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Pest categorisation of small-spored *Alternaria* carrying the genes for the AM- or AK-toxin biosynthesis

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Abstract

The Panel on Plant Health performed a pest categorisation of small-spored *Alternaria* carrying the genes for the AM- or AK-toxin biosynthesis, for the EU. The identity of the pests is clearly defined and reliable methods exist for their detection/identification. They are listed in Annex IIAI of Directive 2000/29/EC as *Alternaria alternata* (non-European pathogenic isolates). Their distribution in the EU is restricted though with some uncertainty. The AM-toxin producer *Alternaria* affect *Malus* spp. and *Pyrus communis* (European pear), whereas the AK-toxin producer affect *Pyrus pyrifolia, Pyrus bretschneideri* and *Pyrus ussuriensis* (Asian pears). The pests could potentially enter the EU on host-planting material and fruit originating in infested countries. There are no biotic/abiotic factors limiting their potential establishment and spread in the EU, as their epidemiology is similar to that of other well-established *Alternaria* spp. Apples and European pears are widespread in the EU; Japanese pears are also present, but no data was found on their abundance/distribution. In the infested areas, the pests cause premature defoliation, fruit spotting and rot resulting in yield/quality losses. It is expected that the introduction and spread of the pests in the EU could impact apple and pear production, although the magnitude is unknown. Cultural practices and chemical measures may reduce the inoculum and the disease, but they cannot eliminate the pests. Phytosanitary measures are available to mitigate the risk of introduction and spread of the pests. The pests do not meet all the criteria assessed by EFSA for consideration as potential Union quarantine pests, as they are not under official control in those EU restricted areas where they have been found. The pests do not meet all the criteria assessed by EFSA to consider them as Union regulated non-quarantine pests, as host plants for planting are not the main means of pest spread.

Keywords: *Alternaria alternata*, Alternaria leaf blotch, black spot of pears, impacts, *Malus* spp., pest distribution, *Pyrus* spp.

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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 categorizations of the harmful organisms included in the annexes of Directive 2000/29/EC, in the cases where recent pest risk assessment/ pest categorisation is not available.

1.1.2. Terms of Reference

EFSA is requested, pursuant to Article 22(5.b) and Article 29(1) of Regulation (EC) No 178/2002[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 the exception of the Union territories as defined in Article 1 point 3 of Regulation (EU) 2016/2031.

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

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

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

1.1.2.1. Terms of Reference: Appendix 1

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

Annex IIAI

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

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

(b) Bacteria

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

(c) Fungi

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

(d) Virus and virus-like organisms

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

Annex IIB

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

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

(b) Bacteria

Curtobacterium flaccumfaciens pv. flaccumfaciens (Hedges) Collins and Jones

(c) Fungi

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

1.1.2.2. Terms of Reference: Appendix 2

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

Annex IAI

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

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

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

Group of Tephritidae (non-EU) such as:

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

(c) Viruses and virus-like organisms

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

1) Andean potato latent virus
2) Andean potato mottle virus
3) Arracacha virus B, oca strain
4) Potato black ringspot virus
5) Potato virus T
6) non-EU isolates of potato viruses A, M, S, V, X and Y (including Yo, Yn and Yc) and Potato leafroll virus

Group of viruses and virus-like organisms of Cydonia Mill., Fragaria L., Malus Mill., Prunus L., Pyrus L., Ribes L.,Rubus L. and Vitis L., such as:

1) Blueberry leaf mottle virus
2) Cherry rasp leaf virus (American)
3) Peach mosaic virus (American)
4) Peach phony rickettsia
5) Peach rosette mosaic virus
6) Peach rosette mycoplasm
7) Peach X-disease mycoplasm
8) Peach yellows mycoplasm
9) Plum line pattern virus (American)
10) Raspberry leaf curl virus (American)
11) Strawberry witches' broom mycoplasma
12) Non-EU viruses and virus-like organisms of *Cydonia Mill., Fragaria L., Malus Mill., Prunus L., Pyrus L., Ribes L., Rubus L.* and *Vitis L.*

Annex IIAI

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

Group of *Margarodes* (non-EU species) such as:

1) *Margarodes vitis* (Phillipi)

2) *Margarodes vredendalensis* de Klerk

3) *Margarodes prieskaensis* Jakubski

1.1.2.3. Terms of Reference: Appendix 3

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

Annex IAI

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

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

(b) Fungi

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

(c) Viruses and virus-like organisms

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

(d) Parasitic plants

Arceuthobium spp. (non-EU)

Annex IAII

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

Meloidogyne fallax Karssen
Popillia japonica Newman
Rhizoecus hibisci Kawai and Takagi

(b) Bacteria

Clavibacter michiganensis (Smith) Davis et al. ssp. *sepedonicus* (Spieckermann and Kotthoff) Davis et al.
Ralstonia solanacearum (Smith) Yabuuchi et al.

(c) Fungi

Melampsora medusae Thümen
Synchytrium endobioticum (Schilbersky) Percival

Annex I B

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

Leptinotarsa decemlineata Say
Liriomyza bryoniae (Kaltenbac

(b) Viruses and virus-like organisms

Beet necrotic yellow vein virus

1.2. Interpretation of the Terms of Reference

Alternaria alternata (non-European pathogenic isolates) is one of a number of pests listed in the Appendices to the Terms of Reference (ToR) to be subject to pest categorisation to determine whether it fulfils the criteria of a harmful regulated pest or those of a regulated non-quarantine pest for the area of the European Union (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.

The EU legislation refers to non-European isolates of *A. alternata* (Fr.) Keissler that are pathogenic to *Cydonia* Mill., *Malus* Mill. and *Pyrus* L.

Based on recent literature revising the taxonomic status and pathogenicity of *A. alternata* (Andrew et al., 2009; Rotondo et al., 2012; Harteveld et al., 2013; Woudenberg et al., 2015), this pest categorisation focuses on the small-spored *Alternaria* carrying the genes for the biosynthesis of the host-specific AM- or AK-toxin, in short 'AM-/AK-toxin producer *Alternaria*' (see Section 3.1.1).

2. Data and methodologies

2.1. Data

2.1.1. Literature search

A search of literature (1997–2017) in the ISI Web of Science bibliographic database was conducted at the beginning of the categorisation. The search focussed on *A. alternata* and its geographic distribution, life cycle, host plants and the damage it causes. The following search terms (TS) and combinations were used: TS=("*Alternaria alternata*" OR "*Alternaria alternata* f. sp. *mali*" or "*Alternaria alternata* f. sp. *kikuchiana*" OR "Alternaria leaf blotch" OR "black spot of pears") AND TS=(geograph* OR distribution OR "life cycle" OR lifecycle OR host OR hosts OR plant* OR damag*).

Further references and information were obtained from experts, from citations within the references and grey literature.

2.1.2. Database search

Pest information, on host(s) and distribution, was retrieved from the EPPO Global Database (EPPO, 2017).

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.

The Europhyt database was consulted for pest-specific notifications on interceptions and outbreaks. Europhyt is a web-based network launched by the Directorate General for Health and Consumers (DG SANCO), 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 the AM-/AK-toxin producer *Alternaria*, following guiding principles and steps presented in the EFSA guidance on the harmonised framework for pest risk assessment (EFSA PLH Panel, 2010) and as defined in the International Standard for Phytosanitary Measures No 11 (FAO, 2013) and No 21 (FAO, 2004).

