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

EFSA Panel on Plant Health (PLH)
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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 X (PVX). 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 PVX has been evaluated with regard to the criteria to qualify as a potential Union quarantine pest. Because non-EU isolates of PVX 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. On the basis of their ability to overcome potato resistance genes, PVX isolates can be divided into several pathotypes. PVX isolates that are not able to overcome resistance genes and PVX isolates that are able to overcome the *Nb* and/or *Nx* resistance genes are already present in the EU. Isolates able to overcome the *Rx* resistance gene have only been reported from South America. These *Rx* breaking isolates could potentially have an additional impact over the current situation in the EU and therefore meet all the criteria to qualify as a potential Union quarantine pest. All other non-EU isolates, should they be introduced, are not expected to have additional impact and therefore do not meet this criterion to qualify as a potential Union quarantine pest.

Keywords: European Union, Non-EU isolate, pest risk, PVX, plant pest, resistance breaking, quarantine

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Table of contents

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

Aleurocanthus 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 X (PVX). Non-EU isolates of PVX 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 PVX 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 that it 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.

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

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 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 PVX 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 PVX. 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 PVX, following the 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 PVX will be provided at species level. Further information will be added at the level of strains/groups of isolates 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 PVX. 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.

[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.

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 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. PVX 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 X is a well-characterised virus in the genus *Potexvirus*, family Alphaflexiviridae (Adams et al., 2011). It 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

PVX is not known to be transmitted by pollen or true seeds (Loebenstein and Gaba, 2012). It is transmitted by vegetative propagation (via tubers) and can be transmitted mechanically, e.g. by contaminated tools, contact, and/or wounds (Jeffries, 1998; CABI cpc, 2019). The Panel does not expect significant differences between PVX isolates for these general properties. Furthermore, transmission by a fungus (*Synchytrium endobioticum* (Schilb.) Percival), an aphid (*Aulacorthum solani* (Kaltenbach)) and two grasshoppers (*Melanoplus differentialis* (Thomas), *Tettigonia viridissima* (Linnaeus)) has been reported in the past (Koenig and Lesemann, 1989; CABI cpc, 2019). However, since transmission by these organisms has not been confirmed in recent literature, vector transmission is not further considered here.

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 lineages and/or 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.

Studies showing an unambiguous relationship between specific virus genotypes (isolates/lineages/strains) and biological properties are limited. Moreover, the interpretation of such data may be hampered because discrimination between strains based on biological data is not always supported by genomic data. Historically, strains have been distinguished for many viruses, including PVX, based on differences in reactions on a set of indicator plants. This differentiation became further established by serology, especially by using monoclonal antibodies specifically selected to discriminate between the earlier distinguished strains. However, with the advent of molecular techniques, it became apparent that the initial biological and/or serological strain differentiation was not always supported by phylogenetic analyses of isolates based on genomic data. Moreover, the discrimination between strains might be further complicated by the existence of recombinant isolates, hampering an unambiguous assignment of isolates to recognised strains. This implies that there is frequent uncertainty about the interpretation of (older) data on strains differentiation and on geographical distribution.

There have been several approaches to distinguish PVX groups of isolates; i.e. based on thermal inactivation points, serological properties, their ability to overcome resistance conferred by the two resistance genes *Nx* and *Nb* in *S. tuberosum* (Cox and Jones, 2010; Loebenstein and Gaba, 2012), and on genomic data. Referring to the property to overcome resistance genes, four pathotype groups have been distinguished based on their resistance-breaking profile; group 1 isolates do not overcome *Nx* and *Nb* resistance genes; group 2 isolates overcome the *Nx* gene; group 3 isolates overcome the *Nb* gene, and group 4 isolates overcome both genes. Additionally, two isolates (PVX-HB and PVX-MS) have been reported to overcome *Nx*, *Nb* and a third resistance gene referred to as *Rx* (Feigelstock et al., 1995; Querci et al., 1995).

