorisation (Section 4)	<i>Synchytrium endobioticum</i> meets all the criteria assessed by EFSA for consideration as potential Union quarantine pest	The criteria for considering <i>S. endobioticum</i> as a potential Union regulated non-quarantine pest are not met since, in addition to potato seed tubers, soil (as commodity, substrate or contaminant) and ware potato tubers are also major means of spread	None
Aspects of assessment to focus on/ scenarios to address in future if appropriate	Given that all the data available in the literature have been explored, the Panel considers that a survey could be carried out using appropriate pest detection and identification methods (see Section 3.1.3) to define the current geographical distribution of <i>S. endobioticum</i> pathotypes, other than pathotype 1(D1), in the risk assessment area before a full PRA is performed to reduce the uncertainty related to the conclusion of this pest categorisation		

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Abbreviations

CPPC	Caribbean Plant Protection Commission
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
MS	Member State

PLH EFSA Panel on Plant Health
TFEU Treaty on the Functioning of the European Union
ToR Terms of Reference