In accordance with the guidance on a harmonised framework for pest risk assessment in the EU (EFSA PLH Panel, 2010), this work was initiated following an evaluation of the EU's plant health regime. Therefore, to facilitate the decision-making process, in the conclusions of the pest categorisation, the Panel addresses explicitly each criterion for a Union quarantine pest and for a Union regulated non-quarantine pest in accordance with Regulation (EU) 2016/2031 on protective measures against pests of plants and includes additional information required as per the specific ToR received by the European Commission. In addition, for each conclusion, the Panel provides a short description of its associated uncertainty.

Table 1 presents the Regulation (EU) 2016/2031 pest categorisation criteria on which the Panel bases its conclusions. All relevant criteria have to be met for the pest to potentially qualify either as a quarantine pest or as a regulated non-quarantine pest. If one of the criteria is not met, the pest will not qualify. A pest that does not qualify as a quarantine pest may still qualify as a regulated non-quarantine pest which needs to be addressed in the opinion. For the pests regulated in the protected zones only, the scope of the categorisation is the territory of the protected zone; thus, the criteria refer to the protected zone instead of the EU territory.

It should be noted that the Panel's conclusions are formulated respecting its remit and particularly with regard to the principle of separation between risk assessment and risk management (EFSA founding regulation (EU) No 178/2002); therefore, instead of determining whether the pest is likely to have an unacceptable impact, the Panel will present a summary of the observed pest impacts. Economic impacts are expressed in terms of yield and quality losses and not in monetary terms, while addressing social impacts is outside the remit of the Panel, in agreement with EFSA guidance on a harmonised framework for pest risk assessment (EFSA PLH Panel, 2010).

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

Criterion of pest categorisation	Criterion in Regulation (EU) 2016/2031 regarding Union quarantine pest	Criterion in Regulation (EU) 2016/2031 regarding protected zone quarantine pest (articles 32–35)	Criterion in Regulation (EU) 2016/2031 regarding Union regulated non-quarantine pest
Identity of the pest (Section 3.1)	Is the identity of the pest established, or has it been shown to produce consistent symptoms and to be transmissible?	Is the identity of the pest established, or has it been shown to produce consistent symptoms and to be transmissible?	Is the identity of the pest established, or has it been shown to produce consistent symptoms and to be transmissible?

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
Absence/presence of the pest in the EU territory (Section 3.2)	Is the pest present in the EU territory? If present, is the pest widely distributed within the EU? Describe the pest distribution briefly!	Is the pest present in the EU territory? If not, it cannot be a protected zone quarantine organism.	Is the pest present in the EU territory? If not, it cannot be a regulated non-quarantine pest. (A regulated non-quarantine pest must be present in the risk assessment area).
Regulatory status (Section 3.3)	If the pest is present in the EU but not widely distributed in the risk assessment area, it should be under official control or expected to be under official control in the near future.	The protected zone system aligns with the pest-free area system under the International Plant Protection Convention (IPPC). The pest satisfies the IPPC definition of a quarantine pest that is not present in the risk assessment area (i.e. protected zone).	Is the pest regulated as a quarantine pest? If currently regulated as a quarantine pest, are there grounds to consider its status could be revoked?
Pest potential for entry, establishment and spread in the EU territory (Section 3.4)	Is the pest able to enter into, become established in, and spread within, the EU territory? If yes, briefly list the pathways!	Is the pest able to enter into, become established in, and spread within, the protected zone areas? Is entry by natural spread from EU areas where the pest is present possible?	Is spread mainly via specific plants for planting, rather than via natural spread or via movement of plant products or other objects? Clearly state if plants for planting is the main pathway!
Potential for consequences in the EU territory (Section 3.5)	Would the pests' introduction have an economic or environmental impact on the EU territory?	Would the pests' introduction have an economic or environmental impact on the protected zone areas?	Does the presence of the pest on plants for planting have an economic impact, as regards the intended use of those plants for planting?
Available measures (Section 3.6)	Are there measures available to prevent the entry into, establishment within or spread of the pest within the EU such that the risk becomes mitigated?	Are there measures available to prevent the entry into, establishment within or spread of the pest within the protected zone areas such that the risk becomes mitigated? Is it possible to eradicate the pest in a restricted area within 24 months (or a period longer than 24 months where the biology of the organism so justifies) after the presence of the pest was confirmed in the protected zone?	Are there measures available to prevent pest presence on plants for planting such that the risk becomes mitigated?
Conclusion of pest categorisation (Section 4)	A statement as to whether (1) all criteria assessed by EFSA above for consideration as a potential quarantine pest were met and (2) if not, which one(s) were not met.	A statement as to whether (1) all criteria assessed by EFSA above for consideration as potential protected zone quarantine pest were met, and (2) if not, which one(s) were not met.	A statement as to whether (1) all criteria assessed by EFSA above for consideration as a potential regulated non-quarantine pest were met, and (2) if not, which one(s) were not met.

The Panel will not indicate in its conclusions of the pest categorisation whether to continue the risk assessment process, but, following the agreed two-step approach, will continue only if requested by the risk managers. However, during the categorisation process, experts may identify key elements and knowledge gaps that could contribute significant uncertainty to a future assessment of risk. It would be useful to identify and highlight such gaps so that potential future requests can specifically target the major elements of uncertainty, perhaps suggesting specific scenarios to examine.

3. Pest categorisation

3.1. Identity and biology of the pest

3.1.1. Identity and taxonomy

Is the identity of the pest established, or has it been shown to produce consistent symptoms and to be transmissible?
Yes, the identity of the pests is well-established

To clarify the identity of the pest considered in the EU legislation, the following background information and taxonomic notes are provided.

Alternaria alternata includes both saprophytic and pathogenic isolates. Pathogenicity is mainly related to toxin production. Some isolates produce host-specific toxins (HSTs) and are pathogenic to specific hosts, including apple, as well as European and Japanese pears; genes for HST biosynthesis are located in a single locus in the genome on single small dispensable chromosomes (Tsuge et al., 2012). Other isolates produce non-HSTs targeting basic cellular processes and causing cell damage (Meena et al., 2016) to several hosts of different genera.

The *A. alternata* pathogenic isolates, mentioned in the EU legislation, are those isolates carrying genes for HST biosynthesis. In the EPPO Global database and CABI Invasive Species Compendium, they are named *Alternaria mali* and *Alternaria gaisen* (syn. *Alternaria kikuchiana*) and they produce the AM and AK HSTs, causing Alternaria leaf blotch/fruit spot of apple and black spot of pear, respectively. In the literature, these isolates have also been considered either pathotypes (*A. alternata* apple pathotype, *A. alternata* Japanese pear pathotype) or *formae speciales* (*A. alternata* f. sp. *mali* and *A. alternata* f. sp. *kikuchiana)* of *A. alternata* (Nishimura, 1980; Woudenberg et al., 2015).

