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

EFSA Panel on Plant Health (PLH),
Claude Bragard, Katharina Dehnen-Schmutz, Paolo Gonthier, Marie-Agnès Jacques, Josep Anton Jaques Miret, Annemarie Fejer Justesen, Alan MacLeod, Christer Sven Magnusson, Panagiotis Milonas, Juan A Navas-Cortes, Stephen Parnell, Roel Potting, Philippe Lucien Reignault, Hans-Hermann Thulke, Wopke van der Werf, Antonio Vicent Civera, Jonathan Yuen, Lucia Zappalà, Thierry Candresse, Christophe Lacomme, Bernard Bottex, Carla Oplaat, Annelien Roenhorst, Martijn Schenk and Francesco Di Serio

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 Y (PVY). The information currently available on geographical distribution, biology, epidemiology, potential entry pathways and potential additional impact of non-EU isolates of PVY, has been evaluated with regard to the criteria to qualify as a potential Union quarantine pest. Because non-EU isolates of PVY 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. Populations of PVY can be subdivided into several strains and groups of isolates: strain C (PVY-C), strain N (PVY-N), strain O (PVY-O) and a wide range of recombinant isolates (PVY-recombinants) which have a worldwide distribution (including the EU). Two groups of isolates, i.e. the Brazilian (PVY-Br) and Chilean (PVY-Ch) isolates, are considered absent from the EU. Non-EU isolates of PVY-C, PVY-N, PVY-O and PVY-recombinants identified so far are not expected to have an additional impact in the EU compared to the PVY isolates already present and, therefore, do not meet the corresponding criterion to qualify as a potential Union quarantine pest. The Panel is unable to conclude on the potential additional impact of isolates of PVY-Br and PVY-Ch in the EU territory, but these isolates meet all the other criteria to qualify as potential Union quarantine pests.

Keywords: European Union, Non-EU isolate, pest risk, plant health, plant pest, PVY, quarantine

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Correspondence: alpha@efsa.europa.eu

Panel members: Claude Bragard, Katharina Dehnen-Schmutz, Francesco Di Serio, Paolo Gonthier, Marie-Agnès Jacques, Josep Anton Jaques Miret, Annemarie Fejer Justesen, Alan MacLeod, Christer Sven Magnusson, Panagiotis Milonas, Juan A Navas-Cortes, Stephen Parnell, Roel Potting, Philippe L Reignault, Hans-Hermann Thulke, Wopke Van der Werf, Antonio Vicent Civera, Jonathan Yuen and Lucia Zappalà.

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1. Introduction

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

1.1.1. Background

Council Directive 2000/29/EC[1] on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community establishes the present European Union plant health regime. The Directive lays down the phytosanitary provisions and the control checks to be carried out at the place of origin on plants and plant products destined for the Union or to be moved within the Union. In the Directive's 2000/29/EC annexes, the list of harmful organisms (pests) whose introduction into or spread within the Union is prohibited, is detailed together with specific requirements for import or internal movement.

Following the evaluation of the plant health regime, the new basic plant health law, Regulation (EU) 2016/2031[2] on protective measures against pests of plants, was adopted on 26 October 2016 and will apply from 14 December 2019 onwards, repealing Directive 2000/29/EC. In line with the principles of the above mentioned legislation and the follow-up work of the secondary legislation for the listing of EU regulated pests, EFSA is requested to provide pest categorisations of the harmful organisms included in the annexes of Directive 2000/29/EC, in the cases where recent pest risk assessment/pest categorisation is not available.

1.1.2. Terms of Reference

EFSA is requested, pursuant to Article 22(5.b) and Article 29(1) of Regulation (EC) No 178/2002,[3] to provide scientific opinion in the field of plant health.

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

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

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

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

[1] Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community. OJ L 169/1, 10.7.2000, p. 1–112.

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

[3] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31/1, 1.2.2002, p. 1–24.

1.1.2.1. Terms of Reference: Appendix 1

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

Annex IIAI

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

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) Fung

Ceratocystis fagacearum (Bretz) Hunt
Chrysomyxa arctostaphyli Diete
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 Y (PVY) (including Yo, Yn and Yc). Non-EU isolates of PVY 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 PVY 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.

The new Plant Health Regulation (EU) 2016/2031[4], 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.

[4] 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.

2. Data and methodologies

2.1. Data

2.1.1. Literature search

A literature search on PVY was conducted in the ISI Web of Science bibliographic database. The scientific name of the pest was used as search term. The search was restricted to the period 2013–2019. Relevant papers were reviewed with a focus on potential differences between isolates of the pest, hosts and geographical distribution. 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; as a consequence, 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 PVY. 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 PVY, 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 PVY will be provided at species level. Further information will be added at the level of strains 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 PVY. For each conclusion, the Panel provides a short description of its associated uncertainty.

Table 1 presents the Regulation (EU) 2016/2031 pest categorisation criteria on which the Panel bases its conclusions. All relevant criteria have to be met for the pest to potentially qualify as a quarantine pest. If one of the criteria is not met, the pest will not qualify.

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

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?
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?

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
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.

The notation of PVY strains with the virus acronym throughout literature is not consistent in using superscript. For clearness, strain acronyms will not be written in superscript throughout this opinion.

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. PVY 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 Y is a well-characterised virus in the genus *Potyvirus*, family Potyviridae (Adams et al., 2011). PVY has a single-stranded positive-sense RNA genome. Complete and/or partial genomic sequences are available for a wide range of isolates.

