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## Pest categorisation of *Clavibacter sepedonicus*

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### Abstract

Following a request from the European Commission, the EFSA Panel on Plant Health performed a pest categorisation of *Clavibacter sepedonicus*, a well-defined and distinguishable bacterial plant pathogen of the family Microbacteriaceae. *C. sepedonicus* causes bacterial ring rot of potato and is reported from North America, Asia and Europe. The bacterium is mostly tuber transmitted, but it can also enter host plants through wounds or via contaminated equipment. *C. sepedonicus* is regulated in Council Directive 2000/29/EC (Annex I AII, as *Clavibacter michiganensis* subsp. *sepedonicus*) as a harmful organism whose introduction into the EU is banned. In addition, Council Directive 1993/85/EEC concerns the measures to be taken within EU Member States (MS) against *C. sepedonicus* to (a) detect it and determine its distribution, (b) prevent its occurrence and spread, and (c) control it with the aim of eradication. The pest is present in several EU MS, but in all cases with a restricted distribution and under official control. *C. sepedonicus* could enter the EU and spread primarily via host plants for planting (i.e. potato tubers). The pest could establish in the EU, as the main host (potato) is commonly grown and climatic conditions are favourable. Direct potato losses following infection by *C. sepedonicus* can be substantial and are due to the destruction of the vascular tissue, wilting of the plant and rotting of the tubers. Infected hosts can remain asymptomatic. The main knowledge gaps are the geographic distribution of the pest and the host range. The criteria assessed by the Panel for consideration of *C. sepedonicus* as a potential quarantine pest are met, while, for regulated non-quarantine pests, the criterion on the widespread presence in the EU is not met.

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**Keywords:** bacterial ring rot of potato, European Union, pest risk, plant health, plant pest, quarantine

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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/EC<sup>1</sup> 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) 2016/2031<sup>2</sup> 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 178/2002<sup>3</sup>, 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 pests 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.

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> 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>Aleurocanthus</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> (Moultext)
<i>Enarmonia packardi</i> (Zeller)	<i>Scolytidae</i> spp. (non-EU)
<i>Enarmonia prunivora</i> Walsh	<i>Scrobipalopsis solanivora</i> Povolny
<i>Grapholita inopinata</i> Heinrich	<i>Tachypterellus quadrigibbus</i> Say
<i>Hishomonus phycitis</i>	<i>Toxoptera citricida</i> Kirk.
<i>Leucaspis japonica</i> Ckll.	<i>Unaspis citri</i> Comstock
<i>Listronotus bonariensis</i> (Kuschel)	

##### **(b) Bacteria**

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

##### **(c) Fungi**

<i>Alternaria alternata</i> (Fr.) Keissler (non-EU pathogenic isolates)	<i>Elsinoe</i> spp. Bitanc. and Jenk. Mendes
<i>Anisogramma anomala</i> (Peck) E. Müller	<i>Fusarium oxysporum</i> f. sp. <i>albedinis</i> (Kilian and Maire) Gordon
<i>Apiosporina 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> Kugelan	<i>Ips sexdentatus</i> Börner
<i>Gilpinia hercyniae</i> (Hartig)	<i>Ips typographus</i> Heer
<i>Gonipterus scutellatus</i> Gyll.	<i>Sternochetus mangiferae</i> Fabricius
<i>Ips amitinus</i> Eichhof	

**(b) Bacteria**

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

**(c) Fungi**

*Glomerella gossypii* Edgerton

*Hypoxyton mammatum* (Wahl.) J. Miller

*Gremmeniella abietina* (Lag.) Morelet

**1.1.2.2. Terms of Reference: Appendix 2**

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

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

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

- |   |   |
|---|---|
| 1) <i>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 pruinosis</i> (Eichhoff)
<i>Diabrotica undecimpunctata howardi</i> Barber	<i>Scaphoideus luteolus</i> (Van Duzee)
<i>Diabrotica undecimpunctata undecimpunctata</i> Mannerheim	<i>Spodoptera eridania</i> (Cramer)
<i>Diabrotica virgifera zea</i> Krysan & Smith	<i>Spodoptera frugiperda</i> (Smith)
<i>Diaphorina citri</i> Kuway	<i>Spodoptera litura</i> (Fabricus)
<i>Heliothis zea</i> (Boddie)	<i>Thrips palmi</i> Karny
<i>Hirschmanniella</i> spp., other than <i>Hirschmanniella 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 II**

##### (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. *Ralstonia solanacearum* (Smith) Yabuuchi et al. *sepedonicus* (Spieckermann and Kotthoff)  
Davis 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

*Clavibacter michiganensis* subsp. *sepedonicus* 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 (RNQP) 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.

The pathogen referred to in the ToR (*C. michiganensis* subsp. *sepedonicus*) has been elevated to species (*Clavibacter sepedonicus*) by Li et al. (2017) on the basis of genome sequence analysis. This pest categorisation will thus deal with *C. sepedonicus*.

## 2. Data and methodologies

### 2.1. Data

#### 2.1.1. Literature search

A literature search on *C. sepedonicus* was conducted at the beginning of the categorisation (June 2018) in the ISI Web of Science bibliographic database, using the different scientific names of the pest as search term. Relevant papers were reviewed and further references and information were obtained from experts, as well as from citations within the references and grey literature.