Phylogenetic sequence analysis divides PVX isolates into two major lineages, lineage I (PVX-I, also referred to as the Eurasian lineage) and lineage II (PVX-II, also referred to as the American lineage) (Cox and Jones, 2010; Hajizadeh and Sokhandan-Bashir, 2017). In contrast to what the lineage names suggests, some European isolates cluster within PVX-II and some American isolates cluster within PVX-I. Cox and Jones (2010) and Massumi et al. (2014) report that the genetic diversity among PVX-I isolates is lower than among PVX-II isolates. As a consequence, PVX-II has been subdivided into three

sublineages, PVX-II-1, PVX-II-2 and PVX-II-3 (Santa Cruz and Baulcombe, 1995; Cox and Jones, 2010; Kutnjak et al., 2014). Sublineage PVX-II-1 isolates have been reported from the EU only (the Netherlands and the United Kingdom), and there is currently no evidence for their existence outside the EU (Santa Cruz and Baulcombe, 1995; Cox and Jones, 2010). Should such isolates exist outside of the EU and be introduced, they would not be expected to have additional impact as compared to those already present. PVX-II-1 isolates are therefore not extensively analysed here.

So far, no relation could be established between the grouping based on phylogenetic sequence analysis and resistance-breaking profiles. The absence of such a relation is associated with uncertainties due to limited information, as sequence and resistance-breaking profile are simultaneously known only for a few PVX isolates, and other groups of isolates or lineages, and recombinants could exist (Table 2).

Table 2: Lineages and sublineages of PVX isolates based on phylogenetic sequence analysis

PVX lineages	Acronym	Other information	Key references
Lineage I	PVX-I	Includes isolates of pathotype groups 1 (non-resistance breaking), 3 and 4 (*Nb* and *Nb*+*Nx* resistance breaking) and *Rx* resistance-breaking isolate PVX-MS (NCBI GenBank Z34261)	Kavanagh et al. (1992), Feigelstock et al. (1995), Santa Cruz and Baulcombe (1995), Cox and Jones (2010), Yu et al. (2010), Kutnjak et al. (2014), Hajizadeh and Sokhandan-Bashir (2017)
Lineage II			
Sublineage II-1	PVX-II-1	Includes isolates of pathotype groups 1 (non-resistance breaking), and 2 (*Nx* resistance breaking)	Santa Cruz and Baulcombe (1995), Cox and Jones (2010)
Sublineage II-2	PVX-II-2	Includes isolates of pathotype groups 1 (non-resistance breaking), 2 and 4 (*Nx* and *Nb*+*Nx* resistance breaking) and *Rx*-breaking isolate PVX-HB (NCBI GenBank X72214)	Moreira et al. (1980), Jones (1985), Orman et al. (1990), Kavanagh et al. (1992), Querci et al. (1993), Cox and Jones (2010)
Sublineage II-3	PVX-II-3	Includes genetically distinct isolates of unknown pathotype, e.g. PVX-GAF2018	Kutnjak et al. (2014)

In the frame of the present categorisation, the ability to overcome potato resistance genes, in particular the extreme resistance *Rx* gene, is analysed by the Panel as the most relevant biological property. This is because the *Nx*, *Nb* and *Rx* resistance genes are deployed in some EU-grown potato varieties (Santa Cruz and Baulcombe, 1995), therefore contributing to the protection of EU potato crops against PVX. In addition, there is only limited evidence for the existence of other types of biological variability between PVX isolates. Because there is no clear link between the lineages/sublineages described above and resistance-breaking properties (Cox and Jones, 2010), the Panel decided to categorise PVX isolates on the basis of their resistance-breaking properties, using information on phylogenetic lineages when appropriate (e.g. geographical distribution).

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 PVX at the species level, and therefore for the identification of non-EU isolates. No molecular or serological method is available for the specific detection of resistance-breaking isolates but these can be identified by bioassays on a panel of potato varieties. The identified mutations responsible for *Rx* resistance breaking could be used to design molecular diagnostic tests.

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).

PVX 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) are available for the detection and identification of PVX (Agindotan et al., 2007; Loebenstein and Gaba, 2012; Kutnjak et al., 2014). Additionally, Kutnjak et al. (2014) described a RT-PCR assay to distinguish between PVX-I, PVX-II-1/2 and PVX-II-3. The test cannot distinguish between PVX-II-1 and PVX-II-2 and the exclusivity and inclusivity of this test is not fully established. Therefore, available methods do not allow reliable identification of all sublineages. However, genomic data are available (Malcuit et al., 2000; Cox and Jones, 2010; Yu et al., 2010; Kutnjak et al., 2014) for the design of additional diagnostic methods. In addition, a bioassay using different potato cultivars is described to determine the resistance-breaking profile of PVX isolates (Moreira et al., 1980; Tozzini et al., 1994). However, this bioassay is time-consuming and might be influenced by environmental factors, and therefore its application in practice might be limited. The mutations responsible for the overcoming of the *Rx* resistance have been identified (Goulden et al., 1993) and could be used to develop a diagnostic test.

