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Pest categorisation of potato virus V (non-EU isolates)

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Abstract

Following a request from the EU Commission, the Panel on Plant Health has addressed the pest categorisation of non-EU isolates of potato virus V (PVV). The information currently available on geographical distribution, biology, epidemiology, potential entry pathways, potential additional impact and availability of control measures of non-EU isolates of PVV has been evaluated with regard to the criteria to qualify as a potential Union quarantine pest. Because non-EU isolates of PVV are absent from the EU, they do not meet one of the requirements to be regulated as a regulated non-quarantine pest (RNQP) (presence in the EU); as a consequence, the Panel decided not to evaluate the other RNQP criteria for these isolates. This categorisation was performed considering two lineages, PVV-I (present in and outside the EU) and PVV-II (not reported in the EU), and isolate PVV-PA4 (unknown distribution). Non-EU isolates of PVV-I and PVV-PA4 do not meet one of the criteria evaluated by EFSA to be regarded as a potential Union quarantine pest, since they are not expected to have an additional impact in the EU. With the exception of the criterion regarding the potential consequences in the EU territory, for which the Panel is unable to conclude, non-EU isolates of PVV-II meet all the other criteria to qualify as a potential Union quarantine pest.

Keywords: European Union, pest risk, plant health, plant pest, PVV, PVV-PA4, 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[1] 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[2] 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 categorisations 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[3], 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

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

(b) Bacteria

Citrus variegated chlorosis
Erwinia stewartii (Smith) Dye
Xanthomonas campestris pv. *oryzae* (Ishiyama) Dye and pv. *oryzicola* (Fang. et al.) Dye

(c) Fungi

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

(d) Virus and virus-like organisms

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

Annex IIB

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

Anthonomus grandis (Boh.)
Cephalcia lariciphila (Klug)
Dendroctonus micans Kugelan
Gilphinia hercyniae (Hartig)
Gonipterus scutellatus Gyll.
Ips amitinus Eichhof
Ips cembrae Heer
Ips duplicatus Sahlberg
Ips sexdentatus Börner
Ips typographus Heer
Sternochetus mangiferae Fabricius

(b) Bacteria

Curtobacterium flaccumfaciens pv. flaccumfaciens (Hedges) Collins and Jones

(c) Fungi

Glomerella gossypii Edgerton
Gremmeniella abietina (Lag.) Morelet
Hypoxylon mammatum (Wahl.) J. Miller

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) *Carneocephala fulgida* Nottingham
2) *Draeculacephala minerva* Ball
3) *Graphocephala atropunctata* (Signoret)

Group of Tephritidae (non-EU) such as:

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

(c) Viruses and virus-like organisms

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

1) Andean potato latent virus
2) Andean potato mottle virus
3) Arracacha virus B, oca strain
4) Potato black ringspot virus
5) Potato virus T
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
2) Cherry rasp leaf virus (American)
3) Peach mosaic virus (American)
4) Peach phony rickettsia
5) Peach rosette mosaic virus
6) Peach rosette mycoplasm
7) Peach X-disease mycoplasm
8) Peach yellows mycoplasm
9) Plum line pattern virus (American)
10) Raspberry leaf curl virus (American)
11) Strawberry witches' broom mycoplasma
12) Non-EU viruses and virus-like organisms of *Cydonia Mill., Fragaria L., Malus Mill., Prunus L., Pyrus L., Ribes L., Rubus L.* and *Vitis L.*

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

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

(b) Fungi

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

(c) Viruses and virus-like organisms

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

(d) Parasitic plants

Arceuthobium spp. (non-EU)

Annex IAII

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

Meloidogyne fallax Karssen
Popillia japonica Newman
Rhizoecus hibisci Kawai and Takagi

(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

EFSA is asked to develop pest categorisations for non-EU isolates of seven potato viruses, i.e. potato leafroll virus and potato viruses A, M, S, V, X and Y (including Yo, Yn and Yc), which are defined by their geographical origin outside the EU. As such, isolates of these viruses occurring outside the EU territory are considered as non-EU isolates. Accordingly, a plant infected with one of these viruses originating in a non-EU country is considered to be infected with a non-EU isolate. All seven viruses are important pathogens of potato and, therefore, there is no uncertainty about the fact that non-EU isolates have an impact on potato crops in absolute terms. However, EU isolates of these viruses already have an impact in the EU; consequently, the Panel decided to evaluate whether the non-EU isolates would have an additional impact compared to the current situation, upon introduction and spread in the EU. This interpretation was agreed with the European Commission.

This scientific opinion presents the pest categorisation of non-EU isolates of potato virus V (PVV). Non-EU isolates of PVV are listed in the Appendices of the Terms of Reference (ToR) to be subject to pest categorisation to determine whether they fulfil the criteria of a quarantine pest for the area of the EU excluding Ceuta, Melilla and the outermost regions of Member States (MSs) referred to in Article 355 (1) of the Treaty on the Functioning of the European Union (TFEU), other than Madeira and the Azores.

Because non-EU isolates of PVV are absent from the EU, they do not meet one of the requirements to be regulated as a regulated non-quarantine pest (RNQP) (presence in the EU); as a consequence, the Panel decided not to evaluate the other RNQP criteria for these isolates.

Despite the fact than *Solanum phureja* is considered by some authorities as an invalid taxon that should be renamed *Solanum tuberosum* Phureja Group,[4] the Panel considered the uncertainty on this aspect high enough and decided, in line with the EPPO Global Database, to separately address *S. phureja* as a distinct entity regulated within the 'potato and other tuber-forming *Solanum* species' in Directive 2000/29/EC.

The new Plant Health Regulation (EU) 2016/2031[5], on the protective measures against pests of plants, will be applying from December 2019. The regulatory status sections (Section 3.3) of the

[4] See https://ec.europa.eu/food/sites/food/files/plant/docs/sc_spmah_20160205_sum.pdf

[5] Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) 228/2013, (EU) 652/2014 and (EU) 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC. OJ L 317, 23.11.2016, pp. 4–104.

present opinion are still based on Council Directive 2000/29/EC, as the document was adopted in November 2019.

2. Data and methodologies

2.1. Data

2.1.1. Literature search

A literature search on PVV was conducted in the ISI Web of Science bibliographic database. The scientific name of the pest was used as search term. Relevant papers were reviewed with a focus on potential differences between isolates and strains. Further references and information were obtained from experts, as well as from citations in the reviewed papers and grey literature. The search was continued until no further information could be found or until the collected information was considered sufficient to perform the pest categorisation; consequently, the presented data is not necessarily exhaustive.

2.1.2. Database search

Information on hosts, vectors and distribution at species level, was retrieved from CABI Crop Protection Compendium (CABI cpc) and relevant publications. Additional data on isolates distribution was obtained from the literature.

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 to identify interceptions of non-EU isolates of PVV. 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 MSs and the phytosanitary measures taken to eradicate or avoid their spread.

2.2. Methodologies

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

General information on PVV will be provided at species level. Further information will be added at the level of strains, lineages and/or non-EU isolates when available and/or applicable.

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 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. As explained in the Interpretation of the Terms of Reference, the criterion on impact focuses on additional impact of non-EU isolates of PVV. 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 as a quarantine pest. If one of the criteria is not met, the pest will not qualify.

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, the Panel will present a summary of the reported impacts. 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.

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.

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 RNQP. (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?
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?

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
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 a 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.

2.3. Nomenclature

Virus nomenclature is reported using the latest release of the official classification by the International Committee on Taxonomy of Viruses (ICTV, Release 2018b.v1, https://talk.ictvonline.org/taxonomy/). Virus names are not italicised throughout this opinion, corresponding to ICTV instructions.

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. PVV is a well-known virus and the definition of 'non-EU isolates', as used in the present opinion, has been clarified (see Section 1.2).