Species of *Alternaria* were traditionally defined based on spore characteristics and sporulation patterns (Simmons, 1992). *Alternaria* spp. that share colony and conidial morphological characteristics have been classified into several morphological species groups, for instance *Alternaria tenuissima*, *Alternaria arborescens* and *A. alternata* species groups (Simmons, 1992, 1994, 1995; Simmons and Roberts, 1993). These morphological species groups were later considered as phylogenetic groups in molecular and metabolite profiling studies (Pryor and Gilbertson, 2000; Andersen et al., 2001; Woudenberg et al., 2013, 2015). Phylogenetic studies have demonstrated a clear distinction between large- and small-spored *Alternaria* species, but boundaries among the small-spored taxa have been a subject of controversy (Andrew et al., 2009). Strains of the former *A. alternata*, including those producing the AM- or the AK-toxin, are now reclassified in different small-spored taxa (Rotondo et al., 2012; Harteveld et al., 2013).

There is no consensus yet between taxonomists regarding relationships between *Alternaria* species, and specifically *A. alternata* and the biosynthesis of HSTs (EFSA CONTAM Panel, 2011). Additionally, it has been suggested that horizontal chromosome transfer may occur between *Alternaria* isolates, conferring the ability for non-pathogenic *Alternaria* isolates to produce a HST and, thus, become pathogenic on specific hosts (Tsuge et al., 2012).

Therefore, this pest categorisation focuses on small-spored *Alternaria* carrying the AM- or AK-toxin genes, which correspond to *A. mali* and *A. gaisen*, respectively, reported in the EPPO Global Database and CABI Invasive Species Compendium.

Based on the above, the pests considered in the EU legislation belong to the family Pleosporaceae, to the genus *Alternaria*, to different small-spored species groups, and carry the genes for the AM- or AK-toxin biosynthesis (in short, for this pest categorisation, 'AM-/AK-toxin producer *Alternaria*').

3.1.2. Biology of the pest

Studies from Japan and Korea indicate that the pest (as *A. mali)* overwinters as conidia on apple leaves, buds and twigs (Lee and Lee, 1972; Sekiguchi, 1976). Filajdić and Sutton (1995) studied the overwintering of *A. mali* in apple orchards in North Carolina, USA. Leaves on the ground were considered the most important source of overwintering conidia. Harteveld et al. (2014) also indicated that in Australia, overwintering of the pest occurred mainly in leaf residue and to a lesser extent on twigs and buds. Filajdić and Sutton (1995) indicated that relatively low inoculum levels are enough for disease development.

Lesions on overwintered leaves resume sporulation, inducing inoculum build-up and initiating primary infections. Afterwards, environmental conditions in late spring determine epidemic development. The optimum temperature for infection, mycelial growth, sporulation and spore germination of small-spored AM- and AK-toxin producer *Alternaria* is 25–30°C and 24–28°C, respectively (Sakuma, 2014; Sawamura, 2014). Filajdić and Sutton (1992a) studied the relationship of temperature and leaf wetness duration on the severity of Alternaria blotch of apple in North Carolina, USA. They estimated an optimum temperature for infection of 23.5°C, with 5.1 hours of leaf wetness required for a low disease severity (i.e. 0.2% leaf area covered with lesions). Filajdić and Sutton (1992a) indicated an incubation period (from infection to symptom expression) of 1–2 days for *A. mali*. This short incubation period is a common feature of the HST producer *Alternaria*, and it was related to the rapid action of these toxins on their specific target plant tissues (Tsuge et al., 2012).

In Korea, Kim et al. (1986) indicated a temperature threshold and four subsequent rain events for the occurrence of Alternaria leaf blotch of apple. After disease onset, the progress of epidemics was related to the frequency of rains. Kim et al. (1986) also found a significant linear relationship between disease progress and cumulative number of airborne conidia of *A. mali*. Likewise, in Australia, the most significant period of spore production on the canopy coincided with the stage of fruit growth (Harteveld et al., 2014). In Australia, Alternaria leaf blotch infection began about 20 days after full bloom and the highest disease incidence occurred from 70 to 110 days after bloom. Fruit infection occurred about 100 days after bloom (Harteveld et al., 2014).

There is little information on the biology of the pest (as *A. gaisen)* on *Pyrus pyrifolia.* Tanaka (1933) indicated that the optimum conditions for infection were 24–30°C and relative humidity over 90%. Likewise, Hsieh and Chiu (1974) reported optimal mycelial growth at 23°C. These conditions are also favourable for most *Alternaria* species affecting different crops (Rotem, 1994).

3.1.3. Detection and identification of the pest

Are detection and identification methods available for the pest?

Yes, the AK-/AM-toxin producer *Alternaria* can be detected and identified based on host association, symptomatology and cultural/morphological characteristics of their colonies in agar media combined with molecular methods for the detection of the genes responsible for the AM- or the AK-toxin biosynthesis.

The AM- and AK-toxin producer *Alternaria* cause leaf blotch/fruit spot on apples and black spot on pears, respectively. Nevertheless, host association and symptomatology are not sufficient for the detection of the pests, as similar symptoms are caused by other biotic or abiotic agents. Moreover, morphological and cultural characteristics are not reliable for the identification of the pests, as other small-spored *Alternaria,* not being AM- or AK-toxin producers, have similar cultural and morphological characteristics. Reliable detection and identification of the pests are only possible by the application of molecular methods to detect the genes responsible for the AM- or AK-toxin biosynthesis (Johnson et al., 2000; Roberts, 2005; Andersen et al., 2006).

Symptoms

<u>Symptoms caused on apples</u>

The first symptoms of the disease appear on leaves in late spring or late summer as small, round, brown to blackish spots, gradually enlarging to 2–5 mm in diameter, with a brownish purple border (Sawamura, 2014). Later, most of those lesions undergo secondary enlargement and become irregular and much darker acquiring a frogeye appearance. If the lesions appear on petioles, the leaves turn yellow and drop prematurely. Symptoms on the current year's shoots appear as round, blackish to brown spots, slightly sunken and bordered by cracks. Sometimes, lenticels appear swollen because of the infection. Only fruit of the susceptible cultivars develop small necrotic spots, which enlarge during the summer.

<u>Symptoms caused on Asian pears</u>

Leaves, petioles, shoots, fruit, flower buds, pistils and flower petals of Asian pears are affected by the disease (Sakuma, 2014). Symptoms on leaves appear as tiny, round, black spots, which enlarge to a diameter of about 10 mm. These large lesions show blackish brown centres. If a lesion appears on a vein, it develops along the midrib and forms in an irregular shape. Severely infected leaves fall prematurely. Lesions, larger than those on leaves, may appear on fruit at any stage of their development resulting in cracking and preharvest fruit drop. Shoot lesions are round, blackish to brown and become sunken and cracked around the margins as they age. Infected flower buds decay and do not sprout during the next flowering season.

Morphology

The several small-spored AM-toxin producer *Alternaria* reported worldwide to be associated with leaf blotch and fruit spot of apples do not have uniform morphological characteristics except for the small, concatenated, multicellular conidia (dictyoconidia) produced in acropetal chains on short conidiophores in bushy clumps (Rotem, 1994).

The conidiophores of the small-spored AK-toxin producer *Alternaria* are olive brown, fasciculate, simple or branched. The conidia (6–22 × 9.5–69.5 μm) are olive to olive brown, mostly oblong, ovate (rarely obclavate), muriform, packet-shaped, with 1–10 transverse and 1–3 longitudinal septa. Conidia do not have a true beak (Sakuma, 2014).