3.1.2. Biology of the pest

PVY has been reported to be transmitted by seeds in the past (Mayee, 1974; Eskarous et al., 1983; Mink, 1993; Sastry, 2013). However, since seed transmission is not reported in later reports (CABI cpc, 2019), the Panel considered PVY not seed-transmissible, with uncertainties. PVY is transmitted by vegetative propagation (via tubers) and can be transmitted mechanically, e.g. by contaminated tools and wounds (Fageria et al., 2014; Dupuis, 2017).

PVY-C, PVY-N, PVY-O and PVY-recombinants are reported to be non-persistently transmitted by many different aphid species (Hemiptera: Aphididae) (Blanco-Urgoiti et al., 1998; Lacomme et al., 2017b). Aphid transmission is not reported for PVY-Br and PVY-Ch isolates, but is likely since other PVY isolates are transmitted by aphids. Multiple studies have reported differences in transmission efficiency of PVY isolates between different aphid populations and species (Radcliffe and Ragsdale, 2002; Verbeek et al., 2010; Karasev and Gray, 2013a). Karasev and Gray (2013a) suggested that the relative importance of any aphid species in spreading PVY also depends on the environmental conditions.

Nevertheless, there are indications that recombinant isolates are more efficiently transmitted than non-recombinant PVY isolates (Verbeek et al., 2010; Srinivasan et al., 2012).

3.1.3. Intraspecific diversity

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

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

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

ICTV does not address taxonomic levels below the species level and, therefore, the names of strains are based on reports in literature. In literature, 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. Additionally, in PVY literature, often the term 'strain group' has been used as a synonym for 'strain'.

Studies showing an unambiguous relationship between specific virus genotypes (isolates/strains) and biological properties are limited. Moreover, the interpretation of such data may be hampered because discrimination between strains on the basis of biological data is not always supported by genomic data. Historically, strains have been distinguished for many viruses, including PVY, 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 combination of molecular, phylogenetic, serological, biological data and different combinations thereof used to assign isolates to strains are not uniform in the literature. This adds uncertainties to the interpretation of (older) data on strain differentiation and/or their geographical distribution.

For PVY, several strains and other isolates have been distinguished over the years (Singh et al., 2008; Karasev and Gray, 2013a; Glais et al., 2017a; Green et al., 2017). Originally, PVY isolates were subdivided in three strains based on their ability to overcome potato-resistance genes and on their symptomatology in tobacco plants, i.e. strain C (PVY-C, also called the stipple streak strain), strain N (PVY-N, also called the tobacco veinal necrosis or necrotic strain), and strain O (PVY-O, also called the ordinary or the common strain) (Bellstedt et al., 2017; Glais et al., 2017a; CABI cpc, 2019). The discrimination of these three strains was confirmed by phylogenetic analyses using genomic data (Moury, 2010; Karasev and Gray, 2013a).

PVY-C, PVY-N and PVY-O have been identified as parental, non-recombinant strains. Recombination between these strains has generated a wide range of recombinant isolates and lineages (Visser et al., 2012; Green et al., 2018). In some cases, these recombinant isolates or lineages can be recognised as a strain, depending on the extent to which they are characterised biologically, serologically, and molecularly (genome-sequence analysis and recombination patterns). Some groups of recombinants have been reported as common, for example PVY-NTN and PVY-N-Wi (Bellstedt et al., 2017; Green et al., 2018), whereas others have been reported as rare, such as PVY-E and PVY-Z (Kerlan et al., 2011; Green et al., 2018). Furthermore, there is evidence for the existence of recombinants for which the (non-recombinant) parental isolate(s) is (are) not yet identified, such as the so-called 'North American' isolate PVY-NE11 (Lorenzen et al., 2008; Green et al., 2018).

In the present opinion, the Panel decided to categorise all recombinant isolates collectively as PVY-recombinants because: (i) there is limited evidence that recombinants possess novel biological properties compared to their parental PVY-C, PVY-N and PVY-O strains, (ii) impact (symptoms) in potato plants has been shown to depend more on the cultivar and growing conditions than on the infecting virus population (Hamm et al., 2009; Funke et al., 2017), and (iii) new recombinant isolates

emerge continuously and the frequency of recombination events is likely to be similar within and outside the EU and, as a consequence, it is impossible to predict whether and where recombinants will arise and what their impact might be.

It should be noted that the strains and groups of isolates categorised here show genetic variability, and therefore not all isolates of a particular strain or group of isolates may share identical biological properties. For example, strain C is divided into the C1 and C2 lineages (Blanco-Urgoiti et al., 1998; Moury, 2010), which have different host preferences (Quenouille et al., 2013).

In this opinion, the three parental strains, the group of recombinant isolates, the Brazilian and Chilean groups of isolates will be categorised (see Table 2). The Panel refers to available reviews for an overview of PVY strains and of PVY overall diversity (Karasev and Gray, 2013a,b; Bellstedt et al., 2017; Glais et al., 2017a; Green et al., 2017, 2018). However, it cannot be excluded that additional divergent PVY isolates exist, particularly in South America (Bellstedt et al., 2017).