Potato virus V is a well-characterised virus in the genus *Potyvirus*, family Potyviridae (Adams et al., 2011). PVV has a single-stranded positive-sense RNA genome and complete and/or partial genomic sequences are available for a number of isolates.

3.1.2. Biology of the pest

PVV is not reported to be transmitted by pollen or true seeds (Jones and Fribourg, 1986). It is transmitted by vegetative propagation (via tubers) and is expected to be mechanically transmitted since it has been shown to be readily transmitted under experimental conditions (Fribourg and Nakashima, 1984; Jones and Fribourg, 1986). The Panel does not expect significant differences between PVV lineages and/or isolates for these general properties.

There is limited information on vector transmission of PVV. Some isolates are reported to be non-persistently transmitted by several aphid species (Hemiptera: Aphididae) including *Myzus persicae* (Sulzer) and *Rhopalosiphoninus latysiphon* (Davidson) (Fribourg and Nakashima, 1984; Bell, 1988). These studies precede the distinction between PVV lineages, so it is not possible to know whether the different lineages categorised here differ in their aphid transmission properties. Therefore, similar transmission properties are assumed for all categorised lineages, with uncertainty.

3.1.3. Intraspecific diversity

Viruses generally exist as quasispecies, which means that they accumulate as a cluster of closely related sequence variants in a single host (Andino and Domingo, 2015). This is likely due to competition among the genomic variants that are generated as a consequence of the error-prone viral replication (higher in RNA than in DNA viruses) and the ensuing selection of the most fit variants in a given environment (Domingo et al., 2012). This genetic variability may have consequences on the virus' biological properties (e.g. host range, transmissibility and pathogenicity) as well as on the reliability of detection methods, especially when they target variable genomic regions.

This pest categorisation focuses on taxonomic levels below the species level, i.e. on isolates, lineages and strains, which are defined in this opinion as follows:

- **Isolate**: virus population as present in a plant
- **Lineage**: group of isolates belonging to a distinct phylogenetic cluster
- **Strain**: group of isolates sharing biological, molecular, and/or serological properties (Garcia-Arenal et al., 2001).

ICTV does not address taxonomic levels below the species level and, therefore, the names of strains are based on reports in literature. In the past, the term 'strain' has also often been used as a synonym for 'isolate'. As a consequence of this inconsistent use of terminology, the literature is often unclear.

There has been no effort to group PVV isolates on the basis of biological properties. Phylogenetic sequence analysis of the partial coat protein (CP) gene of PVV indicated the existence of two lineages (PVV-I and PVV-II) and of two additional minor groups that do not cluster within these lineages (Álvarez Yepes et al., 2016; Gutierrez et al., 2016; Álvarez et al., 2018). Isolates from the two major lineages are reported outside the EU, PVV-I in *S. tuberosum* and PVV-II in *S. phureja* and *Physalis peruviana*, and therefore, will be categorised separately in the current opinion (see Table 2). There is evidence for the existence of genetic variation within these lineages, particularly within PVV-I. This variation is most prominent when PVV-I isolates reported from Europe are compared with isolates reported from Iran and Peru (Oruetxebarria and Valkonen, 2001; Spetz et al., 2003; Mortensen et al., 2010; Álvarez et al., 2018).

One of the minor groups corresponds to a distinct isolate, PVV-PA4, that was detected in *S. tuberosum* cv. Papa Amarillo in post-entry quarantine testing in the USA, without further information on its origin (Shiel et al., 2004). Therefore, PVV-PA4 will be categorised separately in the present opinion (see Table 2).

The second minor group corresponds to two distantly related isolates, PVV-Tamarillo Ec reported in *Solanum betaceum* from Ecuador (NCBI GenBank accession KT803903) (Insuasti et al., 2016), and Ecuadorian rocoto virus reported in *Capsicum pubescens* from Ecuador (NCBI GenBank accession EU495234) (Janzac et al., 2008). These two viruses have been considered to represent one or two distinct species (Janzac et al., 2008; Álvarez et al., 2018). Because no full-length genomic sequence is available for these two isolates, their taxonomy remains uncertain and the ICTV has not validated their status as distinct species. It is noteworthy that their coat protein gene has nucleotide and encoded amino-acid identity levels with PVV isolates that are within the ICTV species discrimination criteria for the genus *Potyvirus*. However, a similar situation also exists for wild potato mosaic virus (WPMV) and Peru tomato mosaic virus (PTMV) which are nevertheless recognised as distinct species. This taxonomic uncertainty can only be resolved when the full genomes of PVV-Tamarillo Ec and Ecuadorian rocoto virus become available. Therefore, the Panel decided to follow the analysis of Álvarez et al. (2018) and Janzac et al. (2008) and considered these isolates as distinct from PVV. Therefore, they are not categorised here.

Table 2: Categorised virus and isolate in the present opinion

Group of isolates	Acronym	Other information	Key references
Potato virus V, lineage I	PVV-I	Isolates reported in *Solanum tuberosum*	Álvarez Yepes et al. (2016); Álvarez et al. (2018)
Potato virus V, lineage II	PVV-II	Isolates reported in *Solanum phureja* and *Physalis peruviana*	Álvarez et al. (2018)
Potato virus V, isolate PA4	PVV-PA4	Reported in *S. tuberosum* cv Papa Amarillo	Shiel et al. (2004); Álvarez et al. (2018)

3.1.4. Detection and identification of the pest

Are detection and identification methods available for the pest?

Yes. Methods are available for detection and identification of PVV at the species level, and therefore for the identification of non-EU isolates. Identification of the lineages and PVV-PA4 would require partial genomic sequencing.

As mentioned in the pest categorisation of non-EU viruses and viroids of potato (EFSA PLH Panel, 2020), virus detection and identification is complicated by several recurrent uncertainties. ICTV lists species demarcation criteria, but it is not always clear whether these are met in diagnostic tests. Furthermore, in the absence or near absence of information on genetic variability, it is not possible to guarantee that a given test will detect all variants of a species. On the contrary, generic tests may detect closely related viruses in addition to the target species. This implies that the reliability of a test depends on its validation for the intended use. For initial screening, it is important to prevent false negative results, which means that the following performance characteristics are most relevant: analytical sensitivity, inclusivity of analytical specificity (coverage of the intra-species variability) and selectivity (matrix effects). For identification, it is important to prevent false positives and, therefore, the possible occurrence of cross-reactions should be determined, i.e. the exclusivity of the analytical specificity (the resolution should be sufficient to discriminate between related species).

PVV is a well-known virus for which detection methods are available. Bioassays associated with enzyme-linked immunosorbent assay (ELISA) and/or real-time polymerase chain reaction (RT-PCR) (Oruetxebarria et al., 2000; Spetz et al., 2003) are available for the detection and identification of PVV.

PVV-PA4 could not be detected by ELISA when using the commonly used PVV antibodies (Shiel et al., 2004) but it can be detected using bioassays and identified by partial genome sequencing.

In addition, based on available sequences, molecular methods could be developed to identify the PVV lineages and PVV-PA4 isolates categorised here, with uncertainties on their specificity (inclusivity and exclusivity).

3.2. Pest distribution

3.2.1. Pest distribution outside the EU

There is limited information on the geographical distribution of PVV. Isolates have been reported from Asia, Europe and South America (Loebenstein et al., 2001; Shamsadden-Saeed et al., 2014).

Reports of specific PVV lineages include the presence of PVV-I isolates in Iran, Norway and Peru (Shamsadden-Saeed et al., 2014; Gutierrez et al., 2016) and PVV-II isolates in Colombia (Álvarez et al., 2018).

PVV-PA4 has been detected in post-entry quarantine testing in the USA (Shiel et al., 2004), without further information on the origin of this isolate and, therefore, its geographical distribution is unknown.