#### 2.1.2. Database search

Pest information, on hosts and distribution, was retrieved from the European and Mediterranean Plant Protection Organization (EPPO) Global Database (EPPO, 2019) 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 SANTE) 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 *C. sepedonicus*, following guiding principles and steps in the International Standard for Phytosanitary Measures No 11 (FAO, 2013) and No 21 (FAO, 2004).

This work was started 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 RNQP 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 RNQP. 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 RNQP that needs to be addressed in the opinion. For the pests regulated in the protected zones only, the scope of the categorisation is the territory of the protected zone; thus, the criteria refer to the protected zone instead of the EU territory.

It should be noted that the Panel's conclusions are formulated respecting its remit and particularly with regard to the principle of separation between risk assessment and risk management (EFSA founding regulation (EU) No 178/2002); therefore, instead of determining whether the pest is likely to have an unacceptable impact, the Panel will present a summary of the observed pest impacts. Economic impacts are expressed in terms of yield and quality losses and not in monetary terms, whereas addressing social impacts is outside the remit of the Panel.

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

Criterion of pest categorisation	Criterion in Regulation (EU) 2016/2031 regarding Union quarantine pest	Criterion in Regulation (EU) 2016/2031 regarding protected zone quarantine pest (articles 32–35)	Criterion in Regulation (EU) 2016/2031 regarding Union regulated non-quarantine pest
<b>Identity of the pest (Section 3.1)</b>	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?
<b>Absence/ presence of the pest in the EU territory (Section 3.2)</b>	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 RNQP. (A RNQP must be present in the risk assessment area).
<b>Regulatory status (Section 3.3)</b>	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
<b>Pest potential for entry, establishment and spread in the EU territory (Section 3.4)</b>	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!
<b>Potential for consequences in the EU territory (Section 3.5)</b>	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?
<b>Available measures (Section 3.6)</b>	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?
<b>Conclusion of pest categorisation (Section 4)</b>	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 RNQP 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 established. *C. sepedonicus* is the current valid name of the bacterium responsible for bacterial ring rot of potato (*Solanum tuberosum*).

*C. sepedonicus* is a bacterium of the family Microbacteriaceae. The name of the bacterium has been recently updated based on whole-genome sequence analyses (Li et al., 2017). This bacterial pathogen was previously called *Clavibacter michiganensis* subsp. *sepedonicus* (Davis et al., 1984; Spieckermann and Kotthoff, 1914).

### 3.1.2. Biology of the pest

*C. sepedonicus* is a Gram-positive, non-motile bacterium displaying a pleomorph coryneform morphology. *C. sepedonicus* is aerobic, but a slow growth can be observed in anaerobic conditions. Colonies are creamy and yellowish. Its optimal growth temperature is 20–23°C (Li et al., 2017). Neither mycelium nor spores are formed by this bacterium. The first *C. sepedonicus* genome sequence released indicated a length of 3.26 Mb plus two plasmids (pCS1, 50kb and pCSL1, 95 kb), a high (72.6%) GC content (the proportion of guanine (G) or cytosine (C) nucleotide bases), and in comparison to other *Clavibacter* genome sequences a high number of Insertion Elements involved in genome rearrangements and potentially in gene translocation (Bentley et al., 2008; Tambong, 2017).

*C. sepedonicus* causes the well-named bacterial ring rot of potato (*S. tuberosum*). As the infection most often starts on a tuber via infection in stolon, the infected vascular tissue of the tuber becomes yellowish and cheesy in texture due to bacterial oozing. A corky-brown tissue may develop in infected vascular tissue. As rot progresses, tuber surface cracks and dark blotches may become visible immediately beneath the periderm. Sometimes rot progresses to such an extent that tubers can be transformed into hollow shells. Tuber symptoms can be confused with those caused by the *Ralstonia solanacearum* species complex (Van der Wolf et al., 2005a; CABI, 2019).

Potato plants may present wilting, chlorosis and necrosis of the foliar limb starting from leaf margins. These symptoms are usually expressed late in the growing season and confusion can be made with those due to *Verticillium* wilt (De Boer and McCann, 1989).

*C. sepedonicus* is mostly seed (tuber) transmitted, but it can also enter host plants through wounds (e.g. by cutting potato tubers when planting them) and hydathodes (Robert, 2013), essentially through contact with infected tubers, or via contaminated equipment used for potato production such as knives, planters, harvesters and storage containers. The bacterium colonises the xylem vessels of plants and from tuber spreads to stems, petioles, roots and developing tubers through stolons. Following an asymptomatic colonisation of the plants that can last nearly the entire growth period of potato (De Boer and McCann, 1989), symptoms may develop in the aerial parts of the plant. Highly infected plants may also die.

The optimum growth temperature of *C. sepedonicus* is rather low, i.e. 20–23°C. High bacterial population density can be consistently detected in stems from the most susceptible varieties from 3 weeks after planting infected seeds, but in some resistant varieties bacterial population densities remain low and symptoms are rarely expressed (De Boer and McCann, 1989).

*C. sepedonicus* can persist in the field in unharvested potato tubers, i.e. volunteers and ground keepers, and in infected potato plant debris (De Boer et al., 2017). The pest survives poorly in the presence of microbial competition outside the host plant and can persist under dry and cold conditions (Nelson, 1980, 1982, 1985). Smear and ooze from infected tubers allow a long survival of the bacterium. In this dry state, the bacterium remained infectious at temperatures from 5 to –40°C for at least 18 months in burlap sacks and for 63 months in infected potato stems (Nelson, 1985). As a consequence, contaminated farm and storage equipments are important means of pathogen survival within farms and of spread among production units.