3.2. Pest distribution

3.2.1. Pest distribution outside the EU

The EPPO Global Database provides the geographical distribution of the AM-/AK-toxin producer *Alternaria* as *A. mali* (Figure 1, Table 2) and *A. gaisen* (Figure 2, Table 3) reported worldwide on *Malus* spp. and *P. pyrifolia* showing leaf blotch/fruit spot and fruit black spot symptoms, respectively.

There is uncertainty with respect to the distribution of the AM-/AK-toxin producer *Alternaria* on *Malus* spp. and *Pyrus* spp. outside the EU, particularly for those reports where identification was based on morphological observations and pathogenicity tests, and not on the detection of the genes responsible for the biosynthesis of the AM- or the AK-toxin (see Section 1.2).

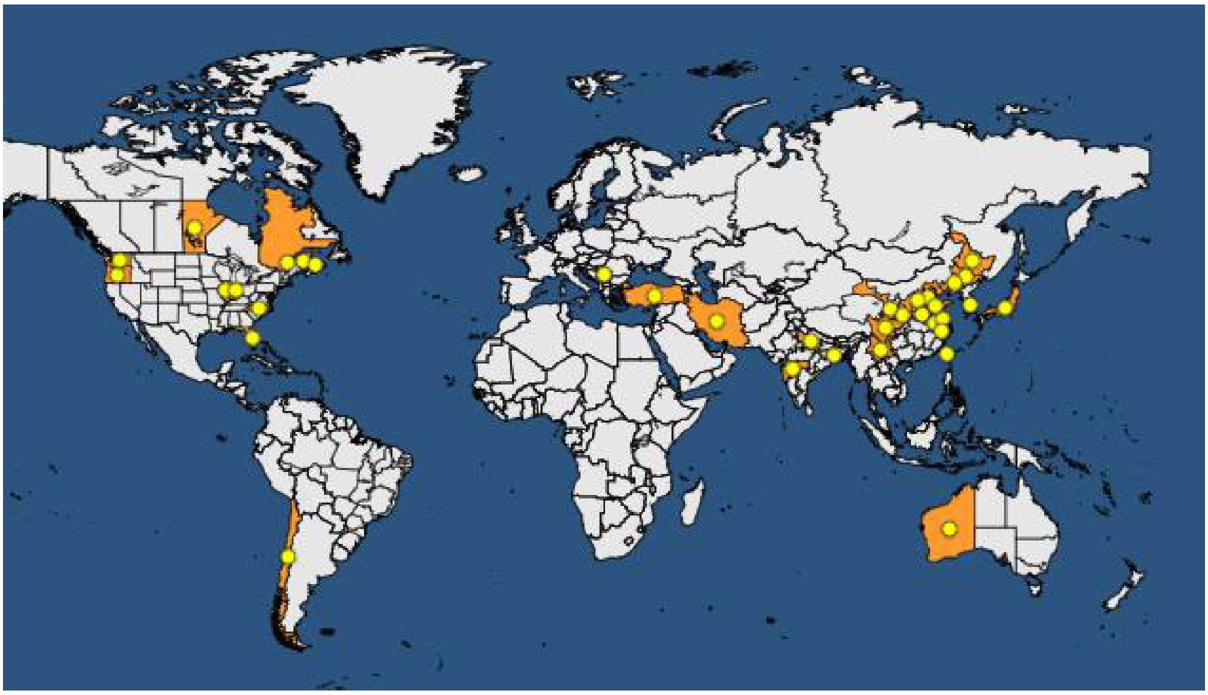

Figure 1: Global distribution map for *Alternaria mali* extracted from the EPPO Global Database (last updated: 13/9/2017; last accessed: 22/11/2017). According to Gur et al. (2017), small-spored *Alternaria* carrying the gene for AM-toxin biosynthesis are present in Israel. The pests (as *A. mali*) are also present in Pakistan (CABI, 2017)

Table 2: Global distribution of small-spored AM-toxin producer *Alternaria* based on information extracted from the EPPO Global Database (as *A. mali*) (last updated: 13/9/2017; last accessed: 11/10/2017), CABI Invasive Species Compendium (as *A. mali*) (last updated: 12/7/2017; last accessed: 11/10/2017) and other sources

Continent	Country	Status	Sources
America	Canada	Present, restricted distribution	EPPO
	Chile	Present, no details	EPPO
	United States of America	Present, restricted distribution	EPPO
Asia	China	Present, no details	EPPO
	India	Present, no details	EPPO
	Iran	Present, restricted distribution	EPPO
	Israel	Present	Gur et al. (2017)
	Japan	Present, widespread	EPPO
	Korea, Republic	Present, no details	EPPO
	Pakistan	Present	CABI
	Taiwan	Present, restricted distribution	EPPO
Europe	Serbia	Present, few occurrences	EPPO
	Turkey	Present, restricted distribution	EPPO
Oceania	Australia	Present, restricted distribution	EPPO

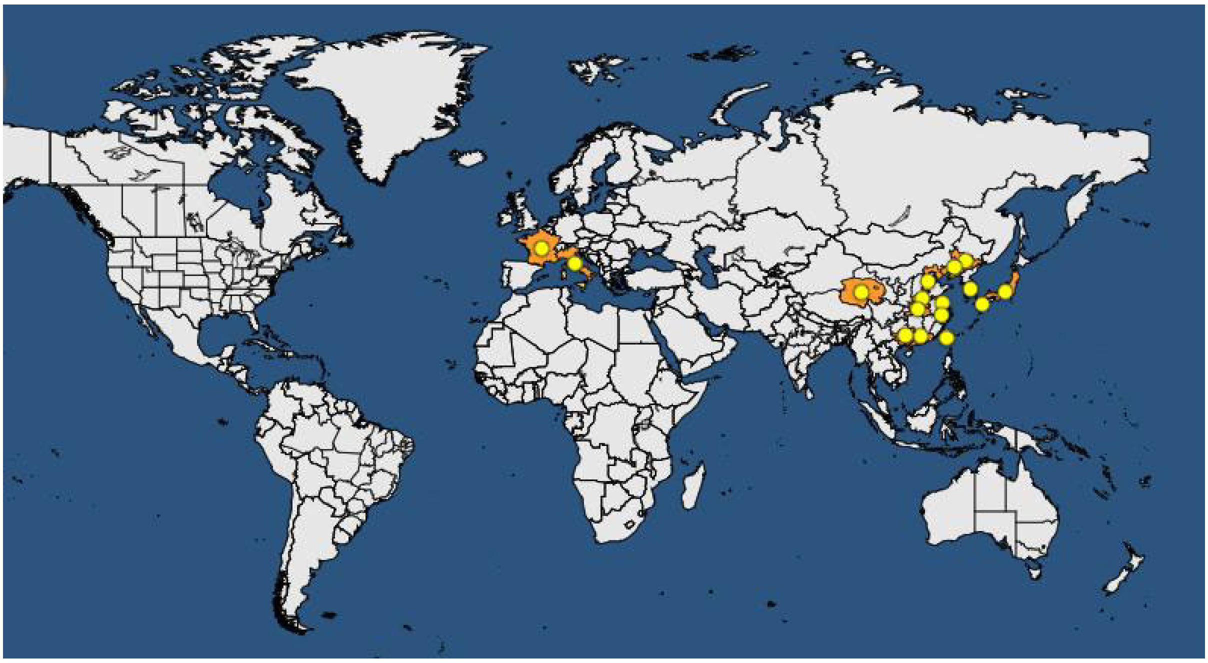

Figure 2: Global distribution map for *Alternaria gaisen* extracted from the EPPO Global Database (last updated: 13/9/2017; last accessed: 27/9/2017). According to CABI Invasive Species Compendium (2017), *A. gaisen* is also present in Pakistan