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. PVV-I isolates are present in the EU

No. PVV-II and PVV-PA4 are not reported in the EU.

PVV-I isolates are reported from several EU MSs, i.e. Finland, the Netherlands, Sweden and United Kingdom (Álvarez et al., 2018).

PVV-II isolates and PVV-PA4 have not been reported in the EU.

The geographic distribution of the PVV lineages/isolates is associated with uncertainties since several PVV isolates have been reported in potato from France, Germany, the Netherlands and the United Kingdom (Jeffries, 1998; Oruetxebarria et al., 2000) without characterisation of the lineage(s) involved, and because of the limited surveys. Therefore, PVV-I, PVV-II and PVV-PA4 might be more widespread.

3.3. Regulatory status

3.3.1. Council Directive 2000/29/EC

Non-EU isolates of PVV are specifically listed in Council Directive 2000/29/EC and are regulated in Annex IAI (Table 3).

Table 3: Non-EU isolates of PVV in Council Directive 2000/29/EC

Annex I, Part A	**Harmful organisms whose introduction into, and spread within, all member states shall be banned**
Section I	**Harmful organisms not known to occur in any part of the community and relevant for the entire community**
(d)	**Viruses and virus-like organisms**
2.	Potato viruses and virus-like organisms such as: (g) non-European isolates of potato viruses A, M, S, V, X and Y (including Y^o, Y^n and Y^c) and Potato leafroll virus

3.3.2. Legislation addressing potato

Table 4 reports on the articles in Council Directive 2000/29/EC which address potato or tuber-forming species of *Solanum* L. PVV may also infect other hosts; references to the corresponding legislation is reported in section 3.4.1.

Table 4: Overview of the regulation in Annexes III, IV and V of Council Directive 2000/29/EC that applies to potato or tuber-forming *Solanum* species

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 *Solanum tuberosum* L., seed potatoes	Third countries other than Switzerland
11.	Plants of stolon- or tuber-forming species of *Solanum* L. or their hybrids, intended for planting, other than those tubers of *Solanum tuberosum* L. as specified under Annex III A (10)	Third countries
12.	Tubers of species of *Solanum* L., and their hybrids, other than those specified in points 10 and 11	Without prejudice to the special requirements applicable to the potato tubers listed in Annex IV, Part A Section I, third countries other than Algeria, Egypt, Israel, Libya, Morocco, Syria, Switzerland, Tunisia and Turkey, and other than European third countries which are either recognised as being free from *Clavibacter michiganensis* ssp. *sepedonicus* (Spieckermann and Kotthoff) Davis et al., in accordance with the procedure referred to in Article 18(2), or in which provisions recognised as equivalent to the Community provisions on combating *Clavibacter michiganensis* ssp. *sepedonicus* (Spieckermann and Kotthoff) Davis et al. in accordance with the procedure referred to in Article 18(2), have been complied with
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 *Solanum tuberosum* L., originating in countries where *Synchytrium endobioticum* (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 *Synchytrium endobioticum* (Schilbersky) Percival (all races other than Race 1, the common European race), and no symptoms of *Synchytrium endobioticum* (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 *Synchytrium endobioticum* (Schilbersky) Percival in accordance with the procedure referred to in Article 18(2) have been complied with, in the country of origin
25.2.	Tubers of *Solanum tuberosum* L.	Without prejudice to the provisions listed in Annex (A) (10), (11) and (12) and Annex IV(A)(I) (25.1), official statement that: (a) the tubers originate in countries known to be free from *Clavibacter michiganensis* ssp. *sepedonicus* (Spieckermann and Kotthoff) Davis et al.; or

		(b) provisions recognised as equivalent to the Community provisions on combating *Clavibacter michiganensis* ssp. *sepedonicus* (Spieckermann and Kotthoff) Davis et al. in accordance with the procedure referred to in Article 18(2), have been complied with, in the country of origin
25.3.	Tubers of *Solanum tuberosum* L., other than early potatoes, originating in countries where Potato spindle tuber viroid is known to occur	Without prejudice to the provisions applicable to the tubers listed in Annex III(A) (10), (11) and (12) and Annex IV(A)(I) (25.1) and (25.2), suppression of the faculty of germination
25.4.	Tubers of *Solanum tuberosum* L., intended for planting	Without prejudice to the provisions applicable to the tubers listed in Annex III(A)(10), (11) and (12) and Annex IV(A)(I) (25.1), (25.2) and (25.3), official statement that the tubers originate from a field known to be free from *Globodera rostochiensis* (Wollenweber) Behrens and *Globodera pallida* (Stone) Behrens and (aa) either, the tubers originate in areas in which *Ralstonia solanacearum* (Smith) Yabuuchi et al. is known not to occur; or (bb) in areas where *Ralstonia solanacearum* (Smith) Yabuuchi et al. is known to occur, the tubers originate from a place of production found free from *Ralstonia solanacearum* (Smith) Yabuuchi et al., or considered to be free thereof, as a consequence of the implementation of an appropriate procedure aiming at eradicating *Ralstonia solanacearum* (Smith) Yabuuchi et al. which shall be determined in accordance with the procedure referred to in Article 18(2) and (cc) either the tubers originate in areas where *Meloidogyne chitwoodi* Golden et al. (all populations) and *Meloidogyne fallax* Karssen are known not to occur; or (dd) in areas where *Meloidogyne chitwoodi* Golden et al. (all populations) and *Meloidogyne fallax* Karssen are known to occur, — either the tubers originate from a place of production which has been found free from *Meloidogyne chitwoodi* Golden et al. (all populations), and *Meloidogyne fallax* Karssen based on an annual survey of host crops by visual inspection of host plants at appropriate times and by visual inspection both externally and by cutting of tubers after harvest from potato crops grown at the place of production, or — the tubers after harvest have been randomly sampled and, either checked for the presence of symptoms after an appropriate method to induce symptoms, or laboratory tested, as well as inspected visually both externally and by cutting the tubers, at appropriate times and in all cases at the time of closing of the packages or containers before marketing according to the provisions on closing in Council Directive 66/403/EEC of 14 June 1996 on the marketing of seed potatoes (1) and no symptoms of *Meloidogyne chitwoodi* Golden et al. (all populations) and *Meloidogyne fallax* Karssen have been found
25.4.1.	Tubers of *Solanum tuberosum* L., other than those intended for planting	Without prejudice to the provisions applicable to tubers listed in Annex III(A) (12) and Annex IV(A)(I) (25.1), (25.2) and (25.3), official statement that the tubers originate in areas in which *Ralstonia solanacearum* (Smith) Yabuuchi et al. is not known to occur