Our knowledge regarding molecular mechanisms of virulence for *C. sepedonicus* is relatively scarce. A cellulase, *CelA*, has been clearly demonstrated to be involved in symptom development (Laine et al., 2000). A serine-protease encoded by the *chp7* gene has also been shown to be involved in symptom development in potato and hypersensitive induction in the non-host plant tobacco (Nissinen et al., 1997).

### 3.1.3. Intraspecific diversity

*C. sepedonicus* appears to be a genetically homogenous species, while presenting some phenotypic variation in colony morphology. Genomic fingerprints based on the repetitive element using the BOX-A1R primers showed remarkably homogeneous patterns for a set of 35 strains chosen to represent the largest possible diversity of the organism including various colony morphologies (Smith et al., 2001). Based on genome sequence analyses, homogeneity was also demonstrated, but on a smaller collection of strains. Three strains isolated from potato in Canada (ATCC 33113 in 1968; CFIA-Cs3N in 1976 and CFIA-CsR14 in 1991) (personal communication, Sean Li, Canadian Food Inspection Agency, December

2018) showed identical nucleotide sequence for the seven housekeeping genes (*acnA*, *gapA*, *icdA*, *mdh*, *mltD*, *pgi* and *proA*) that were used. These three strains had pairwise average nucleotide identity values of 99.96 to 99.98% and digital DNA–DNA hybridisation values of 98.8–99.8% reflecting highly homogeneous genome sequences (Li et al., 2017). Limited intraspecific variation based on rep-polymerase chain reaction (PCR), PCR melting profile and VNTR analysis has been described (Fousek et al., 2002; Żaczek et al., 2019).

### 3.1.4. Detection and identification of the pest

*Are detection and identification methods available for the pest?*

**Yes**, a comprehensive range of detection methods from serological to molecular methods is available to specifically detect *C. sepedonicus*.

Visual inspections of tubers or potato plants in the field are not sufficient to detect *C. sepedonicus* infections. Plants can be latently infected and, in case of symptoms, confusion is possible with those due to infection by the *Ralstonia solanacearum* species complex or *Verticillium* sp. (CABI, 2019) and symptoms may be masked due to natural senescence (Van der Wolf et al., 2005a).

Isolation of the pathogen is required to confirm infection of latently infected seed (tuber) lots. An intermediate enrichment in eggplant may facilitate *C. sepedonicus* isolation using a semi-selective isolation medium (Jansing and Rudolph, 1998). *C. sepedonicus* is a slow-growing bacterium (De Boer et al., 2017) and hence enrichment after inoculation of eggplant with the potato extract pellet limits the fast-growing saprophytic bacterium that may overgrow *C. sepedonicus* in direct isolation procedures (Van der Wolf et al., 2005a).

An immunofluorescence test using polyclonal antibodies is available to detect and identify *C. sepedonicus* but may lead to non-specific reactions (Van der Wolf et al., 2005a). As a consequence, other molecular tests should be used to confirm a positive IF detection. A fluorescent *in situ* hybridisation assay (Van Beuningen et al., 1995) and a comprehensive range of DNA-based PCR tests have been developed. Here again, lack of specificity has been observed for some of these tests (reviewed by Van der Wolf et al., 2005a). However, a loop-mediated isothermal amplification assay has been now developed for detection of *C. sepedonicus* and the other plant pathogens formerly considered to be subspecies of *C. michiganensis* (Dobhal et al., 2019). The PCR-based test proposed by Pastrik (2000) performed well in an EU ring test (EPPO, 2006) and the one proposed by Schaad et al. (1999) had the advantage of robustness and specificity using the TaqMan technology. These tests are used to both detect and identify *C. sepedonicus* in plant material.