3.2. Pest distribution

3.2.1. Pest distribution outside the EU

PVX occurs worldwide wherever potato is grown (Loebenstein et al., 2001). In the absence of specific surveys, there is only limited information on the geographical distribution of the PVX lineages and sublineages, and resistance-breaking isolates.

PVX-I isolates are reported worldwide, including in the EU (Cox and Jones, 2010; Kutnjak et al., 2014; Hajizadeh and Sokhandan-Bashir, 2017). The only known *Rx*-breaking isolate in the PVX-I lineage (PVX-MS) has been reported from Argentina (Tozzini et al., 1994; Feigelstock et al., 1995; Jung et al., 2000).

PVX-II-2 isolates are reported from Bolivia, Peru and the USA (Jones, 1985; Querci et al., 1995; Cox and Jones, 2010; Kutnjak et al., 2014). The only known *Rx*-breaking isolate of this sublineage (PVX-HB) has been reported from Bolivia (Moreira et al., 1980; Santa Cruz and Baulcombe, 1995).

PVX-II-3 isolates are reported from Colombia and Peru (Kutnjak et al., 2014).

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. Non-resistance breaking isolates, *Nb, Nx,* and *Nb*+*Nx* resistance-breaking isolates of PVX are present in the EU.

No. *Rx* resistance-breaking isolates of PVX are not known to be present in the EU.

As indicated in the previous section, isolates belonging to the PVX-I lineage are reported worldwide, including several EU MSs (Estonia, Ireland, the Netherlands, Spain, United Kingdom) (Santa Cruz and Baulcombe, 1995; Cox and Jones, 2010). This lineage includes isolates of pathotype 1 (non-resistance breaking) and pathotypes 3 and 4 (*Nb* and *Nb*+*Nx* resistance breaking). In addition, isolates of pathotype 2 (*Nx* resistance breaking) belonging to lineage PVX-II-1 are only reported in the EU.

Isolates of sublineages PVX-II-2 (which includes isolates of pathotype 2 (*Nx* resistance breaking)) and PVX-II-3 are not reported in the EU (Santa Cruz and Baulcombe, 1995; Cox and Jones, 2010). However, this assessment is associated with uncertainties in the absence of specific surveys.

The only two known *Rx*-breaking isolates have been reported from South-American countries (Moreira et al., 1980; Tozzini et al., 1994; Feigelstock et al., 1995; Santa Cruz and Baulcombe, 1995; Jung et al., 2000). Therefore, *Rx* resistance-breaking isolates are not known to occur in the EU, with uncertainties in the absence of specific surveys.

3.3. Regulatory status

3.3.1. Council Directive 2000/29/EC

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

Table 3: Non-EU isolates of PVX 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. PVX 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.

3.4. Entry, establishment and spread in the EU

3.4.1. Host range

Table 5 provides information on reports of natural hosts (including potato) of PVX including the associated uncertainties and regulation. In general, information on host range is not available below the species level. There is no indication that the host range of resistance-breaking isolates, including those overcoming *Rx*, is different from that of other PVX isolates.

Table 5: Natural hosts of PVX. Data regarding natural hosts was retrieved from the CABI cpc and literature up to October 8, 2019