25.4.2.	Tubers of *Solanum tuberosum* L.	Without prejudice to the provisions applicable to tubers listed in Annex III(A) (10), (11) and (12) and Annex IV(A)(I) (25.1), (25.2), (25.3), (25.4) and (25.4.1), official statement that: (a) the tubers originate in a country where *Scrobipalpopsis solanivora* Povolny is not known to occur; or (b) the tubers originate in an area free from *Scrobipalpopsis solanivora* Povolny, established by the national plant protection organisation in accordance with relevant International Standards for Phytosanitary Measures
25.5.	Plants of Solanaceae, intended for planting, other than seeds, originating in countries where Potato stolbur mycoplasm is known to occur	Without prejudice to the provisions applicable to tubers listed in Annex III(A) (10), (11), (12) and (13), and Annex IV(A)(I) (25.1), (25.2), (25.3) and (25.4), official statement that no symptoms of Potato stolbur mycoplasm have been observed on the plants at the place of production since the beginning of the last complete cycle of vegetation
Section II	**Plants, plant products and other objects originating in the Community**	
	Plants, plant products and other objects	**Special requirements**
18.1.	Tubers of *Solanum tuberosum* L., intended for planting	Official statement that: (a) the Union provisions to combat *Synchytrium endobioticum* (Schilbersky) Percival have been complied with; and (b) either the tubers originate in an area known to be free from *Clavibacter michiganensis* ssp. *sepedonicus* (Spieckermann and Kotthoff) Davis et al. or the Union provisions to combat *Clavibacter michiganensis* ssp. *sepedonicus* (Spieckermann and Kotthoff) Davis et al. have been complied with; and (d) (aa) either, the tubers originate in areas in which *Ralstonia solanacearum* (Smith) Yabuuchi et al. is known not to occur; or (bb) in areas where *Ralstonia solanacearum* (Smith) Yabuuchi et al. is known to occur, the tubers originate from a place of production found free from *Ralstonia solanacearum* (Smith) Yabuuchi et al., or considered to be free thereof, as a consequence of the implementation of an appropriate procedure aiming at eradicating *Ralstonia solanacearum* (Smith) Yabuuchi et al.; and (e) either, the tubers originate in areas in which *Meloidogyne chitwoodi* Golden et al. (all populations) and *Meloidogyne fallax* Karssen are known not to occur, or in areas where *Meloidogyne chitwoodi* Golden et al. (all populations) and *Meloidogyne fallax* Karssen are known to occur: — either, the tubers originate from a place of production which has been found free from *Meloidogyne chitwoodi* Golden et al. (all populations) and *Meloidogyne fallax* Karssen based on an annual survey of host crops by visual inspection of host plants at appropriate times and by visual inspection both externally and by cutting of tubers after harvest from potato crops grown at the place of production, or

		— the tubers after harvest have been randomly sampled and, either checked for the presence of symptoms after an appropriate method to induce symptoms or laboratory tested, as well as inspected visually both externally and by cutting the tubers, at appropriate times and in all cases at the time of closing of the packages or containers before marketing according to the provisions on closing in Council Directive 66/403/EEC, and no symptoms of *Meloidogyne chitwoodi* Golden et al. (all populations) and *Meloidogyne fallax* Karssen have been found
18.1.1.	Tubers of *Solanum tuberosum* L., intended for planting, other than those to be planted in accordance with Article 4.4(b) of Council Directive 2007/33/EC	Without prejudice to the requirements applicable to the tubers of *Solanum tuberosum* L., intended for planting in Annex IV, Part A, Section II (18.1), official statement that the Union provisions to combat *Globodera pallida* (Stone) Behrens and *Globodera rostochiensis* (Wollenweber) Behrens are complied with
18.2	Tubers of *Solanum tuberosum* 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 *Solanum* L., or their hybrids, intended for planting, other than those tubers of *Solanum tuberosum* 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	(a) The plants shall have been held under quarantine conditions and shall have been found free of any harmful organisms in quarantine testing; (b) the quarantine testing referred to in (a) shall: (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; (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; (cc) be executed on each unit of the material; – 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, – by testing, in accordance with appropriate methods to be submitted to the Committee referred to in Article 18:

		– in the case of all potato material at least for: – 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 Yo, Yn and Yc) and Potato leaf roll virus, – *Clavibacter michiganensis* ssp. *sepedonicus* (Spieckermann and Kotthoff) Davis et al., – *Ralstonia solanacearum* (Smith) Yabuuchi et al., – in the case of true seed potato of least for the viruses and viroid listed above; (dd) by appropriate testing on any other symptom observed in the visual examination in order to identify the harmful organisms having caused such symptoms; (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); (d) each organisation or research body holding this material shall inform their official Member State plant protection service of the material held
18.3.1.	Seeds of *Solanum tuberosum* L., other than those specified in point 18.4.	Official statement that: The seeds derive from plants complying, as applicable, with the requirements set out in points 18.1., 18.1.1, 18.2 and 18.3; and (a) the seeds originate in areas known to be free from *Synchytrium endobioticum* (Schilbersky) Percival, *Clavibacter michiganensis* ssp. *sepedonicus* (Spieckermann and Kotthoff) Davis et al., *Ralstonia solanacearum* (Smith) Yabuuchi et al. and Potato spindle tuber viroid; or (b) the seeds comply with all of the following requirements: (i) they have been produced in a site where, since the beginning of the last cycle of vegetation, no symptoms of disease caused by the harmful organisms referred to in point (a) have been observed; (ii) they have been produced at a site where all of the following actions have been taken: separation of the site from other solanaceous plants and other host plants of Potato spindle tuber viroid; prevention of contact with staff and items, such as tools, machinery, vehicles, vessels and packaging material, from other sites producing solanaceous plants and other host plants of Potato spindle tuber viroid, or appropriate hygiene measures concerning staff or items from other sites producing solanaceous plants and other host plants of Potato spindle tuber viroid to prevent infection; only water free from all harmful organisms referred to in this point is used

18.4	Plants of stolon, or tuber-forming species of *Solanum* 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 *Solanum tuberosum* 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 *Ralstonia solanacearum* (Smith) Yabuuchi et al. and that (a) the Union provisions to combat *Synchytrium endobioticum* (Schilbersky) Percival, and (b) where appropriate, the Union provisions to combat *Clavibacter michiganensis* ssp. *sepedonicus* (Spieckermann and Kotthoff) Davis et al., and (c) the Union provisions to combat *Globodera pallida* (Stone) Behrens and *Globodera rostochiensis* (Wollenweber) Behrens are complied with

Annex IV, Part 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 certain protected zones**		
	Plants, plant products and other objects	**Special requirements**	Protected zone(s)
20.1.	Tubers of *Solanum tuberosum* L., intended for planting	Without prejudice to the provisions applicable to the plants listed in Annex III(A) (10), (11), Annex IV(A)(I) (25.1), (25.2), (25.3), (25.4), (25.5), (25.6), Annex IV(A)(II) (18.1), (18.2), (18.3), (18.4), (18.6), official statement that the tubers: (a) were grown in an area where Beet necrotic yellow vein virus (BNYVV) is known not to occur; or (b) were grown on land, or in growing media consisting of soil that is known to be free from BNYVV, or officially tested by appropriate methods and found free from BNYVV; or (c) have been washed free from soil	F (Britanny), FI, IRL, P (Azores), UK (Northern Ireland)

20.2.	Tubers of *Solanum tuberosum* L., other than those mentioned in Annex IV(B) (20.1)	(a) The consignment or lot shall not contain more than 1% by weight of soil, or (b) the tubers are intended for processing at premises with officially approved waste disposal facilities which ensures that there is no risk of spreading BNYVV	F (Britanny), FI, IRL, P (Azores), UK (Northern Ireland)
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 *Solanum* L. or their hybrids, intended for planting.		
Section II	**Plants, plant products and other objects which are potential carriers of harmful organisms of relevance for certain protected zones and which must be accompanied by a plant passport valid for the appropriate zone when introduced into or moved within that zone** Without prejudice to the plants, plant products and other objects listed in Part I.		
1.5.	Tubers of *Solanum tuberosum* L., 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 *Solanum tuberosum* L.		

3.3.3. Legislation addressing the organisms that vector PVV (Directive/2000/29/EC)

PVV is reported to be transmitted by aphid vectors (see Section 3.1.2), which are not subject to specific regulation.

3.4. Entry, establishment and spread in the EU

3.4.1. Host range

Table 5 provides information on reports of natural hosts (including potato) of PVV-I, PVV-II and PVV-PA4, including the associated uncertainties and regulation.

Solanum lycopersicum is reported as a natural host of PVV without information on the lineage (Jeffries, 1998; CABI, 2019). The only experimental hosts reported are in the Solanaceae and Chenopodiaceae families (Fribourg and Nakashima, 1984; Loebenstein et al., 2001), indicating that the host range might be restricted.