Table 3: Global distribution of small-spored AK-toxin producer *Alternaria* based on information extracted from the EPPO Global Database (as *A. gaisen*) (last updated: 30/9/2016; last accessed: 11/10/2017) and CABI Invasive Species Compendium (as *A. gaisen*) (last updated: 22/6/2017; last accessed: 22/11/2017)

Continent	Country	Status	Sources
Asia	China	Present, restricted distribution	EPPO
	Japan	Present, widespread	EPPO
	Korea, Republic	Present, no details	EPPO
	Pakistan	Present	CABI
	Taiwan	Present, restricted distribution	EPPO

3.2.2. Pest distribution in the EU

Is the pest present in the EU territory?

Yes, small-spored *Alternaria* carrying the gene for the AM- or AK-toxin biosynthesis are known to be present in the EU territory.

If present, is the pest widely distributed within the EU?

The distribution of the pests in the risk assessment area may be considered restricted, with some uncertainty.

Small-spored *Alternaria* carrying the gene for the AM-toxin biosynthesis are present in Denmark and Italy (Table 4).

In Denmark, two small-spored *Alternaria* isolates originating from apple flowers and tested positive for the AM-toxin gene were used in Andersen et al. (2006) phenotypic studies.

In northern Italy, symptoms similar to those described for Alternaria blotch (Tweedy and Powell, 1962) appeared in Alto Adige on apple leaves and fruits, starting from 1990s. *Alternaria* spp. were isolated from these lesions and one representative isolate was compared with a reference strain and identified as *A. alternata*. Pathogenicity tests carried out with that isolate and cultural filtrates showed typical Alternaria blotch symptoms (Marschall and Bertagnoll, 2006). Later, the disease was also observed in Trentino (Gobber et al., 2004) and the isolation and pathogenicity of *A. alternata* were confirmed. The disease has also been found in Lombardy (ERSAF, 2016), Friuli (ERSA, 2015), Veneto (Anonymous, 2017), Piedmont (Anonymous, 2015) even though pathogenicity tests were not performed.

Rotondo et al. (2012) carried out a further study by using a collection of 173 isolates from different areas in northern Italy and four reference strains, three of which were Japanese strains of small-spored *Alternaria* pathogenic on apple and one was a type isolate for *A. mali*. Isolates have been characterised based on: (i) morphological characters, following Simmons (2002), to determine their 'species group'; (ii) pathogenicity by using a bioassay on both leaves and fruit, based on artificial inoculation with spore suspensions and culture filtrates; (iii) molecular analysis to determine the presence of the AM-toxin gene following Johnson et al. (2000). Of the 173 isolates, 44 were pathogenic and belonged to the following species groups: *A. tenuissima, A. arborescens*, and *A. alternata*; three of the four reference strains exhibited *A. tenuissima* sporulation habit, while one was characterised by an *A. arborescens* sporulation pattern. Ten of these pathogenic isolates were positive for the presence of the AM-toxin gene, as the three Japanese strains did. Therefore, the production of the AM-toxin may be involved in pathogenesis by some of the Italian isolates of *Alternaria* from apple.

According to the EPPO Global Database and CABI Invasive Species Compendium, small-spored AK-toxin producer *Alternaria* are present in France, Hungary and Italy (Table 5).

Table 4: Current distribution of small-spored AM-toxin producer *Alternaria* in the 28 EU MS based on information from the EPPO Global Database (as *A. mali*) (last updated: 13/9/2017; last accessed: 11/10/2017) and other sources

Country	Status	Sources
Denmark	Present[(a)]	Andersen et al. (2006)
Italy	Present[(a)]	Rotondo et al. (2012)
Netherlands	Absent, confirmed by survey	EPPO

(a): The gene for the AM-toxin biosynthesis was also detected.

Table 5: Current distribution of small-spored AK-toxin producer *Alternaria* in the 28 EU MS based on information from the EPPO Global Database (as *A. gaisen*) (last updated: 30/9/2016; last accessed: 11/10/2017), CABI Invasive Species Compendium (as *A. gaisen*) (last updated: 22/6/2017; last accessed: 11/10/2017), and other sources

Country	Status	Sources
France	Present, few occurrences	EPPO
Greece	Absent, invalid record	EPPO
Hungary	Present	CABI
Italy	Present, restricted distribution	EPPO
Netherlands	Absent, intercepted only	EPPO
Portugal[(a)]	Present	Woudenberg et al. (2015)

(a): Host plant unknown.

There is uncertainty with respect to the distribution of the AM-/AK-toxin producer *Alternaria* on *Malus* spp. and *Pyrus* spp. in the EU, particularly for those reports where identification was based on morphological observations and pathogenicity tests, and not on the detection of the genes responsible for the biosynthesis of the AM- or the AK-toxins.

3.3. Regulatory status

3.3.1. Council Directive 2000/29/EC

Small-spored AM-/AK-toxin producer *Alternaria* (as *A. alternata*) are listed in Council Directive 2000/29/EC. Details are presented in Tables 6 and 7.

Table 6: Small-spored AM-/AK-toxin producer *Alternaria* (as *Alternaria alternata*) in Council Directive 2000/29/EC

Annex II, Part A	**Harmful organisms whose introduction into, and spread within, all member states shall be banned if they are present on certain plants or plant products**	
Section I	**Harmful organisms not known to occur in the community and relevant for the entire community**	
(c)	Fungi	
	Species	Subject of contamination
1.	*Alternaria alternata* (Fr.) Keissler (non-European pathogenic isolates)	Plants of *Cydonia* Mill., *Malus* Mill. and *Pyrus* L. intended for planting, other than seeds, originating in non-European countries

3.3.2. Legislation addressing the hosts of small-spored AM-/AK-toxin producer *Alternaria* (as *Alternaria alternata*)

Table 7: Regulated hosts and commodities that may involve small-spored AM-/AK-toxin producer *Alternaria* (as *Alternaria alternata*) in Annexes III, IV and V of Council Directive 2000/29/EC

Annex III, Part A	**Plants, plant products and other objects the introduction of which shall be prohibited in all Member States**	
	Description	Country of origin
9.	Plants of *Chaenomeles* Ldl., *Cydonia* Mill., *Crateagus* L., *Malus* Mill., *Prunus* L., *Pyrus* L., and *Rosa* L., intended for planting, other than dormant plants free from leaves, flowers and fruit	Non-European countries
18.	Plants of *Cydonia* Mill., *Malus* Mill., *Prunus* L. and *Pyrus* L. and their hybrids, and *Fragaria* L., intended for planting, other than seeds	Without prejudice to the prohibitions applicable to the plants listed in Annex III A (9), where appropriate, non-European countries, other than Mediterranean countries, Australia, New Zealand, Canada, the continental states of the USA

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
1.1	Plants, intended for planting, other than seeds, of *Amelanchier* Med., *Chaenomeles* Lindl., *Cotoneaster* Ehrh., *Crataegus* L., *Cydonia* Mill., *Eriobotrya* Lindl., *Malus* Mill., *Mespilus* L., *Photinia davidiana* (Dcne.) Cardot, *Prunus* L., other than *Prunus laurocerasus* L. and *Prunus lusitanica* L., *Pyracantha* Roem., *Pyrus* L. and *Sorbus* L.
Part B	Plants, plant products and other objects originating in territories, other than those 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
3.	Fruits of: – *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf., and their hybrids, *Momordica* L. and *Solanum melongena* L., – *Annona* L., *Cydonia* Mill., *Diospyros* L., *Malus* Mill., *Mangifera* L., *Passiflora* L., *Prunus* L., *Psidium* L., *Pyrus* L., *Ribes* L. *Syzygium* Gaertn., and *Vaccinium* L., originating in non-European countries, – *Capsicum* L.