Hosts	Rationale and/or uncertainty	Regulation
Brassica campestris spp. *rapa* (Samad et al., 1991), *Capsicum annuum* (Palkovics et al., 2011; Massumi et al., 2014), *C. fructigena* (Ravanbod et al., 2018), *Datura stramonium* (Loebenstein et al., 2001), *Nicandra physalodes* (Jeffries, 1998), *Nicotiana* spp. (Loebenstein et al., 2001), *Orychophragmus violaceaus* (Cox and Jones, 2010), *Petunia hybrida* (Loebenstein et al., 2001), *Physalis peruviana* (Gutierrez et al., 2015; Hajizadeh and Sokhandan-Bashir, 2017), *Pisum sativum* (Cox and Jones, 2010), *Rumex patientia* L. x *Rumex tianschanicus* A. Los (Petrzik, 2009), *Sanicula chinensis* (Cox and Jones, 2010), *Solanum betaceum* (Loebenstein et al., 2001), *S. lycopersicum* (Loebenstein et al., 2001), *S. melongena* (Ravanbod et al., 2018), *S. nigrum* (Loebenstein et al., 2001), *S. phureja* (García Ruíz et al., 2015) and *S. tuberosum* (Jeffries, 1998)	Relatively wide natural host range; it is unlikely that all natural hosts have been identified. Only limited information on hosts that might be specific for particular isolates	***Brassica* sp.:** IVAII 24.1; IVB 22; VAI 2.1. ***Capsicum* sp.:** IVAI 16.6, 25.7, 36.3, IVAII 18.6.1, 18.7; VBI 1,3. ***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

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 PVX 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) and plants for planting of other hosts.

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

PVX is transmitted by vegetative propagation and therefore seed potatoes and more generally, potato plants for planting, are considered the most important pathway for entry. The potential pathway for entry of non-EU isolates via seed potatoes of *S. tuberosum* and plants for planting of other tuber-forming *Solanum* species and their hybrids is addressed by the current EU legislation (table 4; (EU) 2000/29 Annex IIIA, 10 and 11), which sets that import is not allowed from third countries except Switzerland. However, 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). PVX is reported in Canada (NCBI GenBank, e.g. MH069212) and Switzerland (Massumi et al., 2014; Turco et al., 2018). By definition, the PVX isolates present in these countries are considered to be non-EU isolates. Therefore, the pathway of plants for planting is considered partially regulated for PVX at the species level.

The PVX-I lineage, which contains non-resistance breaking isolates and *Nb* or *Nb*+*Nx* resistance-breaking isolates, is reported from Canada and Switzerland (Cox and Jones, 2010; Turco et al., 2018). The potato plants for planting pathway is therefore considered partially regulated for such non-EU isolates. PVX-II-2 lineage is only known to occur in countries for which there is no import derogation, therefore the pathway is closed for *Nx* resistance-breaking isolates. *Rx* resistance-breaking isolates are only reported from South America therefore, the potato plants for planting pathway is considered closed by legislation for these non-EU isolates.

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). PVX is or should be considered present in these specified countries given its worldwide distribution. By definition, the PVX isolates present in these countries are considered non-EU isolates. They can in principle enter the EU via the ware potato pathway as there are no specific measures in place that mitigate the risk of entry. As reported in the pest categorisation of non-EU viruses and viroids of potato (EFSA PLH Panel, 2020), the majority of the imported ware potatoes comes from Egypt and Israel (47 and 47.2%, respectively). Note that as long as ware potatoes are used for the intended use (consumption or processing) the ability of the non-EU isolates of PVX to establish is 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 Global Database: 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. When considering the groups of isolates separately, only PVX-I is known to be present in the countries for which derogations apply (Soliman et al., 2000; Massumi et al., 2014). Therefore, the ware potato pathway is considered partially regulated for non-EU isolates that are non-resistance breaking or *Nb* or *Nb*+*Nx* resistance-breaking, and belong to the PVX-I lineage. PVX-II-2 sublineage is only known to occur in countries for which there is no import derogation, therefore the pathway is closed for isolates of this sublineage, which also includes *Nx* resistance-breaking isolates. Since *Rx* resistance-breaking isolates are only reported from South America, the ware potato pathway is considered closed by legislation.