Table 5: Natural hosts of PVV. Data regarding natural hosts was retrieved from the CABI cpc and literature up to October 3, 2019

Group of isolates	Hosts	Rationale and/or uncertainty	Regulation(1)
PVV-I	*Solanum tuberosum* (Álvarez et al., 2018)	Limited information, additional natural hosts may exist	***Solanum* sp.:** IIIA 10,11,12; IVAI 25.1, 25.2, 25.3, 25.4, 25.4.1, 25.4.2, 25.5, 25.6, 25.7, 25.7.1, 25.7.2, 28.1, 36.2, 45.3, 48; IVAII 18.1, 18.1.1, 18.2, 18.3, 18.3.1, 18.4, 18.5, 18.6, 18.6.1, 18.7, 26.1, 27; IVBI 20.1, 20.2; VAI 1.3, 2.4; VAII 1.5; VBI 1, 3, 4. ***Solanaceae***: IIIA 13
PVV-II	*Solanum phureja* (Gutierrez et al., 2016), *Physalis peruviana* (Álvarez et al., 2018)	Limited information, additional natural hosts may exist	
PVV-PA4	*Solanum tuberosum* (Shiel et al., 2004)	Limited information, additional natural hosts may exist Experimentally, PVV-PA4 infects a similar host range than other PVV isolates, except for tobacco (Shiel et al., 2004)	

PVV: potato virus V.
(1): Including regulation of hosts without information of the lineage(s) involved.

3.4.2. Entry

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

Yes. Non-EU isolates of PVV, including PVV-PA4, may enter the EU territory via plants for planting, i.e. seed potatoes (tubers) and/or microplants. Additional pathways include: ware potatoes (i.e. tubers intended for consumption or processing), plants for planting and fruits of other hosts, and viruliferous aphid vectors.

The following pathways can be considered for entry of non-EU isolates of PVV into the EU: potato plants for planting (seed potatoes, microplants), ware potatoes (i.e. tubers intended for consumption or processing), plants for planting and fruits of other natural hosts, and viruliferous aphid vectors (see Table 6 for the major pathways).

PVV is transmitted by vegetative propagation and therefore seed potatoes and more generally, plants for planting, are considered the most important pathway for entry. The potential pathways for entry of non-EU isolates via seed potatoes of *S. tuberosum* and plants for planting of other tuber-forming *Solanum* species (such as *S. phureja*) and their hybrids are addressed by the current EU legislation (Table 4; (EU) 2000/29 Annex IIIA, 10 and 11), which states that import is not allowed from third countries except Switzerland. Furthermore, import of seed potatoes from Canada into Greece, Spain, Italy, Cyprus, Malta and Portugal is allowed by a derogation (2011/778/EU, 2014/368/EU, document C (2014) 3878). There are no reports of PVV from Canada and Switzerland. Therefore, the pathway of plants for planting is considered closed by legislation for non-EU isolates of PVV-I, with uncertainties. *S. tuberosum* is not reported as a natural host of PVV-II, but *S. phureja* is and it is

similarly regulated as *S. tuberosum*. Therefore, the potato plants for planting pathway is also considered closed by legislation for non-EU isolates of PVV-II, with uncertainties. In the absence of information on the geographical distribution of PVV-PA4, the Panel is unable to conclude on the potato plants for planting pathway for this isolate.

Entry of ware potatoes is addressed by the current EU legislation (Table 4, Annex IIIA, 12). Import of ware potatoes is prohibited from third countries other than Algeria, Egypt, Israel, Libya, Morocco, Syria, Switzerland, Tunisia and Turkey, and from European non-EU countries which do not meet a series of requirements addressing several other pathogens (see Table 4). Note that as long as ware potatoes are used for the intended use (consumption or processing) the ability of non-EU isolates of the virus to establish is very low. In addition, there are specific measures in place (Annex IV 25.3) for countries where potato spindle tuber viroid is known to occur (according to EPPO: Egypt, Israel and Turkey) aimed at mitigating the risk of establishment by suppression of the faculty of germination of ware potatoes, other than early potatoes, from these countries. Since there are no reports of PVV isolates in these countries, the pathway of ware potatoes is considered closed by legislation for non-EU isolates of PVV-I, with uncertainties. *S. tuberosum* is not reported as a natural host of PVV-II, but *S. phureja* is and it produces tubers that may be imported as ware potatoes. PVV-II is not known to be present in countries with import derogations and therefore, the ware potatoes pathway is also considered closed by legislation for non-EU isolates of PVV-II, with uncertainties. In the absence of information on the geographical distribution of PVV-PA4, the Panel is unable to conclude on the ware potato pathway for this isolate.

PVV has a limited number of natural hosts other than potato (see Section 3.4.1); they all belong to the Solanaceae family. Plants for planting of Solanaceae other than potato are regulated but there is an import derogation for European and Mediterranean countries. PVV-I is present in at least one country with import derogation (Norway) while PVV-II is not known to be present in these countries. Therefore, the pathway of plants for planting of other hosts is considered partially regulated for non-EU isolates of PVV-I and closed by legislation for non-EU isolates of PVV-II. In the absence of information on the geographical distribution of PVV-PA4, the Panel is unable to conclude on the plants for planting pathway of other hosts for this isolate. This assessment is affected by uncertainties because the information on geographical distribution of PVV isolates is limited and the possible existence of other natural hosts cannot be excluded.

Viruliferous aphid vectors are a pathway of entry for non-EU isolates of PVV (see Section 3.1.2). Since the relevant aphid species are not subject to specific regulation and no indications exist that specific isolates are not transmitted by aphids, this pathway is considered open for all non-EU isolates of PVV. PVV is transmitted by aphids in a non-persistent way, which implies that viruliferous aphids will lose the ability to transmit the virus within a short period. This pathway is therefore considered as minor and is not listed in Table 6.

Import of fruits can be an additional pathway for entry of non-EU isolates of PVV, however, the lack of seed transmission (see Section 3.1.2) reduces the relevance of this potential pathway. Aphid vectors can probe the infected fruits and acquire the virus for later transmission, as shown for other potyviruses such as papaya ringspot virus and zucchini yellow mosaic virus from melons, and plum pox virus from peaches (Lecoq et al., 2003; Gildow et al., 2004). Fruits of *Solanum lycopersicum* (natural host of PVV without lineage specification) and *Physalis peruviana* (natural host for PVV-II) can be imported from countries where PVV is present. Therefore, this pathway is considered open for all non-EU isolates of PVV but given the relatively unlikely series of events involved (aphids feeding sequentially on imported infected fruits then on susceptible plants) and the absence of seed transmission, this pathway is considered as minor and is not listed in Table 6.

Table 6: Identified major pathways for potential entry of non-EU isolates of PVV and the extent to which these pathways are addressed by current legislation

Group of isolates	Potato plants for planting[(1)]	Ware potatoes[(1)]	Plants for planting of other hosts[(1),(2)]	Uncertainties
PVV-I	Pathway closed: plants for planting of potato are banned from countries where PVV-I is reported	Pathway closed: import of ware potatoes is banned from countries where PVV-I is reported	Pathway partially regulated: PVV-I present in at least one country with import derogations for solanaceous plants for planting other than potato	Geographic distribution Existence of other natural hosts
PVV-II	Pathway closed: plants for planting of potato (*S. phureja*) are banned from countries where PVV-II is reported	Pathway closed: import of ware potatoes (*S. phureja*) is banned from countries where PVV-II is reported	Pathway closed: not known to occur in countries with import derogations	Geographic distribution Existence of other natural hosts
PVV-PA4	Unable to conclude: unknown geographical distribution of PVV-PA4	Unable to conclude: unknown geographical distribution of PVV-PA4	Unable to conclude: unknown geographical distribution of PVV-PA4	Geographic distribution Existence of other natural hosts

(1): '**Pathway open**': no regulation or ban that prevents this pathway, '**Pathway closed**' (as opposed to 'pathway open'): ban that prevents entry. '**Pathway possibly open**': no direct evidence of the existence of the pathway (not closed by current legislation), but existence cannot be excluded based on comparisons with the biology of closely related viruses (in the same genus or family). '**Pathway regulated**': regulations exist that limit the probability of entry along the pathway, but there is not a complete ban on imports. '**Pathway partially regulated**': pathway consists of several sub-pathways, some are open, while others are closed (e.g. regulation for some hosts, but not for others; a ban exists for some non-EU MSs but not for all). '**Not a pathway**': no evidence supporting the existence of the pathway.