Table 2: Overview of categorised strains and groups of isolates

PVY	Acronym	Other information	Key references
Parental strain			
C: stipple streak	PVY-C	Including lineages; PVY-C1 and PVY-C2	Blanco-Urgoiti et al. (1998), Singh et al. (2008), Kehoe and Jones (2011)
N: veinal necrosis	PVY-N	Including lineage PVY-EU-N and isolate PVY-N605	Glais et al. (2004), Singh et al. (2008), Glais et al. (2017a), Green et al. (2018)
O: ordinary	PVY-O	Including lineages; PVY-O5, PVY-O-J1 and PVY-O-J2	Singh et al. (2008), Karasev et al. (2011), Ogawa et al. (2012)
Group of isolates			
Recombinant strains, lineages and isolates	PVY-recombinants	Recombinant isolates of PVY-C, PVY-N, and/or PVY-O; including strains, lineages and isolates: PVY-E, PVY-NTN, PVY-N-Wi, PVY-Z, PVY-N:O, PVY-NA-N, PVY-NE11, PVY-SYR-I-II-III, PVY-261-4 and so-called 'rare-unclassified isolates'	Singh et al. (2008), Galvino-Costa et al. (2012), Karasev and Gray (2013a), Glais et al. (2017a), Green et al. (2018)
Brazilian	PVY-Br	–	Janzac et al. (2015), Bellstedt et al. (2017)
Chilean	PVY-Ch	–	Moury (2010), Bellstedt et al. (2017)

PVY: potato virus Y.

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 PVY at the species and strain level, and therefore for the identification of non-EU isolates. Identification of PVY-Ch and PVY-Br would require partial genomic sequencing.

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

Different techniques have been used for the detection and identification of PVY at the species and strains level, as reviewed by Glais et al. (2017b). To distinguish the major PVY strains, biological characterisation using indicator plants, and serological methods (essentially enzyme-linked immunosorbent assay (ELISA)) using both poly- and monoclonal antibodies were initially developed. In addition, polymerase chain reaction (PCR)-based tests (Lorenzen et al., 2006) have been described to identify PVY strains and/or lineages. However, since these tests were developed using a limited number of isolates, (re)validation and/or adaptation might be required.

Genomic data are available for PVY-Br and PVY-Ch (Moury, 2010; Janzac et al., 2015) but no specific tests for detection and identification, other than sequencing, have been developed yet.

3.2. Pest distribution

3.2.1. Pest distribution outside the EU

PVY occurs worldwide wherever potato is grown (Bellstedt et al., 2017; CABI cpc, 2019). Isolates of the PVY-C strain are reported in Asia and Oceania (Bellstedt et al., 2017). Isolates of the PVY-N and PVY-O strain are reported in Africa, Asia and South America (Bellstedt et al., 2017). In addition, PVY-O isolates are reported in North America (Bellstedt et al., 2017). Specific lineages of PVY-O have been reported from a more narrow geographical region, e.g. lineage PVY-O5 has only been reported from Canada and the USA (Ellis et al., 1997; Gray et al., 2010; Karasev and Gray, 2013b) and PVY-O-J1 and PVY-O-J2 have only been reported from Japan (Ogawa et al., 2012). The geographical distribution at strain level, however, is associated with uncertainties because in many reports the strain(s) involved has (have) not been identified.

PVY-recombinants have been reported worldwide, some with a more restricted distribution than others. For example PVY-E has only been reported from South America (Bellstedt et al., 2017) and PVY-Z from North America and Oceania (Kerlan et al., 2011; Bellstedt et al., 2017).

PVY-Br has been reported from Brazil (Janzac et al., 2015) and PVY-Ch from Chile (Moury, 2010).

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. Isolates of PVY-C, PVY-N, PVY-O and PVY-recombinants are present in the EU.

No. Isolates of PVY-Br and PVY-Ch are not reported to be present in the EU. Some specific recombinants may also be absent from the EU.

Isolates of PVY-C, PVY-N, PVY-O and PVY-recombinants are present in the EU (Bellstedt et al., 2017). The geographical distribution of PVY at the level of strains and/or groups of isolates is associated with uncertainties because systematic surveys at strain level are lacking.

3.3. Regulatory status

3.3.1. Council Directive 2000/29/EC

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

Table 3: Non-EU isolates of PVY 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. PVY 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 (Brittany), 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 (Brittany), FI, IRL, P (Azores), UK (Northern Ireland)

Annex V	**Plants, plant products and other objects which must be subject to a plant health inspection (at the place of production if originating in the Community, before being moved within the Community—in the country of origin or the consignor country, if originating outside the Community) before being permitted to enter the Community**
Part A	**Plants, plant products and other objects originating in the Community**
Section I	**Plants, plant products and other objects which are potential carriers of harmful organisms of relevance for the entire Community and which must be accompanied by a plant passport**
1.3.	Plants of stolon- or tuber-forming species of *Solanum* L. or their hybrids, intended for planting
Section II	**Plants, plant products and other objects which are potential carriers of harmful organisms of relevance for certain protected zones and which must be accompanied by a plant passport valid for the appropriate zone when introduced into or moved within that zone** Without prejudice to the plants, plant products and other objects listed in Part I.
1.5.	Tubers of *Solanum tuberosum* L., intended for planting.
Part B	**Plants, plant products and other objects originating in territories, other than those territories referred to in Part A**
Section I	**Plants, plant products and other objects which are potential carriers of harmful organisms of relevance for the entire Community**
4.	Tubers of *Solanum tuberosum* L.

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

Non-EU isolates of PVY are reported to be transmitted by aphid vectors (see Section 3.1.2), which are not subject to specific regulation.