PVX has a relatively wide host range (see Section 3.4.1). It is unclear whether some or all of the regulated solanaceous hosts can be infected by the various PVX lineages/sublineages. There are no indications that the natural host range of *Rx* resistance-breaking isolates might differ from that of other PVX isolates. Although the import of plants for planting of solanaceous species is addressed by the legislation, it is possible to import such plants for planting from Mediterranean countries, some of them being subject to import derogations. As a consequence, the pathway of plants for planting of other solanaceous hosts is considered as partially regulated for non-EU isolates that are non-resistance breaking or *Nb* or *Nb*+*Nx* resistance breaking, and belong to lineage PVX-I. Plants for planting of *Orychophragmus violaceus, Pisum sativum, Rumex patientia* L. x *Rumex tianschanicus* A. Los, *Sanicula chinensis* can be imported from Bolivia, Peru and the USA; therefore the pathway is possibly open for *Nx* resistance-breaking isolates of lineage PVX-II-2. Similarly, *Rx* resistance-breaking isolates being only reported from South America, plants for planting of these hosts could provide a probably minor pathway. The plants for planting pathway of other hosts than potato is therefore considered possibly open for *Rx* resistance-breaking PVX isolates. This assessment is affected by uncertainties on trade and host range.

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

Resistance-breaking properties	Potato plants for planting[(1)]	Ware potatoes[(1)]	Plants for planting of other hosts[(1),(2)]	Uncertainties
Non-resistance breaking and *Nb* and/or *Nx* resistance breaking	Pathway partially regulated for non-resistance breaking and for *Nb* and *Nb*+*Nx* resistance breaking isolates of lineage PVX-I: plants for planting of potato can be imported from Canada and Switzerland Pathway closed for *Nx* resistance-breaking isolates of lineage PVX-II-2: only known to occur in countries for which there is no import derogation	Pathway partially regulated for non-resistance breaking and for *Nb* and *Nb*+*Nx* resistance breaking isolates of lineage PVX-I: import of ware potatoes is allowed from Algeria, Bosnia-Herzegovina, Egypt, Israel, Libya, Morocco, Serbia, Switzerland, Syria, Tunisia and Turkey Pathway closed for *Nx* resistance-breaking isolates of lineage PVX-II-2: only known to occur in countries for which there is no import derogation	Pathway partially regulated for non-resistance breaking and for *Nb* and *Nb*+*Nx* resistance breaking isolates of lineage PVX-I: plants for planting of solanaceous host species can be imported from Mediterranean countries, as well as plants for planting of host species for which there is no import ban Pathway possibly open for *Nx* resistance-breaking isolates of lineage PVX-II-2: plants for planting of several host species can be imported	Geographic distribution Existence of other natural hosts
Rx resistance breaking	Pathway closed: import of plants for planting of potato is banned from countries where *Rx* resistance-breaking isolates are reported	Pathway closed: import of ware potatoes is banned from countries where *Rx* resistance-breaking isolates are reported	Pathway possibly open: plants for planting of several host species can be imported	Geographic distribution Existence of other natural hosts Trade of plants for planting of non-regulated 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 subpathways, 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 of other hosts which are listed in Table 5.

Table 7 reports two interceptions of PVX by EU MSs during the period between 1995 and 8 August 2019. Only interceptions involving consignments imported from outside the EU were considered. There is no information on the resistance-breaking status of the isolates involved.

Table 7: Interceptions of PVX by EU MSs on imported material from outside the EU. Data retrieved from the Europhyt database on August 8, 2019

Virus	Europhyt interception ID	Year of interception	Origin	Plant species on which it has been intercepted
PVX	8509	2000	United States	*Solanum tuberosum*(1)
PVX	109175	2017	Peru	*Solanum tuberosum*(2)

(1): Intercepted during post-entry quarantine testing.
(2): Illegal import.

3.4.3. Establishment

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

Yes. Non-EU isolates of PVX 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

Potato is widely grown in the EU, as reported in the pest categorisation of non-EU viruses and viroids of potato (EFSA PLH Panel, 2020).

3.4.3.2. Climatic conditions affecting establishment

Except for those conditions affecting survival of the host plants, no ecoclimatic constrains exist for the PVX 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 PVX can spread via plants for planting and by mechanical transmission (See Section 3.1.2).

3.5. Impacts

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

Yes: *Rx* resistance-breaking isolates of PVX are expected to have an additional impact if introduced in the EU. The magnitude of this impact is however uncertain.

No: Non-resistance-breaking and *Nb* and/or *Nx* resistance-breaking non-EU isolates of PVX are not expected to have an additional impact on the EU territory, since isolates with similar resistance-breaking profiles are already present 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.