(2): Plants for planting, including seeds and pollen, of other hosts which are listed in Table 5.

The Europhyt database does not report any interception of PVV by EU MSs between 1995 and 8 August 2019.

3.4.3. Establishment

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

Yes. Non-EU isolates of PVV are likely to become established in the EU territory, as EU isolates and the main hosts are already present in the EU.

3.4.3.1. EU distribution of main host plants

Solanum tuberosum is widely grown in the EU, as reported in the pest categorisation of non-EU viruses and viroids of potato (EFSA PLH Panel, 2020). *S. phureja* is also grown in the EU (De Maine, 1996), although there are no data on production scale.

3.4.3.2. Climatic conditions affecting establishment

Except for those conditions affecting survival of the host plants, no eco-climatic constrains exist for the PVV isolates categorised here. Therefore, it is expected that these isolates are able to establish wherever their hosts may live. Potato is widely cultivated in the EU and therefore the Panel considers that climatic conditions will not impair the ability of the viruses addressed here to establish in the EU. However, it must be taken into consideration that virus impact, accumulation and distribution within natural hosts are dependent on environmental conditions. The same applies to expression of symptoms, vector populations and virus transmission being affected by climatic conditions.

3.4.4. Spread

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

Yes. Non-EU isolates of PVV can spread via plants for planting, by mechanical transmission, and by aphid vectors.

Non-EU isolates of PVV can be transmitted by aphids (see Section 3.1.2), including *Myzus persicae* (Sulzer), which is widespread in and outside the EU (see Figure 1).

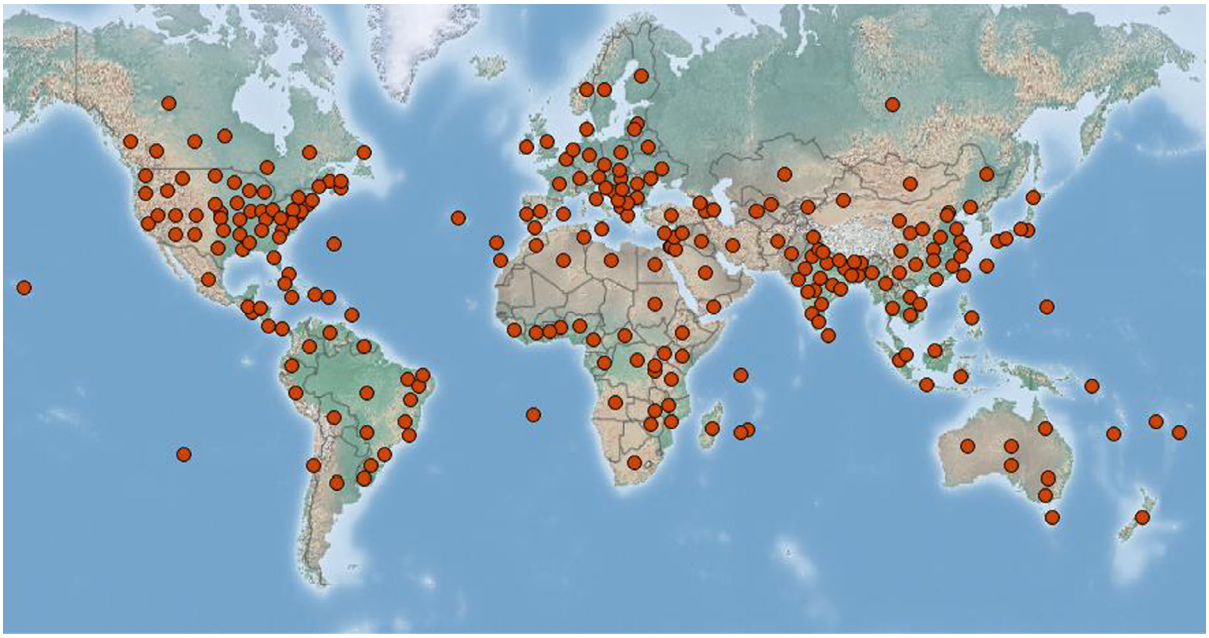

Figure 1: Global distribution map of *Myzus persicae* (Sulzer). Extracted from CABI cpc on 8 August 2019

3.5. Impacts

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

No. Non-EU isolates of PVV-I and PVV-PA4 are not known to be more pathogenic than PVV isolates already present in the EU and no additional impact is therefore expected on the EU territory

Unable to conclude. The pathogenicity of PVV-II is not established and therefore the Panel is unable to reach a conclusion on a potential impact in the EU.

As mentioned in the pest categorisation of non-EU viruses and viroids of potato (EFSA PLH Panel, 2020), symptoms caused by viruses are influenced by different factors, such as the isolate of the virus, the host and variety, and environmental conditions. A causal relation between a virus and reported symptoms is not always clear, for example in the case of mixed infections. Mixed infections are especially common in vegetative-propagated crops such as potato and the presence of additional viruses might increase or attenuate the observed symptoms. Therefore, reports on the symptomatology of individual viruses might not be conclusive, leading to uncertainties on the causal relation between a virus and the symptoms reported.

Natural PVV infections are reported in some potato cultivars and are often virtually symptomless or with only mild leaf chlorosis (Jones and Fribourg, 1986). Mosaic and necrotic spots are reported on older leaves only in a few cultivars (Calvert et al., 1980; Fribourg and Nakashima, 1984; Jones and Fribourg, 1986). PVV is reported to induce a hypersensitive reaction upon infection in some potato cultivars (Jones, 1990). In addition, extreme resistance to PVV was reported in potato cultivars that contain the *Ry* gene (Barker, 1997).

Spetz et al. (2003) compared the symptoms of three PVV-I isolates – two from Peru (PVV-PA10 and PVV-PA11) and one from the UK (PVV-DV42) – in different potato cultivars. Minor differences in symptomatology were observed (e.g. the absence or presence of necrotic local lesions). However, there are no clear indications that the non-EU isolates of PVV-I might differ and have a more severe impact than those already present in the EU. No additional impact over the current situation is therefore expected, should these non-EU isolates be introduced and spread in the EU, with uncertainties.

PVV-II isolates are reported only outside the EU. They are able to infect *S. phureja* and *P. peruviana*, but there are no reports of natural infection in *S. tuberosum* or other plant species. Infection in *S. phureja* was reported to be associated with symptoms (Gutierrez et al., 2016). However, the association of PVV with these symptoms remains uncertain because in some cases other viruses were present, while in other cases the virome of the plants was not extensively analysed (Gutiérrez-Sánchez et al., 2014; Gutierrez et al., 2016). This leaves open the possibility that the observed symptoms could have been caused by co-infecting viruses rather than by PVV. The same situation applies to symptoms reported in *P. peruviana,* since plants with leaf symptoms were co-infected by PVV and Potato virus Y (PVY) (Álvarez et al., 2018). As a consequence, the Panel considers that the pathogenicity of PVV-II is not established, and therefore is unable to conclude on the impact of PVV-II isolates on the EU territory.