Additional movement restrictions for the hosts exist in relation to other pests, such as *Erwinia amylovora* or Apple proliferation mycoplasma.

3.4. Entry, establishment and spread in the EU

3.4.1. Host range

The main hosts of small-spored AM-toxin producer *Alternaria* (as *A. mali* or *A. alternata* f. sp. *mali* or *A. alternata* apple pathotype) are *Malus* spp. and *Pyrus communis* (European pear) (Tanahashi et al., 2016; EPPO, 2017).

The small-spored AK-toxin producer *Alternaria* (as *A. gaisen* or *A. kikuchiana* or *A. alternata* f. sp. *kikuchiana* or *A. alternata* Japanese pear pathotype) affect *P. pyrifolia* (Japanese pears) (Tanaka, 1933; Simmons and Roberts, 1993). Chinese pears (*Pyrus bretschneideri* and *Pyrus ussuriensis*) are also affected in northeastern China (CABI, 2017). *A. gaisen* has not been shown to affect *P. communis* (European pear) or its hybrid *P.* × *lecontei*. Therefore, there is uncertainty whether European pear and its hybrid *P.* × *lecontei* are hosts of the small-spored AK-toxin producer *Alternaria*.

The EU legislation includes *Cydonia* in addition to *Malus* and *Pyrus.* Farr et al. (1989), based on Joly (1964), reported *A. mali* on *Cydonia oblonga*. However, Joly (1964) also considered *A. mali* to be synonymous with *Alternaria citri* and *Alternaria chartarum,* with the latter having a very wide host range among which species belonging to several families of poaceous and woody plants. Joly (1964) was most likely referring to small-spored *A. alternata*-like fungi detected on those plant species, including apples, and not to AM-toxin producer *Alternaria.* Therefore, as no other literature could be found to support the host status of *Cydonia,* the Panel decided not to include this plant genus in the host range of the pests in this pest categorisation.

All the above-mentioned hosts are regulated.

3.4.2. Entry

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

Yes, under the current EU legislation, the small-spored AM/AK-toxin producer *Alternaria* could potentially enter the risk assessment area via the dormant host plants for planting and the fresh fruit pathways

The PLH Panel identified the following pathways for the entry of the pests into the EU territory:

1) host plants for planting, including dormant plants, and
2) fresh fruit of host plants originating in infested Third countries.

No evidence exists for small-spored AM-/AK-toxin producer *Alternaria* affecting *Malus* spp. and *Pyrus* spp. to be seed-borne.

Although there is no quantitative data available, spores of the pests may be also present as contaminants on other substrates (e.g. non-host plants, plant products and other objects) imported into the EU. Nevertheless, this is considered to be a minor pathway for the entry of small-spored AM-/AK-toxin producer *Alternaria* into the risk assessment area.

Under the current EU legislation, the import of host plants for planting, excluding seeds and dormant plants, from non-EU countries is prohibited. Therefore, only the host plants for planting at dormant stage and the fresh fruit pathways are relevant for the entry of the pests into the risk assessment area.

No data exists in Eurostat on imports of dormant host plants for planting from Third countries into the EU territory (Source: Eurostat, search done on 12/10/2017). The volume of apples and pears imported into the EU from non-EU countries and continents infested with the AM- and AK-toxin producer *Alternaria* is presented in Tables 8 and 9, respectively.

Table 8: Total volume (in tons) of apples imported during the period 2011–2015 into the 28 EU Member States from non-EU28 countries and from continents where AM-toxin producer *Alternaria* are reported as present (Source: Eurostat, extracted on 12/10/2017)

Total EU 28 apple imports (in tons) from	2011	2012	2013	2014	2015
Non-EU countries	595,914	504,178	668,796	495,034	455,291
Infested American countries	181,631	144,282	181,623	173,460	118,650
Infested Asian countries	5,699	3,459	7,921	2,552	1,182
Australia	275	480	469	95	699
Serbia	32,247	2,166	38,860	5,258	23,150
Turkey	127	127	302	166	222

Based on the above data, during the period 2011–2015, 30–37% of the total volume of apples imported by the 28 EU MSs from Third countries originated in areas where AM-toxin producer *Alternaria* are reported as present.

Table 9: Total volume (in tons) of pears imported during the period 2012–2015 into the EU Member States from non-EU countries and from continents where AK-toxin producer *Alternaria* are reported as present (Source: Eurostat, extracted on 12/10/2017). No import data available for 2011

Total EU 28 pear imports (in tons) from	2012	2013	2014	2015
Non-EU countries	226,965	284,723	242,205	221,239
Infested Asian countries	11,583	10,397	6,418	9,536

No data available for Pakistan and Taiwan.

Based on the above data, during the period 2011–2015, 3–5% of the total volume of pears imported by the 28 EU MSs from Third countries originated in areas where AK-toxin producer *Alternaria* are reported as present. However, no specific data exist in Eurostat on imports of *P. pyrifolia*, *P. ussuriensis* or *P. bretschneideri* fruit from infested Third countries into the EU.

There are no records of interception of *Alternaria* spp. in the Europhyt database (search done on 11 October 2017).

3.4.3. Establishment

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

Yes, both the biotic (host availability) and abiotic (climate suitability) factors suggest that small-spored AM- and AK-toxin producer *Alternaria* could potentially establish in the risk assessment area, similarly to other well-established *Alternaria* species.

3.4.3.1. EU distribution of main host plants

Hosts of the small-spored AM-toxin producer *Alternaria* (i.e. *Malus* spp., *P. communis*) are widely distributed in the risk assessment area (Tables 10 & 11).

There is no data concerning the abundance and distribution of the hosts of the small-spored AK-toxin producer *Alternaria* (i.e. Asian pears) in the risk assessment area, although enterprises producing plants for planting and fresh fruit of Japanese pears are currently present in the EU territory.