3.4. Entry, establishment and spread in the EU

3.4.1. Host range

The following species have been reported as natural hosts of PVY without information on the strain (s) involved (regulations apply as listed in Table 5): *Abelmoschus esculentus, Amaranthus retroflexus, Capsella bursa-pastoris, Chrysanthemum morifolium, Cotula australis, Erodium cicutarium, Euphorbia hirta, Hibiscus trionum, Lactuca serriola, Lamium purpureum, Moringa oleifera, Nicotiana mutabilis, Petunia hybrida* (Boonham et al., 1999), *Physalis, Senecio vulgaris, Solanum betaceum, S. elaeagnifolium, S. nigrum* (CABI cpc).

Table 5 provides information on reports of natural hosts (including potato) of PVY including the associated uncertainties and regulation.

Table 5: Natural hosts of PVY. Data regarding natural hosts was retrieved from the CABI cpc and literature up to August 22, 2019

PVY	Hosts[1]	Rationale and/or uncertainty	Regulation
Parental strain			
PVY-C	*Capsicum* spp. (Quenouille et al., 2013), *Nicotiana tabacum* (Blanco-Urgoiti et al., 1998), *Solanum lycopersicum* (Quenouille et al., 2013), *S. melongena* (Sadeghi et al., 2008), *S. tuberosum* (Dullemans et al., 2011)	Additional natural hosts may exist	***Capsicum* sp.:** IVAI 16.6, 25.7, 36.3, IVAII 18.6.1, 18.7; VBI 1,3. ***Dendranthema*:** IVAI 27.1, 27.2, 28, 28.1, 32.2; IVAII 20, 21.1; VAI 2.1; VBI 2. ***Hibiscus* sp.:** IVAI 45.1; IVB 24.3; VAII 2.1. ***Lactuca* sp.:** VAI 2.1 ***Nicotiana* sp.:** IVAI 25.7; IVAII 18.7. ***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
PVY-N	*Capsicum* spp. (Margaritopoulos et al., 2010), *Nicotiana tabacum* (Quenouille et al., 2013), *Solanum lycopersicum* (Aramburu et al., 2006), *S. tuberosum* (Dullemans et al., 2011)	Additional natural hosts may exist	
PVY-O	*Capsicum annuum* (Ibaba and Gubba, 2011), *Nicotiana tabacum* (Quenouille et al., 2013), *Solanum lycopersicum* (Ibaba and Gubba, 2011), *S. melongena* (Bhat et al., 1999), *S. tuberosum* (Dullemans et al., 2011)	Additional natural hosts may exist	
Group of isolates			
PVY-recombinants	*Nicotiana tabacum* (Tian et al., 2011), *Solanum lycopersicum* (Aramburu et al., 2006), *S. tuberosum* (Kerlan et al., 2011)	Additional natural hosts may exist	
PVY-Br	*Nicotiana tabacum* (Janzac et al., 2015)	Limited information. Not known whether *S. tuberosum* is a natural host. Additional natural hosts may exist	
PVY-Ch	*Capsicum baccatum* (Moury, 2010), *Nicotiana tabacum* (Bellstedt et al., 2017)	*S. tuberosum* could not be infected by PVY-Ch upon mechanical experimental inoculation (Moury, 2010) Additional natural hosts may exist	

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

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

PVY is transmitted by vegetative propagation and therefore seed potatoes and more generally, plants for planting, are considered the most important pathway for entry. The potential pathway for entry of non-EU isolates via seed potatoes of *Solanum tuberosum* and plants for planting of other tuber-forming *Solanum* species and their hybrids is prohibited 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). PVY-O and PVY-recombinants have been reported from Canada. PVY-O, PVY-N and PVY-recombinants have been reported from Switzerland. PVY-C has not been reported from Canada and Switzerland and therefore, the pathway of potato plants for planting is considered partially regulated for PVY-O, PVY-N and PVY-recombinants and closed for PVY-C. Isolates of PVY-Br and PVY-Ch are not reported to naturally infect potato and therefore potato plants for planting is not considered a pathway for PVY-Br and PVY-Ch, with uncertainties. Should these isolates infect potato, the pathway would be closed by legislation given their geographical distribution.

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). PVY is considered to be present in these specified countries given its worldwide distribution. By definition, the PVY isolates present in these countries are non-EU isolates. They could enter the EU via the ware potato pathway given that 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 come 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 risk of the non-EU isolates of PVY 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: 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 various strains and groups of isolates separately, PVY-N, PVY-O and PVY-recombinants are known to be present in the countries for which derogations apply. Therefore, the ware potato pathway is considered partially regulated for non-EU isolates of PVY-N, PVY-O and PVY-recombinants. PVY-C is not known to be present in the countries subject to import derogations, therefore the ware potatoes pathway is considered closed for PVY-C. PVY-Br and PVY-Ch are not reported to naturally infect potato therefore, ware potatoes are not considered a pathway for PVY-Br and PVY-Ch, with uncertainties. Should these isolates infect potato, the pathway would be closed by legislation given their geographical distribution.

PVY has a number of natural hosts other than potato (see Section 3.4.1). The non-*Solanum* hosts (Abelmoschus esculentus, Amaranthus retroflexus, Capsella bursa-pastoris, Cotula australis, Erodium cicutarium, Euphorbia hirta, Lamium purpureum, Moringa oleifera, Senecio vulgaris) are not regulated. There is no indication that these non-*Solanum* species are hosts of specific PVY strains/group of isolates and it is unclear whether there is a trade of plants for planting of these species. If so, these alternative hosts could provide an additional but probably minor pathway. This pathway is therefore considered partially regulated for non-EU isolates of all PVY strains/groups of isolates considered here. This assessment is affected by uncertainties on trade and host range.