## 3.2. Pest distribution

### 3.2.1. Pest distribution outside the EU

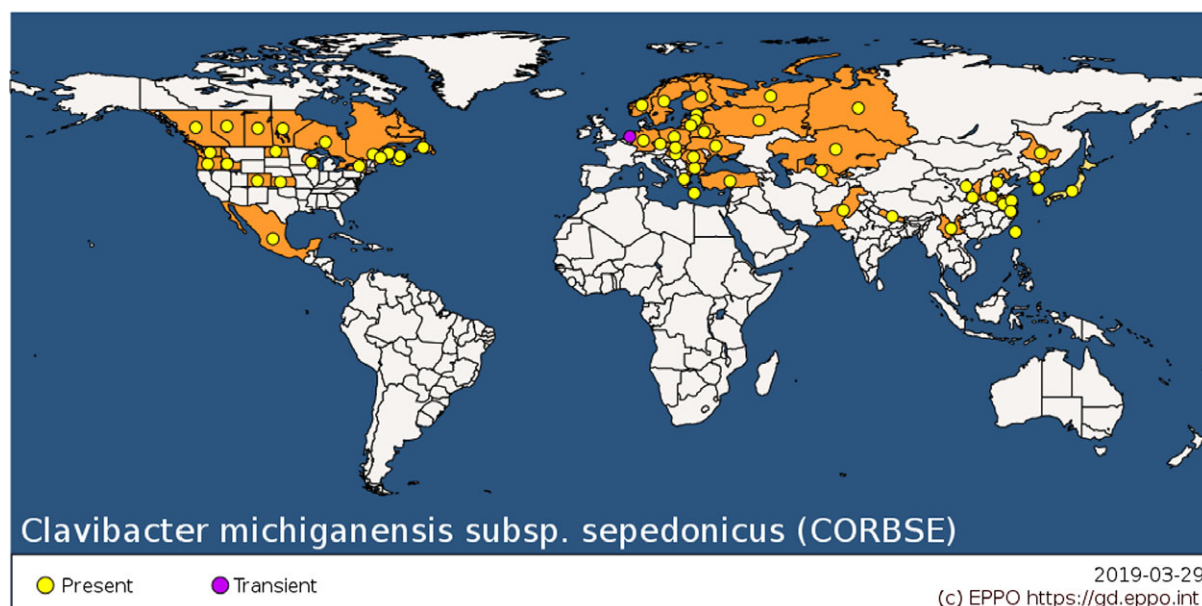
*C. sepedonicus* is distributed in Europe, North America and Asia (Figure 1; CABI, 2019; EPPO, 2019). A finding has been reported in Egypt (Seleim et al., 2014) but not confirmed (EPPO, 2015). One or more strains from Argentina were included in some studies (Mirza et al., 1993; Fousek et al., 2002; Kokošková et al., 2005; Cho et al., 2015), but these are likely to be from an interception and the pathogen is not officially reported from that country (CABI, 2019; EPPO, 2019). The pathogen was first described in northern Europe and has been traditionally seen as a disease restricted to cool northern temperate countries of the world, but is becoming increasingly widespread (EPPO, 2006; CABI, 2019). *C. sepedonicus* is one of the few major plant pathogens which is not widely distributed in the area where the main host crop (*S. tuberosum*) evolved (EPPO, 2006).

In North America, the pathogen is reported from Canada (widespread, with reports from Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland, Nova Scotia, Ontario, Prince Edward Island, Québec and Saskatchewan), the USA (restricted distribution, with reports from Colorado, Idaho, Kansas, Maine, New York, North Dakota, Oregon, Washington and Wisconsin) and Mexico (restricted distribution) (EPPO, 2019).

In Asia, the pathogen is reported from China (restricted distribution, with reports from Anhui, Hebei, Heilongjiang, Henan, Jiangsu, Ningxia, Shaanxi, Yunnan and Zhejiang), Japan, Kazakhstan, North and South Korea, Nepal, Pakistan, Taiwan (few occurrences), Uzbekistan, the Asian part of Russia and Turkey (EPPO, 2019).

In non-EU Europe, the pathogen is reported from Belarus, Norway (restricted distribution), Ukraine (widespread) and European Russia (EPPO, 2019).

Given that the pathogen is likely to be able to establish whenever potatoes are grown, there is uncertainty about its distribution.



**Figure 1:** Global distribution map for *Clavibacter sepedonicus* (from EPPO, 2019, accessed March 2019). Yellow and orange indicate reported presence, and purple stands for reported transient presence

### 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**, *C. sepedonicus* is present within the EU, but with a limited distribution.

Many of the reports on the presence of *C. sepedonicus* within the EU are interceptions or isolated occurrences, which are then followed by procedures for pathogen eradication and other control measures (Table 2) (CABI, 2019; EFSA, 2019; EPPO, 2019). The pathogen is only reported as widespread in Greece (Crete) (CABI, 2019; EPPO, 2019).

**Table 2:** Current distribution of *Clavibacter sepedonicus* in the EU MS based on information from EPPO (2019)

Country	Pest status (absence)	Pest status (presence or transience)
<b>Austria</b>	Absent, pest eradicated	
<b>Belgium</b>	Absent, pest eradicated	
<b>Bulgaria</b>		Present, few occurrences
<b>Croatia</b>	Absent, confirmed by survey	
<b>Cyprus</b>	Absent, pest eradicated	
<b>Czech Republic</b>		Present, restricted distribution
<b>Denmark</b>	Absent, pest eradicated	
<b>Estonia</b>		Present, restricted distribution
<b>Finland</b>		Present, restricted distribution
<b>France</b>	Absent, pest eradicated	
<b>Germany</b>		Present, few occurrences

Country	Pest status (absence)	Pest status (presence or transience)
<b>Greece</b>		Present, widespread (Crete)
<b>Hungary</b>		Present, few occurrences
<b>Ireland</b>	Absent, confirmed by survey	
<b>Italy</b>	Absent, confirmed by survey	
<b>Latvia</b>		Present, restricted distribution
<b>Lithuania</b>		Present, restricted distribution
<b>Malta</b>	Absent, confirmed by survey	
<b>Netherlands</b>	Transient, under eradication	
<b>Poland</b>		Present, restricted distribution
<b>Portugal</b>	Intercepted only (in 2001 – information from Europhyt)	
<b>Romania</b>		Present, restricted distribution
<b>Slovak Republic</b>		Present, few occurrences
<b>Slovenia</b>		Present, restricted distribution
<b>Spain</b>	Absent, pest eradicated	
<b>Sweden</b>		Present, restricted distribution
<b>United Kingdom</b>	Absent, pest eradicated	

### 3.3. Regulatory status

#### 3.3.1. Council Directive 2000/29/EC

*C. sepedonicus* is listed in Council Directive 2000/29/EC as *C. michiganensis* ssp. *sepedonicus*. Details are presented in Tables 3 and 4.