PVV-PA4 is reported to have a similar host range and to elicit symptoms similar to those caused by other PVV isolates, with the exception of its inability to infect at least some tobacco varieties (Shiel et al., 2004). The Panel therefore concludes that no additional impact is expected over the current situation, should this isolate be introduced and spread in the EU, with uncertainties.

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. See Section 3.3 for measures already implemented in the current legislation. Additional measures could be implemented to further regulate the identified pathways or to limit entry, establishment or spread of non-EU isolates of PVV.

3.6.1. Identification of additional measures

Phytosanitary measures are currently applied to potato and other hosts (see sections 3.3 and 3.4.1). Potential additional measures to mitigate the risk of entry of the isolates categorised in this opinion may include:

- Repel import derogations for potato plants for planting;
- Set specific phytosanitary requirements addressing the isolates categorised in this opinion for imported seed potatoes and/or ware potatoes;
- Extension of phytosanitary measures to specifically include hosts other than potato.

In addition, non-EU isolates of PVV may enter in the EU through viruliferous aphids. Measures against aphids may include chemical treatment of consignments identified as potential entry pathways.

3.6.1.1. Additional control measures

Table 7 reports on the potential additional control measures to reduce the likelihood of entry, establishment and/or spread of the categorised non-EU isolates of PVV. The additional control measures are selected form a longer list reported in EFSA PLH Panel (2018). Control measures are measures that have a direct effect on pest abundance.

Table 7: Selected additional control measures to consider to reduce the likelihood of pest entry, establishment and/or spread of non-EU isolates of PVV

Information sheet (with hyperlink to information sheet if available)	Control measure summary	Risk component	Rationale
Growing plants in isolation	Description of possible exclusion conditions that could be implemented to isolate the crop from pests and if applicable relevant vectors. E.g. a dedicated structure such as glass or plastic greenhouses	Spread	Growing plants in insect proof greenhouses may prevent infestation by viruliferous aphid vectors. This measure would not be applicable for potato, with the exception of early stages of seed potato production Production of seed potatoes in areas with low aphid pressure (e.g. high altitude) would minimise the risk of infestation
Chemical treatments on consignments or during processing	Use of chemical compounds that may be applied to plants or to plant products after harvest, during process or packaging operations and storage The treatments addressed in this information sheet are: a) fumigation; b) spraying/dipping pesticides; c) surface disinfectants; d) process additives; e) protective compounds	Entry	a), b) and c) could remove viruliferous aphid vectors. PVV is transmitted by aphids in a non-persistent way, which implies that viruliferous aphids will lose the ability to transmit the virus within a short period Therefore, the additional effect on preventing entry is minimal
Cleaning and disinfection of facilities, tools and machinery	The physical and chemical cleaning and disinfection of facilities, tools, machinery, transport means, facilities and other accessories (e.g., boxes, pots, pallets, palox, supports, hand tools). The measures addressed in this information sheet are: washing, sweeping and fumigation	Spread	Cleaning tools may limit the spread via mechanical transmission
Rogueing and pruning	Rogueing is defined as the removal of infested plants and/or uninfested host plants in a delimited area, whereas pruning is defined as the removal of infested plant parts only, without affecting the viability of the plant	Establishment and spread	Rogueing of infested plants is efficient, in particular to prevent spread of PVV via contact. Pruning is not effective to remove a virus from infected plants
Crop rotation, associations and density, weed/ volunteer control	Crop rotation, associations and density, weed/volunteer control are used to prevent problems related to pests and are usually applied in various combinations to make the habitat less favourable for pests The measures deal with (1) allocation of crops to field (over time and space) (multi-crop, diversity cropping) and (2) to control weeds and volunteers as hosts of pests/vectors	Spread and impact	Viruses are maintained by vegetative propagation and, therefore, control of volunteers is important. Control of weed hosts may be of relevance

Information sheet (with hyperlink to information sheet if available)	Control measure summary	Risk component	Rationale
Use of resistant and tolerant plant species/varieties	Resistant plants are used to restrict the growth and development of a specified pest and/or the damage they cause when compared to susceptible plant varieties under similar environmental conditions and pest pressure It is important to distinguish resistant from tolerant species/ varieties	Spread and impact	Resistant and tolerant cultivars are available and could be used
Timing of planting and harvesting	The objective is to produce phenological asynchrony in pest/ crop interactions by acting on or benefiting from specific cropping factors such as: cultivars, climatic conditions, timing of the sowing or planting, and level of maturity/age of the plant seasonal timing of planting and harvesting	Spread and impact	Relevant to prevent transmission by aphid vectors
Chemical treatments on crops including reproductive material	Chemical treatments on crops may prevent infestations by vectors and seed transmission	Spread and impact	Desiccation/removal of the foliage reduces the risk of transmission via aphid vectors and may prevent transport to the tubers of infected plants
Post-entry quarantine and other restrictions of movement in the importing country	This information sheet covers post-entry quarantine of relevant commodities; temporal, spatial and end-use restrictions in the importing country for import of relevant commodities; Prohibition of import of relevant commodities into the domestic country Relevant commodities are plants, plant parts and other materials that may carry pests, either as infection, infestation, or contamination	Entry and spread	Identifying virus–infected plants and banning their movement limit the risks of entry and spread in the EU

3.6.1.2. Additional supporting measures

Table 8 reports on the possible additional supporting measures which are selected from the list reported in EFSA PLH Panel (2018). Supporting measures are organisational measures or procedures supporting the choice of appropriate risk reduction options that do not directly affect pest abundance.

Table 8: Selected supporting measures in relation to currently unregulated hosts and pathways. Supporting measures are organisational measures or procedures supporting the choice of appropriate risk reduction options that do not directly affect pest abundance

Information sheet title (with hyperlink to information sheet if available)	Supporting measure summary	Risk component	Comments
Inspection and trapping	Inspection is defined as the official visual examination of plants, plant products or other regulated articles to determine if pests are present or to determine compliance with phytosanitary regulations (ISPM 5). The effectiveness of sampling and subsequent inspection to detect pests may be enhanced by including trapping and luring techniques	Entry and spread	Visual inspection may detect potentially infected material Only applicable when visible symptoms on leaves and/or propagating tissues occur, which is dependent on the isolate, host/cultivar, and environmental conditions
Laboratory te sting	Examination, other than visual, to determine if pests are present using official diagnostic protocols. Diagnostic protocols describe the minimum requirements for reliable diagnosis of regulated pests	Entry and spread	Laboratory testing may detect/ identify non-EU isolates of PVV on sampled material
Certified and approved pre mises	Mandatory/voluntary certification/ approval of premises is a process including a set of procedures and of actions implemented by producers, conditioners and traders contributing to ensure the phytosanitary compliance of consignments. It can be a part of a larger system maintained by a National Plant Protection Organization in order to guarantee the fulfilment of plant health requirements of plants and plant products intended for trade. Key property of certified or approved premises is the traceability of activities and tasks (and their components) inherent the pursued phytosanitary objective. Traceability aims to provide access to all trustful pieces of information that may help to prove the compliance of consignments with phytosanitary requirements of importing countries	Entry and spread	Certified and approved premises may guarantee the absence of the harmful viruses imported for research and/or breeding purposes