Viruliferous aphid vectors are a pathway of entry for non-EU isolates of PVY (see Section 3.1.2). Since the relevant aphid species are not subject to specific regulation, this pathway is open for non-EU

isolates of PVY-C, PVY-N, PVY-O and PVY-recombinants and possibly open for non-EU isolates of PVY-Br and PVY-Ch for which aphid transmission is considered likely but not demonstrated. PVY is transmitted by aphids in a non-persistent way, which implies that viruliferous aphids will lose the ability to transmit the virus within a short period. Therefore, this pathway is considered as minor and is not listed in Table 6.

Import of fruits can be an additional pathway for entry of non-EU isolates of PVY, however, the lack of seed transmission (see Section 3.1.2) reduces the relevance of this potential pathway. Aphid vectors can probe the infected fruits and acquire the virus for later transmission, as shown for other potyviruses such as papaya ringspot virus and zucchini yellow mosaic virus from melons, and plum pox virus from peaches (Lecoq et al., 2003; Gildow et al., 2004). Fruits of *Capsicum annuum* and *Solanum lycopersicum,* both hosts of PVY, can be imported from South America, where PVY-Br and PVY-Ch isolates have been reported. Overall, this pathway is considered to be open for non-EU isolates of PVY-C, PVY-N, PVY-O and PVY-recombinants, and possibly open for non-EU isolates of PVY-Br and PVY-Ch for which aphid transmission is considered likely but not demonstrated. Given the relatively unlikely set of events involved (aphids feeding on imported fruits then moving to susceptible plants) and the absence of seed transmission, this pathway is considered as minor and not listed in Table 6.

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

PVY	Potato plants for planting[(1)]	Ware potatoes[(1)]	Plants for planting of other hosts[(1),(2)]	Uncertainties
Parental strain				
PVY-C	Pathway closed: plants for planting of potato are banned from countries where PVY-C is reported	Pathway closed: PVY-C is not reported to be present in the countries subject to import derogations	Pathway partially regulated: no import ban for some hosts	Existence of other natural hosts Relevance of vectors Geographical distribution
PVY-N	Pathway partially regulated: plants for planting of potato can be imported from Canada and Switzerland	Pathway partially regulated: ware potatoes can be imported from non-EU European countries where PVY-N is reported	Pathway partially regulated: no import ban for some hosts	Existence of other natural hosts Relevance of vectors
PVY-O	Pathway partially regulated: plants for planting of potato can be imported from Canada and Switzerland	Pathway partially regulated: ware potatoes can be imported from non-EU European countries where PVY-O is reported	Pathway partially regulated: no import ban for some hosts	Existence of other natural hosts Relevance of vectors
Group of isolates				
PVY-recombinants	Pathway partially regulated: plants for planting of potato can be imported from Canada and Switzerland	Pathway partially regulated: ware potatoes can be imported from non-EU European countries where PVY-recombinants are reported	Pathway partially regulated: no import ban for some hosts	Existence of other natural hosts Relevance of vectors
PVY-Br	Not a pathway: potato is not reported as a natural host. Should potato be a host, the pathway would be closed by legislation given the geographical distribution of these isolates	Not a pathway: potato is not reported as a natural host Should potato be a host, the pathway would be closed by legislation given the geographical distribution of these isolates	Pathway partially regulated: no import ban for some hosts	Existence of the potato plants for planting and ware potatoes pathways Existence of other natural hosts Existence and relevance of vectors
PVY-Ch	Not a pathway: potato is not reported as a natural host. Should potato be a host, the pathway would be closed by legislation given the geographical distribution of these isolates	Not a pathway: potato is not reported as a natural host. Should potato be a host, the pathway would be closed by legislation given the geographical distribution of these isolates	Pathway partially regulated: no import ban for some hosts	Existence of the potato plants for planting and ware potatoes pathways Existence of other natural hosts Existence and relevance of vectors

(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 Member States but not for all). '**Not a pathway**': no evidence supporting the existence of the pathway.

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

Table 7 reports on the interceptions of PVY by EU MSs and covers all interceptions between 1995 and October 10, 2019 that were entered in the Europhyt database. These PVY interceptions are reported without further specification of the strain involved. Two interceptions concerned potato, both illegal imports of ware potatoes from Peru (ID 109175) and Russia (ID 107351) in 2017. The remaining interceptions concerned recent imports of *Capsicum* spp. from India, Rwanda, Senegal and Uganda.

Table 7: Interceptions by EU Member States of the categorised non-EU isolates of PVY. Data was retrieved from the Europhyt database on 10 October 2019

Potato virus Y	Europhyt interception ID	Year of interception	Origin	Plant species on which it has been intercepted
PVY	107351	2017	Russia	*Solanum tuberosum*(1)
PVY	109175	2017	Peru	*Solanum tuberosum*(1)
PVY	127666	2019	Senegal	*Capsicum* sp.
PVY	127728	2019	Senegal	*Capsicum frutescens*
PVY	128297	2019	Senegal	*Capsicum annuum*
PVY	128298	2019	Senegal	*Capsicum annuum*
PVY	128516	2019	India	*Capsicum*
PVY	128655	2019	Uganda	*Capsicum annuum*
PVY	128766	2019	Uganda	*Capsicum annuum*
PVY	128881	2019	Rwanda	*Capsicum chinense*
PVY	128885	2019	Rwanda	*Capsicum chinense*
PVY	128889	2019	Rwanda	*Capsicum chinense*
PVY	128892	2019	Rwanda	*Capsicum chinense*
PVY	129120	2019	Uganda	*Capsicum*
PVY	129361	2019	Uganda	*Capsicum chinense*
PVY	129490	2019	Uganda	*Capsicum*

PVY: potato virus Y.
(1): Illegal import.