In addition, Council Directive 1993/85/EEC concerns the measures to be taken within EU MS against *C. sepedonicus* to (a) detect it and determine its distribution, (b) prevent its occurrence and spread, and (c) control it with the aim of eradication.

**Table 3:** *Clavibacter sepedonicus* in Council Directive 2000/29/EC

<b>Annex I, Part A</b>	Harmful organisms whose introduction into, and spread within, all Member States shall be banned
<b>Section II</b>	Harmful organisms known to occur in the Community and relevant for the entire Community
(b)	Bacteria
	Species
1.	<i>Clavibacter michiganensis</i> (Smith) Davis et al. ssp. <i>sepedonicus</i> (Spieckermann and Kotthoff) Davis et al.

### 3.3.2. Legislation addressing the hosts of *Clavibacter sepedonicus*

**Table 4:** Regulated hosts and commodities that may involve *Clavibacter sepedonicus* in Annexes III, IV and V of Council Directive 2000/29/EC

<b>Annex III, Part A</b>		
<b>Plants, plant products and other objects the introduction of which shall be prohibited in all Member States</b>		
	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
<b>Annex IV, Part A</b>		
<b>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</b>		
<b>Section I</b>		
<b>Plants, plant products and other objects originating outside the Community</b>		
	Plants, plant products and other objects	Special requirements
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: <ul style="list-style-type: none"><li>— Turkey,</li><li>— Belarus, Georgia, Moldova, Russia, Ukraine,</li><li>— non-European countries, other than Algeria, Egypt, Israel, Libya, Morocco, Tunisia</li></ul>	Official statement that: (a) the growing medium, at the time of planting, was: <ul style="list-style-type: none"><li>— either free from soil, and organic matter,</li><li>or</li><li>— 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,</li></ul> or <ul style="list-style-type: none"><li>— subjected to appropriate heat treatment or fumigation to ensure freedom from harmful organisms, and</li></ul> (b) since planting: <ul style="list-style-type: none"><li>— either appropriate measures have been taken to ensure that the growing medium has been maintained free from harmful organisms,</li><li>or</li><li>— within two weeks prior to dispatch, the plants were shaken free from the medium leaving the minimum amount</li></ul>

		necessary to sustain vitality during transport, and, if replanted, the growing medium used for that purpose meets the requirements laid down in (a).
<b>Section II</b>	<b>Plants, plant products and other objects originating in the Community</b>	
	Plants, plant products and other objects	Special requirements
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)	<p>Without prejudice to the special requirements applicable to the tubers listed in Annex IV(A)(II) (18.1), official statement that the tubers:</p> <ul style="list-style-type: none"> <li>— belong to advanced selections such a statement being indicated in an appropriate way on the document accompanying the relevant tubers,</li> <li>— have been produced within the Community,</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>— 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.</li> </ul>
18.3	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. 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>(a) The plants shall have been held under quarantine conditions and shall have been found free of any harmful organisms in quarantine testing;</p> <p>(b) the quarantine testing referred to in (a) shall:</p> <ul style="list-style-type: none"> <li>(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;</li> <li>(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;</li> <li>(cc) be executed on each unit of the material, <ul style="list-style-type: none"> <li>— 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,</li> <li>— by testing, in accordance with appropriate methods to be submitted to the Committee referred to in Article 18: <ul style="list-style-type: none"> <li>— in the case of all potato material at least for <ul style="list-style-type: none"> <li>— Andean potato latent virus,</li> <li>— Arracacha virus B. oca strain,</li> <li>— Potato black ringspot virus,</li> <li>— Potato spindle tuber viroid,</li> <li>— Potato virus T,</li> <li>— Andean potato mottle virus,</li> </ul> </li> </ul> </li> </ul> </li> </ul>



		<ul style="list-style-type: none"> <li>— common potato viruses A, M, S, V, X and Y (including Y<sup>o</sup>, Y<sup>n</sup> and Y<sup>c</sup>) and Potato leaf roll virus,</li> <li>— <i>Clavibacter michiganensis</i> ssp. <i>sepedonicus</i> (Spieckermann and Kotthoff) Davis et al.,</li> <li>— <i>Ralstonia solanacearum</i> (Smith) Yabuuchi et al.,</li> </ul> <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.
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.
<b>Annex V</b>	<b>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</b>	
<b>Part A</b>	<b>Plants, plant products and other objects originating in the Community</b>	
<b>Section I</b>	<b>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</b>	
1.3.	Plants of stolon- or tuber-forming species of <i>Solanum</i> L. or their hybrids, intended for planting.	
<b>Part B</b>	<b>Plants, plant products and other objects originating in territories, other than those territories referred to in Part A</b>	
<b>Section I</b>	<b>Plants, plant products and other objects which are potential carriers of harmful organisms of relevance for the entire Community</b>	
4.	Tubers of <i>Solanum tuberosum</i> L.	
7.	<p>(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.</p> <p>(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:</p> <ul style="list-style-type: none"> <li>— Turkey</li> <li>— Belarus, Moldova, Russia, Ukraine,</li> <li>— non-European countries, other than Algeria, Egypt, Israel, Libya, Morocco, Tunisia.</li> </ul>	

### 3.4. Entry, establishment and spread in the EU

#### 3.4.1. Host range

The natural host of *C. sepedonicus* seems to be potato only, but the entire host range is somewhat uncertain. No other host of *C. sepedonicus* has been consistently reported. When inoculated, *C. sepedonicus* is able to cause symptoms or persist on a large range of other solanaceous plants including tomato (*Solanum lycopersicon*), eggplant (*Solanum melongena*) and *Solanum rostratum* (Knorr, 1948; Slack, 1987; Van der Wolf et al., 2005b). In 2014, natural infections of a limited number of tomato plants due to *C. sepedonicus* were reported in Belgium (Van Vaerenbergh et al., 2016).