Information sheet title (with hyperlink to information sheet if available)	Supporting measure summary	Risk component	Comments
Delimitation of buffer zones	ISPM 5 defines a buffer zone as 'an area surrounding or adjacent to an area officially delimited for phytosanitary purposes in order to minimize the probability of spread of the target pest into or out of the delimited area, and subject to phytosanitary or other control measures, if appropriate' (ISPM 5). The objectives for delimiting a buffer zone can be to prevent spread from the outbreak area and to maintain a pest free production place, site or area	Spread	Buffer zones may contribute to reduce the spread of non-EU isolates of PVV after entry in the EU
Sampling	According to ISPM 31, it is usually not feasible to inspect entire consignments, so phytosanitary inspection is performed mainly on samples obtained from a consignment. It is noted that the sampling concepts presented in this standard may also apply to other phytosanitary procedures, notably selection of units for testing For inspection, testing and/or surveillance purposes the sample may be taken according to a statistically based or a non-statistical sampling methodology	Spread	
Phytosanitary certificate and plant passport	An official paper document or its official electronic equivalent, consistent with the model certificates of the IPPC, attesting that a consignment meets phytosanitary import requirements (ISPM 5) a) export certificate (import) b) plant passport (EU internal trade)	Entry and spread	
Certification of reproductive material (voluntary/ official)	Certification of reproductive material when not already implemented would contribute to reduce the risk associated with spread	Spread	
Surveillance	Official surveillance may contribute to early detection of non-EU isolates of PVV, favouring immediate adoption of control measures if they come to establish	Spread	

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

- Symptomless infections for some of the non-EU isolates of PVV in some hosts
- Uneven virus distribution or low concentrations limiting the reliability of the detection
- Absence of a validated diagnostic protocol allowing the identification of PVV isolates.

3.7. Uncertainty

The Panel identified the following knowledge gaps and uncertainties:

Identity and biology

- Lack of information to support the assignment of isolates to a particular PVV lineage in reports without genomic data;
- Limited biological data, in particular at lineage level, i.e. on host range, transmission and pathogenicity in potato or in other hosts;
- Uncertainty on the existence of other non-EU isolates of PVV that have not yet been identified and might have additional impact on the EU territory;
- Uncertainty whether the biological differences reported in the literature are general features of PVV groups of isolates or apply only to a fraction of the isolates in a given group.

Pest distribution

- Uncertainty on the geographical distribution of the categorised lineages because of the absence of systematic surveys.

Regulatory status

- The concept of "non-EU isolates" leaves some room for interpretation, which may create confusion or difficulties when enforcing the legislation (see Section 1.2).

Entry, establishment and spread in the EU (host range, entry, establishment, spread)

- Uncertainty on the host range of the categorised groups of isolates of PVV, particularly in the case of PVV-PA4.

Impact

- Uncertainty on the pathogenicity of PVV-II
- Uncertainty on the magnitude of the impact of non-EU isolates and whether this impact would exceed that of the isolates already present in the EU.

4. Conclusions

The information currently available on geographical distribution, biology, epidemiology, potential additional impact over the present situation, and potential entry pathways of non-EU isolates of PVV has been evaluated with regard to the criteria to qualify as a potential Union quarantine pest. The conclusions of the Panel are summarised in Table 9.

Non-EU isolates of PVV-I and PVV-PA4 do not meet one of the criteria evaluated by EFSA to be regarded as a potential Union quarantine pest, since they are not expected to have an additional impact in the EU.

With the exception of the criterion regarding the potential consequences in the EU territory for which the Panel is unable to conclude (see Section 3.5), non-EU isolates of PVV-II meet all the other criteria to qualify as a potential Union quarantine pest.

The Panel wishes to stress that these conclusions are associated with uncertainties because of limited information on distribution, biology and impact of PVV isolates at the lineage or isolate level. In particular, the magnitude of the potential impact over the present situation is generally unknown. Furthermore, other potentially harmful non-EU isolates of PVV might exist and/or emerge that are currently unknown.

Table 9: 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) for non-EU isolates of PVV

Criterion of pest categorisation	Panel's conclusions against criterion in Regulation (EU) 2016/2031 regarding Union quarantine pest	Key uncertainties
Identity of the pest (Section 3.1)	The identity of PVV is well established Methods are available for detection and identification of non-EU isolates of PVV	Uncharacterised PVV isolates may exist
Absence/ presence of the pest in the EU territory (Section 3.2)	PVV-I isolates are present in the EU PVV-II isolates and PVV-PA4 are not reported in the EU	Unreported presence of PVV-II and PVV-PA4 in the EU
Regulatory status (Section 3.3)	Non-EU isolates of PVV are currently regulated in Annex IAI	Interpretation of the concept of "non-EU isolate"
Pest potential for entry, establishment and spread in the EU territory (Section 3.4)	Non-EU isolates of PVV are able to enter into the EU The pathways of plants for planting of potato and ware potatoes are closed by legislation for non-EU isolates of PVV-I and PVV-II The pathway of plants for planting of other hosts is partially regulated for PVV-I, and closed for PVV-II For PVV-PA4, the Panel is unable to conclude on the pathways of plants for planting of potato, of ware potatoes and of plants for planting of other hosts The minor pathways of viruliferous aphids and import of fruits of hosts species are open for all non-EU isolates of PVV If non-EU isolates of PVV were to enter the EU territory, they could become established and spread	– Geographical distribution – Existence of other natural hosts – Existence and relevance of vectors
Potential for consequences in the EU territory (Section 3.5)	Non-EU isolates of PVV-I and PVV-PA4 are not expected to have an additional impact over the current situation For non-EU isolates of PVV-II, the Panel was unable to conclude on potential additional consequences in the EU territory due to limited information	– Uncertainty on the magnitude of impact of non-EU isolates – Pathogenicity of PVV-II
Available measures (Section 3.6)	Phytosanitary measures are available to reduce the likelihood of entry and spread of non-EU isolates of PVV in the EU	No uncertainty
Conclusion on pest categorisation (Section 4)	Non-EU isolates of PVV-I and PVV-PA4 do not meet one of the criteria evaluated by EFSA to be regarded as a potential Union quarantine pest, since they are not expected to have an additional impact in the EU With the exception of the criterion regarding the potential consequences in the EU territory for which the Panel is unable to conclude (see Section 3.5), non-EU isolates of PVV-II meet all the other criteria evaluated by EFSA to qualify as a potential Union quarantine pest	

Criterion of pest categorisation	Panel's conclusions against criterion in Regulation (EU) 2016/2031 regarding Union quarantine pest	Key uncertainties
Aspects of assessment to focus on/ scenarios to address in future if appropriate	The main knowledge gaps or uncertainties identified concern: – Lack of information on the biology of the categorised lineages (e.g. host range, vector transmission, pathogenicity) – Geographic distribution of the categorised lineages of PVV – Uncertainty on magnitude of impact of non-EU isolates of PVV Given the limited information on the distribution of PVV-PA4, and on the biological differences between lineages of PVV, in particular the pathogenicity of PVV-II, the development of a full PRA is unlikely to allow to resolve the uncertainties attached to the present categorisation until more data become available	

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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)
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)
Isolate	Virus population as present in a plant
Lineage	Group of isolates belonging to a distinct phylogenetic cluster
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)
Strain	Group of isolates sharing biological, molecular and/or serological properties

Abbreviations

CABI cpc	CABI Crop Protection Compendium
CP	coat protein
DG SANTÉ	Directorate General for Health and Food Safety
ELISA	enzyme-linked immunosorbent assay
EPPO	European and Mediterranean Plant Protection Organization
FAO	Food and Agriculture Organization
ICTV	International Committee on Taxonomy of Viruses
IPPC	International Plant Protection Convention
ISPM	International Standards for Phytosanitary Measures
MS	Member State
PLH	EFSA Panel on Plant Health
PTMV	Peru tomato mosaic virus
PVV	potato virus V
PVY	Potato virus Y
RNQP	regulated non-quarantine pest
RT-PCR	real-time polymerase chain reaction
TFEU	Treaty on the Functioning of the European Union
ToR	Terms of Reference
WPMV	wild potato mosaic virus