3.4.3. Establishment

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

Yes. Non-EU isolates of PVY 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 PVY 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 PVY can spread via plants for planting and by mechanical transmission. Transmission by aphid vectors also occurs, with the possible exception of PVY-Br and PVY-Ch, for which it has not been demonstrated.

Most non-EU isolates of PVY can be transmitted by aphids (see Section 3.1.2), including *Myzus persicae* (Sulzer), which is widespread in and outside the EU (see Figure 1). For PVY-Br and PVY-Ch aphid transmission has not been demonstrated but is nevertheless considered a possibility.

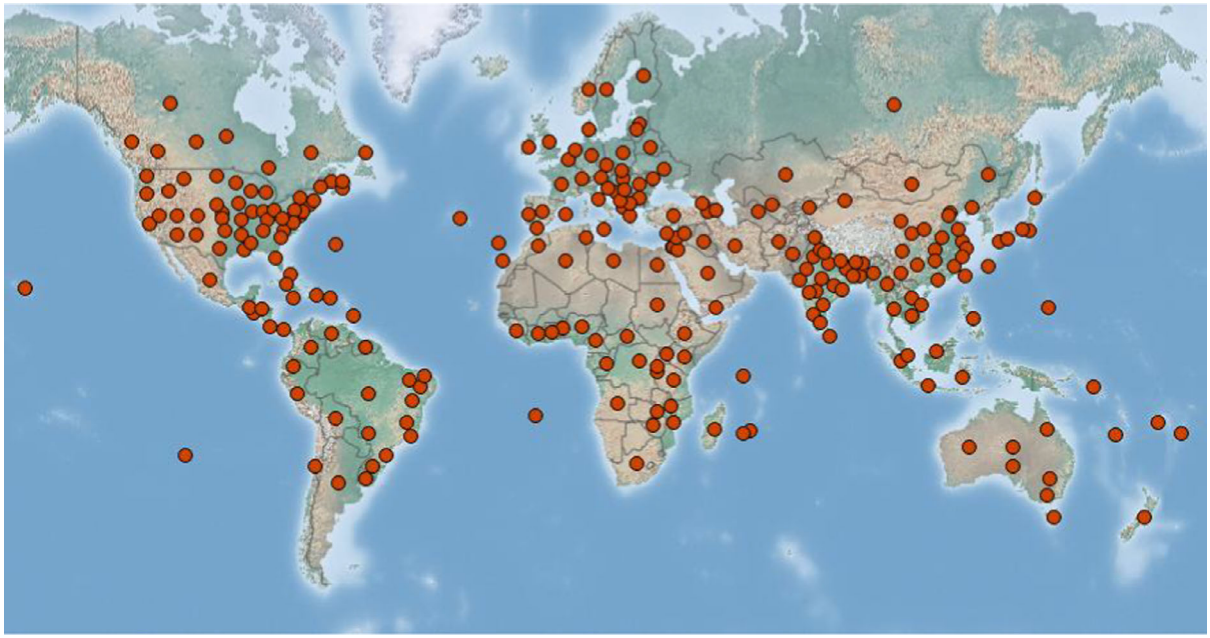

Figure 1: Global distribution map of *Myzus persicae* (Sulzer). Extracted from CABI cpc on 8 August 2019

3.5. Impacts

Sources: impact reports and other literature

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

No. Non-EU isolates of PVY-C, PVY-N, PVY-O and PVY-recombinants are not known to differ from isolates already present in the EU and therefore no additional impact is expected on the EU territory.

Unable to conclude. The lack of information on possible differences in biological properties (host range, vector transmission, pathogenicity) does not allow the Panel to reach a conclusion on a potential additional impact of isolates of PVY-Br and PVY-Ch on the EU territory.

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.

PVY is considered to be one of the ten most important plant viruses (Scholthof et al., 2011) and is a threat for various crops, i.e. eggplant, pepper, potato, tobacco and tomato (Blanchard et al., 2008;

Lacomme et al., 2017a; Moury et al., 2017). Some PVY isolates are reported to cause potato ringspot necrotic disease, resulting in unmarketable potatoes. A study testing infected seed potatoes from more than 30 potato cultivars grown in pots demonstrated yield reductions between 50 and 85% compared to uninfected seed tubers (Valkonen, 2007). In addition, field studies have reported yield losses in potato (reviewed by Valkonen, 2007; Lacomme et al., 2017a). PVY is considered to have an impact at the species level and various control measures have already been implemented (e.g. certification schemes for plants for planting) to mitigate the impact.

PVY-C, PVY-N, PVY-O and PVY-recombinants occur in the EU and there is no evidence for differences in molecular or biological properties between EU and non-EU isolates. Uncertainties exist, because new recombinant isolates emerge continuously and the frequency of recombination events is likely to be similar within and outside the EU, and as a consequence it is impossible to predict whether and where recombinants will arise and what their impact might be. Therefore, based on current knowledge, non-EU isolates of PVY-C, PVY-N, PVY-O and PVY-recombinants are not expected to have an additional impact over the current situation, with uncertainties.