*C. sepedonicus* may persist (after inoculation) in various plants that are cropped in rotation with potato in Europe, such as maize, bush bean, broad bean, oilseed rape and pea as well as weeds commonly found in potato fields, including *Poa annua*, *Elymus repens*, *Taraxacum officinale*, *Urtica dioica* and *Veronica chameadrys* (Van der Wolf et al., 2005a, 2005b). However, no natural infections have been reported from these plant species.

Two plant species (*Beta vulgaris* and *Solanum sarrachoides*) were reported as natural hosts of *C. sepedonicus* (CABI, 2019); these reports were, however, not confirmed by following studies. Sugar beet has been described as a natural asymptomatic host of *C. sepedonicus*. Indeed, colonies of *C. sepedonicus* were isolated from asymptomatic sugar beet seeds produced in fields in Oregon, USA. The *C. sepedonicus* strains were pathogenic on potatoes but did not consistently induce symptoms on sugar beet after inoculation (Bugbee and Gudmestad, 1988). Hairy nightshade plants (*S. sarrachoides*) were reported contaminated by *C. sepedonicus* in a Colorado (USA) field (Zizz and Harrison, 1991).

*C. sepedonicus* is not regulated on particular host or commodity: its introduction into the EU is banned (Annex IAI) (see Section 3.3.1).

#### 3.4.2. Entry

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

**Yes**, mainly by the movement of infected planting material, such as seed tubers.

The primary route by which *C. sepedonicus* can enter the EU is via infected potato tubers for planting (Van der Wolf et al., 2005a). Limited survival in soil could take place in connection with plant debris (Ward et al., 2001). The pathogen can also survive on agricultural machinery and implements, and potato storage material (crates and sacks), if conditions are cool and dry.

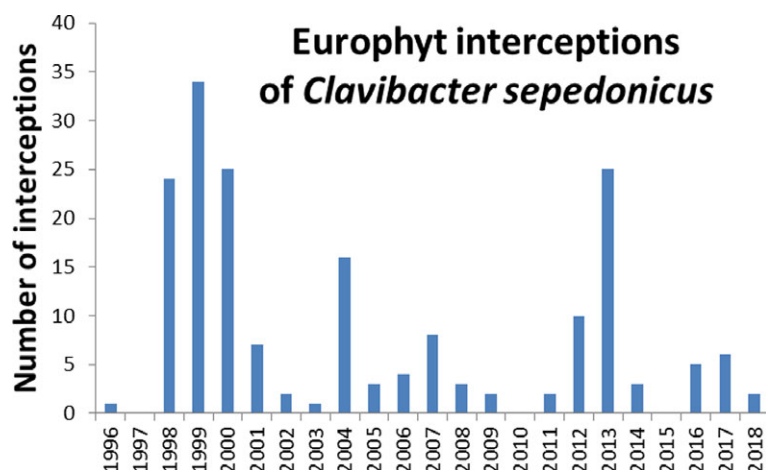
The following potential pathways of entry of *C. sepedonicus* into the EU territory are regulated by the current EU legislation (see Section 3.3):

- tubers of *S. tuberosum*, seed potatoes (prohibited; Annex IIIA),
- 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 (special requirements; Annex IVAI),
- 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 (prohibited; Annex IIIA).

The following potential pathway of entry of *C. sepedonicus* into the EU is currently not regulated:

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

As of December 2018, there were 183 interceptions of *C. sepedonicus* in the Europhyt database (Figure 2), all of them on *S. tuberosum*. About 40% of the interceptions had the Netherlands as destination (most of them until 2000). About 50% of the interceptions originated in Germany (most of them until 2000), with another 30% of the interceptions originating in Poland (most of them since 2004).



**Figure 2:** Temporal development of the interceptions of *Clavibacter sepedonicus* in Europhyt (as of December 2018)

### 3.4.3. Establishment

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

**Yes**, cultivation of the main host (potato) is widespread within the EU territory and the conditions for establishment of *C. sepedonicus* correspond to areas where potato is cultivated.

#### 3.4.3.1. EU distribution of main host plants

The main host of *C. sepedonicus* (potato) is grown throughout the EU (EFSA et al., 2019) (Table 5).