Table 10: Area cultivated with apples in the EU between 2011 and 2015 (in 1,000 ha). Source: Eurostat, extracted on 28/8/2017

EU Member States[(a)]	2011	2012	2013	2014	2015	Mean of EU apple-growing area (in 1,000 ha)
EU28	548.36	558.62	536.75	524.50	537.91	541.23
Poland	183.50	194.70	162.40	163.10	180.40	176.82
Romania	52.72	55.37	60.28	56.13	55.88	56.08
Italy	54.07	54.13	53.01	52.00	52.16	53.07
France	52.80	51.79	50.68	50.17	49.65	51.02
Hungary	33.09	32.04	33.36	33.26	32.80	32.91
Germany	31.76	31.74	31.74	31.74	31.74	31.74
Spain	31.51	30.79	30.79	30.73	30.72	30.91
United Kingdom	16.00	16.00	20.00	16.00	16.00	16.80
Portugal	12.54	12.90	13.66	13.85	14.01	13.39
Greece	13.48	12.47	12.93	12.26	11.76	12.58
Lithuania	10.11	11.83	11.67	11.27	10.68	11.11

(a): Only Member States growing more than 10,000 ha are reported.

Apples are also grown, but to a lesser extent, in the Czech Republic, the Netherlands, Belgium, Austria, Croatia, Bulgaria, Slovakia, Latvia, Slovenia, Denmark, Sweden, Estonia, Cyprus, Ireland, Finland and Luxembourg.

Table 11: Area cultivated with pears in the EU between 2011 and 2015 (in 1,000 ha) – Source: Eurostat, extracted on 28/8/2017

EU Member States[(a)]	2011	2012	2013	2014	2015	Mean of EU apple-growing area (in 1,000 ha)
EU28	129.42	124.66	120.38	117.01	117.07	121.71
Italy	36.34	34.24	31.53	30.15	30.86	32.62
Spain	27.01	25.48	24.24	23.64	22.88	24.65
Portugal	10.97	11.23	12.01	12.01	12.12	11.67
Poland	11.70	10.90	9.50	9.20	9.20	10.10

(a): Only Member States growing more than 10,000 ha are reported.

Pears are also grown, but to a lesser extent, in Belgium, the Netherlands, France, Greece, Romania, Hungary, Germany, the United Kingdom, Croatia, the Czech Republic, Lithuania, Austria, Bulgaria, Denmark, Slovakia, Slovenia, Latvia, Sweden, Cyprus and Luxembourg.

3.4.3.2. Climatic conditions affecting establishment

Small-spored *Alternaria* species have already been established in the EU and AM-/AK-toxin producer *Alternaria* have been detected in both southern and northern EU MSs (e.g. Italy, Denmark). In addition, the biology and epidemiology of small-spored AM-/AK-toxin producer *Alternaria* is similar to that of other well-established in the EU *Alternaria*. Therefore, the climatic conditions in the risk assessment area are not a limiting factor for the establishment of small-spored AM-/AK-toxin producer *Alternaria.*

3.4.4. Spread

3.4.4.1. Vectors and their distribution in the EU

Is the pest able to spread within the EU territory following establishment? Yes *How?* By natural and human-assisted means

Small-spored AM-/AK-toxin producer *Alternaria* can spread in the risk assessment area by both natural and human-assisted means.

Spread by natural means. Long-distance spread of *Alternaria* is likely by means of windborne conidia produced on symptomatic host plant tissues, whereas short-distance spread (within a tree or between trees) is by water splash and/or wind-driven rain carrying conidia. Conidial release is favoured by rain events or sudden changes in relative humidity (Rotem, 1994).

No information was found in the literature on the distance over which conidia of the pests can be carried by air currents.

Dispersion indices, two-dimensional distance analysis and spatial autocorrelation analysis used to study the spatial distribution pattern of small-spored AM-toxin producer *Alternaria* (formerly *A. mali*) in apple orchards in the USA and Korea, suggested that arthropods may also be responsible for the introduction of inoculum into the orchards (Filajdić and Sutton, 1994; Filajdić et al., 1995a,b; OunHa et al., 1997).

Spread by human assistance. The pests can spread over long distances via the movement of infected host plants for planting (rootstocks, grafted plants, scions, etc.), including dormant plants and fresh fruits.

3.5. Impacts

Would the pests' introduction have an economic or environmental impact on the EU territory? Yes, the introduction of the pests could potentially cause yield and quality losses to *Malus* and *Pyrus* grown in the risk assessment area.

Alternaria leaf blotch and fruit spot of apple are economically important diseases in Southeast Asia, Southeast USA, Australia and northern Italy causing premature defoliation and fruit spotting (Filajdić and Sutton, 1991, 1992b; Rotondo et al., 2012; Harteveld et al., 2013; Sawamura, 2014). The disease mostly affects high-value apple cultivars that are susceptible to the AM-toxin, such as Golden Delicious, Red Delicious, Gala, Royal Gala, Fuji, Pink Lady, Indo, etc. (Filajdić and Sutton, 1991; Ferree and Warrington, 2003; Horlock, 2006; Rotondo et al., 2012). Leaf infection can result in 60–85% defoliation in susceptible cultivars (Filajdić and Sutton, 1992b; Jung, 2007). Fruit symptoms are usually limited to small, corky, dark lesions often associated with the lenticels. The disease may cause soft rot, especially on fruit already damaged by other means (Jung, 2007), such as mechanical injuries, red mites (Filajdić et al., 1995a,b), apple aphids (Filajdić et al., 1995b) or cracks around the calyx (Stern et al., 2013; Ginzberg et al., 2014). Affected fruits, if not dropped, are downgraded from premium fresh fruit to juice, resulting in significant financial losses to the growers (Persley and Horlock, 2009).

In addition to yield and quality losses of fruit, premature defoliation also depletes the carbohydrate reserves in the trees, giving rise to reduced tree vigour and productivity in the following seasons (Cordes, 1987; Suzuki et al., 1987).

Filajdić and Sutton (1991) reported that, during the summers of 1987 and 1988, the disease caused 60% defoliation of the variety Delicious in the apple-growing areas of North Carolina, USA.

In Australia, the disease occurs in all apple-growing regions causing yield losses of 15–25% in high value cultivars to the apple industry (Horlock, 2006; Harteveld et al., 2013). Severe leaf infection can result in 60–85% defoliation on susceptible apple cultivars (Persley and Horlock, 2009).

Severe outbreaks of Alternaria leaf blotch and fruit spot were recently observed in cv. Pink Lady apples in northern Israel, especially on fruit (Gur et al., 2017). Symptoms involved cracks and rot around the calyx and external fruit rot. Up to 80% of the fruit in some orchards were affected by the disease.

In northern Italy, Alternaria leaf blotch and fruit spot of apple cause damages that vary from 3–4% to 40% of the fruit showing symptoms (Anonymous, 2005; Antoniacci and Montuschi, 2006; Ortalda, 2006).

Black spot disease caused by small-spored AK-toxin producer *Alternaria* (as *A. gaisen* or *A. kikuchiana* or *A. alternata* f. sp. *kikuchiana* or *A. alternata* Japanese pear pathotype) is one of the most serious diseases of a limited number of cultivars of Japanese pear (*P. pyrifolia*) grown in Asia, including the commercially important cvs. Nijisseiki and Shinsui (Kohmoto et al., 1992; Tanaka, 1933; Nakashima et al., 1985; Otani et al., 1985; Terakami et al., 2016). Nevertheless, no quantified data on yield/quality losses could be retrieved from the literature.

Overall, there is uncertainty with respect to the contribution of small-spored AM-/AK-toxin producer *Alternaria* on the impact caused by the small-spored *Alternaria* detected on apples and pears worldwide, particularly for those reports where identification was based on morphological observations and pathogenicity tests, and not on the detection of the genes responsible for the biosynthesis of the AM- or the AK-toxins.