Table 8 reports on the expected additional impact of non-EU isolates of PVX in comparison to the PVX isolates already present in the EU. PVX is considered to have an impact at the species level and various control measures are already implemented (e.g. certification schemes for plants for planting). To determine whether non-EU isolates would have an additional impact, a comparison of biological properties was made between non-EU isolates and isolates already present in the EU. No information on yield and quality losses is available at lineage or group of isolates level.

Table 8: Expected additional impact and rationale of non-EU isolates of PVX on the EU territory

Resistance-breaking properties	Additional impact on the EU territory?	Rationale and/or uncertainty
Non-resistance breaking and *Nb* and/or *Nx* resistance-breaking isolates	No	Non-resistance breaking and *Nb, Nx* and *Nb*+*Nx* resistance-breaking isolates of PVX already occur in the EU. The introduction and spread of non-EU isolates with similar resistance-breaking properties is not expected to cause additional impact
Rx resistance-breaking isolates	Yes	EU isolates are not known to be able to overcome the *Rx* resistance gene, which is present in some EU-grown potato varieties (Nyalugwe et al., 2012). The introduction and spread of non-EU isolates able to overcome this resistance is expected to have an impact in such varieties. This statement is associated with uncertainties on the geographical distribution of *Rx*-breaking isolates. In addition, the magnitude of the expected impact is uncertain, in particular because the extent to which current measures (certification schemes) would limit this impact is unclear

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 PVX.

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;
- Banning import of plants for planting of non-potato hosts from countries where *Rx* resistance-breaking isolates of PVX are present;
- Extension of certification schemes and testing requirements to non-Solanum natural hosts;
- Extension of plant passport requirements to specifically include hosts other than stolon- and tuber-forming *Solanum* species.

3.6.1.1. Additional control measures

Table 9 reports on the potential additional control measures to reduce the likelihood of entry, establishment and/or spread of the categorised non-EU isolates of PVX. 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 9: Selected additional control measures to consider to reduce the likelihood of pest entry, establishment and/or spread of non-EU isolates of PVX

Information sheet title (with hyperlink to information sheet if available)	Control measure summary	Risk component (entry/ establishment/ spread/impact)	Comments
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 and machinery 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 PVX 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
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
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 limits the risks of entry and spread in the EU

3.6.1.2. Additional supporting measures

Table 10 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 10: 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 (entry/ establishment/ spread/impact)	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 testing	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 PVX on sampled material
Certified and approved premises	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 PVX imported for research and/or breeding purposes

Information sheet title (with hyperlink to information sheet if available)	Supporting measure summary	Risk component (entry/ establishment/ spread/impact)	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 PVX 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 testingFor 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 PVX, 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 PVX in some hosts.
- Uneven virus distribution or low concentrations limiting the reliability of the detection.
- Absence of validated molecular or serological diagnostic protocols allowing the typing of the resistance-breaking properties of PVX isolates.

3.7. Uncertainty

The Panel identified the following knowledge gaps and uncertainties:

Identity and biology

- Lack of data to relate biological properties, such as resistance-breaking, to the phylogenetic lineages and sublineages of PVX.
- Lack of information on whether PVX isolates might differ by other biological properties than their ability to overcome various potato-resistance genes.
- Uncertainty on the relative contribution of potato-resistance genes and other control methods, such as certification schemes of potato, to the current control of PVX in the EU.
- Uncertainty on the existence of other non-EU isolates of PVX that have not yet been identified and might have an additional impact on the EU territory.

Pest distribution

- Uncertainty on the geographical distribution and prevalence of the categorised groups of isolates of PVX 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 presence of *Rx* resistance-breaking isolates outside South America.

Impact

- In the absence of specific surveys, uncertainty on the presence of *R*x resistance-breaking isolates in the EU.
- Uncertainty on the magnitude of the impact of *R*x resistance-breaking isolates, should they be introduced, 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 PVX 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 11.

Non-EU isolates that are either unable to overcome potato-resistance genes or that are only able to overcome the *Nb* and/or *Nx* resistance, do not meet one of the criteria evaluated by EFSA to qualify as a potential Union quarantine pest, since they are not expected to have an additional impact in the EU.

Rx resistance-breaking isolates meet all the criteria evaluated by EFSA to qualify as a potential Union quarantine pest, as they are expected to have an additional impact over the current situation in the EU.