**Table 5:** Area (in 1,000 ha) cultivated with *Solanum tuberosum* in the 28 EU Member States between 2013 and 2017 (Source: Eurostat, accessed September 2018)

Countries	2013	2014	2015	2016	2017
European Union	1,741	1,663	1,656	1,688	1,740
Austria	21	21	20	21	23
Belgium	75	80	79	89	90
Bulgaria	13	10	11	8	13
Croatia	10	10	10	10	10
Cyprus	5	5	5	5	5
Czech Republic	23	24	23	23	23
Denmark	40	20	42	46	50
Estonia	5	4	4	4	3
Finland	22	22	22	22	21
France	161	168	167	179	192
Germany	243	245	237	243	251
Greece	25	24	21	18	11
Hungary	21	21	19	16	16
Ireland	11	9	9	9	9
Italy	50	52	50	48	49
Latvia	12	11	10	11	22
Lithuania	28	27	23	22	19
Luxembourg	1	1	1	1	1
Malta	1	1	1	1	1
Netherlands	156	156	156	156	161

Countries	2013	2014	2015	2016	2017
Poland	337	267	293	301	321
Portugal	27	27	25	23	24
Romania	208	203	196	186	172
Slovakia	9	9	8	8	7
Slovenia	3	4	3	3	3
Spain	72	76	72	72	74
Sweden	24	24	23	24	25
United Kingdom	139	141	129	139	145

### 3.4.3.2. Climatic conditions affecting establishment

Pathogen survival seems favoured by lower temperatures (see Section 3.1.2), but disease development is more rapid at higher temperatures (Bishop and Slack, 1982; Van der Wolf et al., 2005a). The distribution map of the pathogen (Figure 1) indicates that the conditions for establishment of *C. sepedonicus* correspond to areas where potato is cultivated. The disease has been reported from both colder areas, such as Canada and Finland, as well as warmer climates such as Mexico, Pakistan and Taiwan (EPPO, 2019).

### 3.4.4. Spread

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

**Yes**, mainly by the movement of infected tubers.

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

**Yes**, spread would take place mainly via infected tubers for planting.

The main mechanism of spread is vertical transmission from infected potato tubers. Horizontal transmission can take place via contaminated tools (such as those used for cutting tubers for planting) or equipment used in potato production, storage, and grading (EPPO, 1997). Limited plant to plant spread in the field has been demonstrated (Mansfeld-Giese, 1997), and some data indicate that some insects may vector the bacteria (Christie et al., 1991).

## 3.5. Impacts

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

**Yes**, the pest introduction would have an economic impact on 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?<sup>4</sup>*

**Yes**, the pest introduction would have an impact on the intended use of plants for planting.

Direct losses due to infection by *C. sepedonicus* are due to the destruction of the vascular tissue, wilting of the plant, and rotting of the tubers. These losses can be very high, with losses of 41–56% reported in inoculated studies (Hukkanen et al., 2005). Historic losses in the absence of regulatory control measures have been considerable (EPPO, 1997; Van der Wolf et al., 2005a).

There are many (157) recent (all since 2012) reports of *C. sepedonicus* (all, when the information is available, on *S. tuberosum*) in the Europhyt database of plant disease outbreaks, with about 60% reports from Lithuania and a further 20% from Romania. About 40% of the reports were made in 2018, with a further 27% in 2016 and another 15% in 2015.

<sup>4</sup> See Section 2.1 on what falls outside EFSA's remit.

### 3.6. Availability and limits of mitigation measures

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

**Yes**, measures to prevent entry, establishment and spread are available (see Sections 3.3 and 3.6).

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

**Yes**, measures to prevent pest presence on plants for planting are available.

#### 3.6.1. Identification of additional measures

Phytosanitary measures are currently applied to tubers and planting material of *S. tuberosum* (see Section 3.3).

Additional measures for surveillance and control are documented in Council Directive 93/85/EEC.

##### 3.6.1.1. Additional control measures

Potential additional control measures are listed in Table 6.

**Table 6:** Selected control measures (a full list is available in EFSA PLH Panel, 2018) for pest entry/establishment/spread/impact in relation to currently unregulated hosts and pathways. Control measures are measures that have a direct effect on pest abundance

Information sheet title (with hyperlink to information sheet if available)	Risk reduction option (RRO) summary	Risk component (entry/establishment/spread/impact)
<a href="#">Crop rotation, associations and density, weed/volunteer control</a>	Crop rotation and weed/volunteer control are essential control measures given that the pest can survive several generations in potato volunteers as well as in weeds (Gudmestad, 1994; Van der Wolf et al., 2005a)	Impact
Biological control and behavioural manipulation	Few reports of biological control are available (De la Cruz et al., 1992; Gamard and De Boer, 1995)	Impact

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

- Infected hosts can remain asymptomatic (Gudmestad et al., 2009)

##### 3.6.1.3. Biological or technical factors limiting the ability to prevent the presence of the pest on plants for planting

- Latent infection has been documented on various hosts.

### 3.7. Uncertainty

Given that the pathogen is likely to be able to establish wherever potatoes are grown, there is uncertainty about its distribution.

There is uncertainty about the host range.

## 4. Conclusions

*C. sepedonicus* meets the criteria assessed by EFSA for consideration as a potential quarantine pest (Table 7).