In the absence of information on the biology and, in particular, about biological differences in comparison with the isolates of PVY already present in the EU, the Panel is unable to conclude on whether PVY-Br and PVY-Ch isolates would have additional impact over the present situation, should they be introduced in the EU.

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 PVY.

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 PVY-Br and PVY-Ch isolates are present;
- Extension of certification schemes or testing requirements to non-solanaceous natural hosts;
- Extension of plant passport requirements to specifically include hosts other than stolon- and tuber-forming *Solanum* species.

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

3.6.1.1. Additional control measures

Table 8 reports on the potential additional control measures to reduce the likelihood of entry, establishment and/or spread of the categorised non-EU isolates of PVY. The additional control measures are selected from a longer list reported in EFSA PLH Panel (2018). Control measures are measures that have a direct effect on pest abundance.

Table 8: Selected additional control measures to consider to reduce the likelihood of pest entry, establishment and/or spread of non-EU isolates of PVY

Information sheet (with hyperlink to information sheet if available)	Control measure summary	Risk component	Rationale
Growing plants in isolation	Description of possible exclusion conditions that could be implemented to isolate the crop from pests and if applicable relevant vectors. E.g. a dedicated structure such as glass or plastic greenhouses	Spread	Growing plants in insect proof greenhouses may prevent infestation by viruliferous aphid vectors. This measure would not be applicable for potato, with the exception of early stages of seed potato production Production of seed potatoes in areas with low aphid pressure (e.g. high altitude) would minimise the risk of infestation
Chemical treatments on consignments or during processing	Use of chemical compounds that may be applied to plants or to plant products after harvest, during process or packaging operations and storage The treatments addressed in this information sheet are: a) fumigation; b) spraying/dipping pesticides; c) surface disinfectants; d) process additives; e) protective compounds	Entry	a), b) and c) could remove viruliferous aphid vectors PVY is transmitted by aphids in a non-persistent way, which implies that viruliferous aphids will lose the ability to transmit the virus within a short period Therefore, the additional effect on preventing entry is minimal
Cleaning and disinfection of facilities, tools and machinery	The physical and chemical cleaning and disinfection of facilities, tools, machinery, transport means, facilities and other accessories (e.g. boxes, pots, pallets, palox, supports, hand tools). The measures addressed in this information sheet are: washing, sweeping and fumigation	Spread	Cleaning tools may limit the spread via mechanical transmission
Roguing and pruning	Roguing 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	Roguing of infested plants is efficient, in particular to prevent spread of PVY 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
Timing of planting and harvesting	The objective is to produce phenological asynchrony in pest/crop interactions by acting on or benefiting from specific cropping factors such as: cultivars, climatic conditions, timing of the sowing or planting, and level of maturity/age of the plant seasonal timing of planting and harvesting	Spread and impact	Relevant to prevent transmission by aphid vectors

Information sheet (with hyperlink to information sheet if available)	Control measure summary	Risk component	Rationale
Chemical treatments on crops including reproductive material	Chemical treatments on crops may prevent infestations by vectors and seed transmission	Spread and impact	Desiccation/removal of the foliage reduces the risk of transmission via aphid vectors and may prevent transport to the tubers of infected plants
Post-entry quarantine and other restrictions of movement in the importing country	This information sheet covers post-entry quarantine of relevant commodities; temporal, spatial and end-use restrictions in the importing country for import of relevant commodities; Prohibition of import of relevant commodities into the domestic country Relevant commodities are plants, plant parts and other materials that may carry pests, either as infection, infestation, or contamination	Entry and spread	Identifying virus–infected plants and banning their movement limit the risks of entry and spread in the EU

3.6.1.2. Additional supporting measures

Table 9 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 9: Selected supporting measures in relation to currently unregulated hosts and pathways. Supporting measures are organisational measures or procedures supporting the choice of appropriate risk reduction options that do not directly affect pest abundance

Information sheet title (with hyperlink to information sheet if available)	Supporting measure summary	Risk component	Comments
Inspection and trapping	Inspection is defined as the official visual examination of plants, plant products or other regulated articles to determine if pests are present or to determine compliance with phytosanitary regulations (ISPM 5) The effectiveness of sampling and subsequent inspection to detect pests may be enhanced by including trapping and luring techniques	Entry and spread	Visual inspection may detect potentially infected material Only applicable when visible symptoms on leaves and/or propagating tissues occur, which is dependent on the isolate, host/cultivar, and environmental conditions
Laboratory 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 PVY on sampled material

Information sheet title (with hyperlink to information sheet if available)	Supporting measure summary	Risk component	Comments
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 the harmful viruses imported for research and/or breeding purposes
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 PVY after entry in the EU
Sampling	According to ISPM 31, it is usually not feasible to inspect entire consignments, so phytosanitary inspection is performed mainly on samples obtained from a consignment. It is noted that the sampling concepts presented in this standard may also apply to other phytosanitary procedures, notably selection of units for testing	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 PVY, 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 PVY in some hosts
- Uneven virus distribution or low concentrations limiting the reliability of the detection
- Absence of a validated diagnostic protocol allowing the typing of some PVY groups of isolates.