The Panel wishes to stress that these conclusions are associated with uncertainties because of limited information on distribution, biology and impact of PVX isolates with respect to their resistance-breaking properties. In particular, the magnitude of the potential additional impact over the present situation is generally unknown. Furthermore, other potentially harmful non-EU isolates of PVX might exist that have not been discovered yet.

Table 11: The Panel's conclusions on the pest categorisation criteria defined in Regulation (EU) 2016/2031 on protective measures against pests of plants (the number of the relevant sections of the pest categorisation is shown in brackets in the first column) for non-EU isolates of PVX

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 PVX is well established Molecular and serological methods are available for detection and identification of PVX at the species level, but not for the identification of lineages or groups of isolates. Identification of resistance-breaking isolates can be achieved by bioassays on a panel of potato varieties. Genomic data are available for the design of further diagnostic tests	Uncharacterised PVX isolates may exist
Absence/presence of the pest in the EU territory (Section 3.2)	Non-resistance breaking isolates, *Nb*, *Nx* and *Nb*+*Nx* resistance-breaking isolates of PVX are present in the EU *Rx* resistance-breaking isolates of PVX are not known to be present in the EU	Unreported or more widespread presence of *Rx* resistance-breaking isolates of PVX in the EU
Regulatory status (Section 3.3)	Non-EU isolates of PVX 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 PVX are able to enter into the EU The pathways of plants for planting of potato and of ware potatoes are considered partially regulated for non-resistance-breaking isolates and for *Nb* and *Nb*+*Nx* resistance-breaking isolates. These pathways are closed by legislation for *Nx* and *Rx* resistance-breaking isolates The pathway of plants for planting of other hosts is partially regulated for non-resistance-breaking isolates and for *Nb* and *Nb*+*Nx* resistance-breaking isolates. The pathway is possibly open for *Nx* and *Rx* resistance-breaking isolates If non-EU isolates of PVX were to enter the EU territory, they could become established and spread	– Geographical distribution – Existence of other natural hosts – Trade of plants for planting of non-solanaceous hosts
Potential for consequences in the EU territory (Section 3.5)	Non-resistance breaking and *Nb* and/or *Nx* resistance-breaking non-EU isolates of PVX are not expected to have an additional impact on the EU territory, since isolates with similar resistance-breaking profiles are already present in the EU *Rx* resitance-breaking isolates are expected to have an additional impact if introduced in the EU	– Potential presence of *Rx* resistance-breaking isolates in the EU – Magnitude of the impact of *Rx* resistance-breaking isolates, should they be introduced, and whether this impact would exceed that of the isolates already present in the EU
Available measures (Section 3.6)	Phytosanitary measures are available to reduce the likelihood of entry and spread of non-EU isolates of PVX in the EU	No uncertainty

Criterion of pest categorisation	Panel's conclusions against criterion in Regulation (EU) 2016/2031 regarding Union quarantine pest	Key uncertainties
Conclusion on pest categorisation (Section 4)	Non-EU isolates that are either unable to overcome potato resistance genes or that are only able to overcome the *Nb* and/or *Nx* resistances do not meet one of the criteria evaluated by EFSA to qualify as a potential Union quarantine pest, since they are not expected to have an additional impact in the EU *Rx* resistance-breaking isolates meet all the criteria evaluated by EFSA to qualify as a potential Union quarantine pest as they are expected to have an additional impact over the current situation in the EU	
Aspects of assessment to focus on/ scenarios to address in future if appropriate	The main knowledge gaps or uncertainties identified concern: • Lack of data to relate biological properties, such as resistance breaking, to the phylogenetic lineages and sublineages of PVX • Lack of information on whether PVX isolates might differ by other biological properties than their ability to overcome various potato-resistance genes • Uncertainty on the geographical distribution and prevalence of the categorised groups of PVX isolates • Uncertainty on the relative contribution of potato-resistance genes and other control methods, such as certification schemes of potato, to the current control of PVX in the EU • Uncertainty on the magnitude of impact of non-EU isolates of PVX	

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Abbreviations

CABI cpc	CABI Crop Protection Compendium
DG SANTÉ	Directorate General for Health and Food Safety
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
PVX	potato virus X
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

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