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

Criterion of pest categorisation	Panel's conclusions against criterion in Regulation (EU) 2016/2031 regarding Union quarantine pest	Panel's conclusions against criterion in Regulation (EU) 2016/2031 regarding Union regulated non-quarantine pest	Key uncertainties
<b>Identity of the pest (Section 3.1)</b>	The identity of <i>C. sepedonicus</i> as a species is clear.	The identity of <i>C. sepedonicus</i> as a species is clear.	None
<b>Absence/ presence of the pest in the EU territory (Section 3.2)</b>	<i>C. sepedonicus</i> is reported to be present in several EU MS, but in all cases with a restricted distribution and under official control.	<i>C. sepedonicus</i> is reported to be present in several EU MS, but in all cases with a restricted distribution and under official control.	None
<b>Regulatory status (section 3.3)</b>	<i>C. sepedonicus</i> is regulated by Council Directive 2000/29/EC (Annex I AII) as a harmful organism whose introduction into, and spread within, all Member States shall be banned. In addition, Council Directive 1993/85/EEC concerns the measures to be taken within EU MS against <i>C. sepedonicus</i> to (a) detect it and determine its distribution, (b) prevent its occurrence and spread, and (c) to control it with the aim of eradication.	<i>C. sepedonicus</i> is regulated by Council Directive 2000/29/EC (Annex I AII) as a harmful organism whose introduction into, and spread within, all Member States shall be banned. In addition, Council Directive 1993/85/EEC concerns the measures to be taken within EU MS against <i>C. sepedonicus</i> to (a) detect it and determine its distribution, (b) prevent its occurrence and spread, and (c) to control it with the aim of eradication.	None
<b>Pest potential for entry, establishment and spread in the EU territory (Section 3.4)</b>	<p>Entry: the pest could enter the EU via host plants for planting (i.e. potato tubers).</p> <p>Establishment: hosts are common and climatic conditions are favourable in the risk assessment area.</p> <p>Spread: the pest could spread following establishment mainly by movement of plants for planting (i.e. potato tubers), but also via contaminated tools, insect vectors and, locally, by natural dispersal.</p>	Spread is mainly via plants for planting.	There is uncertainty about the geographic distribution and host range of the pest.
<b>Potential for consequences in the EU territory (Section 3.5)</b>	The pest introduction would have economic impacts on potato crops.	The pest presence would have an economic impact on the intended use of plants for planting.	None
<b>Available measures (Section 3.6)</b>	Measures to prevent entry, establishment and spread, and to limit impacts, are available.	Measures to prevent pest presence on plants for planting are available.	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
<b>Conclusion on pest categorisation (Section 4)</b>	The criteria assessed by the Panel for consideration of <i>C. sepedonicus</i> as a potential quarantine pest are met. The pest is present in several EU MS, but in all cases with a restricted distribution and under official control.	The criterion on the widespread presence in the EU is not met.	
<b>Aspects of assessment to focus on/ scenarios to address in future if appropriate</b>	The main knowledge gaps are the geographic distribution of the pest and the host range.		

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## Abbreviations

EPPO	European and Mediterranean Plant Protection Organization
EUROSTAT	Statistical Office of the European Communities
FAO	Food and Agriculture Organization
IPPC	International Plant Protection Convention
ISPM	International Standards for Phytosanitary Measures
MS	Member State
PCR	polymerase chain reaction
PHYSAN	Phyto-Sanitary Controls
PLH	EFSA Panel on Plant Health
PZ	protected zone
RNQP	regulated non-quarantine pest
RRO	risk reduction option
TFEU	Treaty on the Functioning of the European Union
ToR	Terms of Reference

## Glossary

Containment (of a pest)	Application of phytosanitary measures in and around an infested area to prevent spread of a pest (FAO, 1995, 2017)
Control (of a pest)	Suppression, containment or eradication of a pest population (FAO, 1995, 2017)
DG SANTE	Directorate General for Health and Food Safety
Entry (of a pest)	Movement of a pest into an area where it is not yet present, or present but not widely distributed and being officially controlled (FAO, 2017)
Eradication (of a pest)	Application of phytosanitary measures to eliminate a pest from an area (FAO, 2017)
Establishment (of a pest)	Perpetuation, for the foreseeable future, of a pest within an area after entry (FAO, 2017)
Impact (of a pest)	The impact of the pest on the crop output and quality and on the environment in the occupied spatial units
Introduction (of a pest)	The entry of a pest resulting in its establishment (FAO, 2017)
Measures	Control (of a pest) is defined in ISPM 5 (FAO 2017) as 'Suppression, containment or eradication of a pest population' (FAO, 1995). Control measures are measures that have a direct effect on pest abundance Supporting measures are organisational measures or procedures supporting the choice of appropriate Risk Reduction Options that do not directly affect pest abundance
Pathway	Any means that allows the entry or spread of a pest (FAO, 2017)
Phytosanitary measures	Any legislation, regulation or official procedure having the purpose to prevent the introduction or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests (FAO, 2017)
Protected zones (PZ)	A Protected zone is an area recognised at EU level to be free from a harmful organism, which is established in one or more other parts of the Union.
Quarantine pest	A pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled (FAO, 2017)
Regulated non-quarantine pest	A non-quarantine pest whose presence in plants for planting affects the intended use of those plants with an economically unacceptable impact and which is therefore regulated within the territory of the importing contracting party (FAO, 2017)
Risk reduction option (RRO)	A measure acting on pest introduction and/or pest spread and/or the magnitude of the biological impact of the pest should the pest be present. A RRO may become a phytosanitary measure, action or procedure according to the decision of the risk manager
Spread (of a pest)	Expansion of the geographical distribution of a pest within an area (FAO, 2017)