3.7. Uncertainty

The Panel identified the following knowledge gaps and uncertainties:

Identity and biology

- Lack of biological data, i.e. host range and aphid transmission, for some PVY-recombinants, PVY-Br and PVY-Ch isolates;
- Uncertainty on the existence of other non-EU isolates of PVY that have not been identified yet and might have an additional impact on the EU territory;
- Lack of information on whether identified biological differences are general features of PVY strains/groups of isolates or apply only to a fraction of the isolates in a given strain/group.

Pest distribution

- Uncertainty on the geographical distribution and prevalence of the categorised strains/groups of isolates of PVY because of the absence of systematic surveys.

Regulatory status

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

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

- Uncertainty on the host range of the categorised strains/groups of isolates of PVY;
- Uncertainty on the ability and efficiency of aphid vectors to transmit non-EU isolates of PVY.

Impact

- Uncertainty on the magnitude of the impact of non-EU isolates of PVY 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 strains/groups of isolates of PVY 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 10.

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

Isolates of PVY-Br and PVY-Ch meet all criteria to qualify as a potential Union quarantine pest, except the criterion regarding the potential consequences in the EU territory for which the Panel is unable to conclude (see Section 3.5).

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

Table 10: 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 PVY

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 PVY is well established Methods are available for detection and identification of PVY at species and strain level, but not for the identification of PVY-Br, PVY-Ch or specific recombinants. However, genomic data are available for the design of diagnostic tests	Uncharacterised PVY isolates may exist and/or emerge
Absence/presence of the pest in the EU territory (Section 3.2)	Isolates of PVY-C, PVY-N, PVY-O and PVY-recombinants occur worldwide and are present in the EU PVY-Br and PVY-Ch isolates are not known to be present in the EU	Unreported presence of PVY-Br and PVY-Ch isolates in the EU
Regulatory status (Section 3.3)	Non-EU isolates of PVY 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 PVY are able to enter into the EU The pathway of plants for planting of potato is partially regulated for non-EU isolates of PVY-N, PVY-O and PVY-recombinants (plants for planting of potato can be imported from countries in which these strains are present) and closed for PVY-C. Potato plants for planting is not a pathway for PVY-Br and PVY-Ch, since potato has not been reported to be a natural host for these two groups of isolates For ware potatoes the pathways are partially regulated for PVY-N, PVY-O and PVY-recombinants (ware potatoes can be imported from countries in which these strains are present) and closed for PVY-C. Ware potatoes is not a pathway for PVY-Br and PVY-Ch, since potato has not been reported to be a natural host For plants for planting of other hosts, the pathways are partially regulated for all non-EU isolates of PVY The minor pathways of viruliferous aphids and of fruits of host species is open for non-EU isolates of PVY-C, PVY-N, PVY-O and PVY-recombinants and possibly open for PVY-Br and PVY-Ch If non-EU isolates of PVY were to enter the EU territory, they could become established and spread	– Geographical distribution – Existence of other natural hosts – Existence and relevance of vectors – Potato as a natural host for PVY-Br and PVY-Ch. – Existence and relevance of trade of plants for planting of non-*Solanum* hosts
Potential for consequences in the EU territory (Section 3.5)	There are no indications that non-EU isolates of PVY-C, PVY-N, PVY-O and PVY-recombinants differ biologically from PVY isolates already present in the EU, therefore, they are not expected to have an additional impact. For isolates of PVY-Br and PVY-Ch, the Panel was unable to conclude on potential additional consequences in the EU territory due to limited information	Uncertainty on the magnitude of impact of non-EU isolates
Available measures (Section 3.6)	Phytosanitary measures are available to reduce the likelihood of entry and spread of non-EU isolates of PVY 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 of PVY-C, PVY-N, PVY-O and PVY-recombinants do not meet one of the criteria evaluated by EFSA to be regarded as a potential Union quarantine pest, since they are not expected to have an additional impact in the EU.With the exception of the criterion regarding the potential consequences in the EU territory for which the Panel is unable to conclude (see Section 3.5), isolates of PVY-Br and PVY-Ch meet all the other criteria evaluated by EFSA to qualify as a potential Union quarantine pest	
Aspects of assessment to focus on/scenarios to address in future if appropriate	The main knowledge gaps or uncertainties identified concern: – Lack of information on the biology of the categorised groups of isolates (e.g. host range, vector transmission, pathogenicity) – Volume of trade and countries of origin of plants for planting of non-potato hosts – Existence of other harmful non-EU isolates – Possible unreported presence of isolates of PVY-Br and PVY-Ch in the EU – Uncertainty on the magnitude of impact of non-EU isolates of PVY Given the absence of information on possible biological differences between isolates of PVY-Br and PVY-Ch and the isolates already present in the EU, the development of a full PRA is unlikely to allow to resolve the uncertainties attached to the present categorisation until more data become available	

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Abbreviations

CABI cpc	CABI Crop Protection Compendium
DG	SANTÉ Directorate General for Health and Food Safety
ELISA	enzyme-linked immunosorbent assay
EPPO	European and Mediterranean Plant Protection Organization
FAO	Food and Agriculture Organization
ICTV	International Committee on Taxonomy of Viruses
IPPC	International Plant Protection Convention
ISPM	International Standards for Phytosanitary Measures
MS	Member State
PCR	polymerase chain reaction
PLH	EFSA Panel on Plant Health
PVY	potato virus Y
RNQP	Regulated non-quarantine pest
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