The Panel considers that the introduction and spread of the pests in the risk assessment area could cause some impacts to apple and pear production, although their magnitude is unknown.

3.6. Availability and limits of mitigation measures

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

Yes, the likelihood of pest entry can be mitigated if host plants for planting (including dormant plants) and fresh fruit are sourced from pest-free areas or pest-free places of production and are inspected and lab tested for the detection of the AM- or AK-toxin biosynthesis genes both at the place of origin and the EU entry point. In infested areas, sanitation, agricultural practices, including resistant cultivars, and fungicide sprays are available for disease management.

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

- sourcing host plant material, including dormant plants and fruit, from pest-free areas or pest-free places of production
- phytosanitary certificate for the export of host plants for planting and fruit from infested countries
- inspection and testing of host plants for planting and fruit prior to export to the EU and at the EU entry point.

Measures for preventing the establishment and spread of the pests in the risk assessment area include:

- use of resistant host varieties
- use of sanitary measures (e.g. removal of infected plants or plant parts and pruning residues, disinfection of pruning and grafting tools)
- application of fungicide sprays
- crop residue management
- restrict the movement of infected plant material.

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

The following biological and technical factors could potentially limit the feasibility and effectiveness of measures to prevent the entry into, establishment and spread within the risk assessment area of small-spored AM- or AK-toxin producer *Alternaria*:

- The similarity of disease symptoms and colony and conidial morphology of the pests with those of other small-spored *Alternaria* species affecting apples and pears worldwide and not carrying the genes for the AM- or AK-toxin biosynthesis makes impossible the detection/identification of the pests based only on symptomatology and cultural/morphological characters.
- Methods for the detection and identification of small-spored *Alternaria* carrying the genes for the AM- or AK-toxin biosynthesis are available but difficult to be implemented on a large scale.

3.6.2. Control methods

In the infested areas, the following agricultural practices and sanitary and chemical measures are used for the management of the diseases caused by small-spored AM-/AK-toxin producer *Alternaria* on *Malus* spp. and *Pyrus* spp. (CABI, 2017):

- Agricultural measures:
  - Use of resistant cultivars (Sawamura, 2014; Shin et al., 1986; EPPO, 2017; Machida et al., 1984; Kim et al., 1985; Kozaki, 1987).
  - Improve orchard ventilation by adequate tree spacing, row orientation and pruning.
- Sanitation measures to reduce inoculum sources in the orchards (e.g. burial of fallen infected leaves, removal of symptomatic fruit) (CABI, 2017).
- Chemical control is achieved using fungicides such as iprodione, mancozeb and captan (although some isolates have developed resistance to some of these fungicides) (Lee and Kim, 1986; Osanai et al., 1987; Asari and Takahashi, 1988). In Japan, the disease requires specific and regular fungicide sprays. Applications of protectant fungicides are made after petal fall (Sekita et al., 1994). Only iprodione was found to be effective for the control of the disease in North Carolina (USA) (Filajdić and Sutton, 1992a). Captafol (Adachi and Fujita, 1984) and guazatine (Yagura et al., 1984) are also used for disease management in the infested areas. However, these two fungicides are not authorised in the EU.

3.7. Uncertainty

1) Pest distribution: There is uncertainty with respect to the distribution of the pests worldwide and in the risk assessment area, particularly for those reports where identification was based on morphological observations and pathogenicity tests, and not on the detection of the genes responsible for the biosynthesis of the AM- or the AK-toxin.
2) Host range: There is uncertainty whether *P. communis* (European pear) or its hybrid *P.* x *lecontei* are hosts of the small-spored AK-toxin producer *Alternaria*.
3) Entry: The absence of data regarding the quantity of dormant host plants for planting imported from affected non-EU countries into the risk assessment area.
4) The absence of data regarding the abundance and distribution of *P pyrifolia*, the host of the small-spored AK-toxin producer *Alternaria*, in the EU28 and on the susceptibility of the grown cultivars; this uncertainty affects entry (transfer of the pests from the pathway of entry to the host grown in the risk assessment area), establishment, spread and impact.
5) Spread: The maximum distance the conidia of the pests could travel by air currents due to lack of knowledge
6) Impacts: The contribution of small-spored AM-/AK-toxin producer *Alternaria* on the impact caused worldwide by small-spored *Alternaria* pathogenic to apples and pears is uncertain.

4. Conclusions

Small-spored AM-/AK-toxin producer *Alternaria* do not meet all the criteria assessed by EFSA for consideration as potential quarantine pests or regulated non-quarantine pests for the EU territory (see Table 12).

Table 12: The Panel's conclusions on the pest categorisation criteria defined in Regulation (EU) 2016/2031 on protective measures against pests of plants (the number of the relevant sections of the pest categorisation is shown in brackets in the first column)

Criterion of pest categorisation	Panel's conclusions against criterion in Regulation (EU) 2016/2031 regarding Union quarantine pest	Panel's conclusions against criterion in Regulation (EU) 2016/2031 regarding Union regulated non-quarantine pest	Key uncertainties
Identity of the pest (Section 3.1)	The identity of the pests is clearly defined and there are reliable methods for their detection and identification	The identity of the pests is clearly defined and there are reliable methods for their detection and identification	None

Criterion of pest categorisation	Panel's conclusions against criterion in Regulation (EU) 2016/2031 regarding Union quarantine pest	Panel's conclusions against criterion in Regulation (EU) 2016/2031 regarding Union regulated non-quarantine pest	Key uncertainties
Absence/ presence of the pest in the EU territory (Section 3.2)	Small-spored AM-toxin producer *Alternaria* are reported in Italy and Denmark, whereas small-spored AK-toxin producer *Alternaria* are reported in France, Hungary, Italy and Portugal. Based on available information, the pest distribution is currently restricted.	Small-spored AM-toxin producer *Alternaria* are reported in Italy and Denmark, whereas small-spored AK-toxin producer *Alternaria* are reported in France, Hungary, Italy and Portugal. Based on available information, the pest distribution is currently restricted.	There is uncertainty about the distribution of the pests in the risk assessment area, particularly where the presence of AM-/AK-toxin genes has not been tested (Uncertainty 1).
Regulatory status (Section 3.3)	Small-spored AM-/AK-toxin producer *Alternaria* are currently officially regulated as quarantine pests on *Cydonia* Mill., *Malus* Mill. and *Pyrus* L., other than seeds, originating in non-European countries (Dir 2000/29/ EC).	Small-spored AM-/AK-toxin producer *Alternaria* are currently officially regulated as quarantine pests on *Cydonia* Mill., *Malus* Mill. and *Pyrus* L., other than seeds, originating in non-European countries (Dir 2000/29/ EC).	None
Pest potential for entry, establishment and spread in the EU territory (Section 3.4)	Small-spored AM-/AK-toxin producer *Alternaria* could potentially enter, become established, and spread within the EU. Pathways of entry: 1. Host plants for planting, excluding seeds but including dormant plants, and 2. Fresh fruit of host plants	Small-spored AM-/AK-toxin producer *Alternaria* could potentially spread in the EU through movement of host plants for planting, fresh fruits of host plants, and natural means (airborne conidia). Therefore, plants for planting is a main means of spread, but not the only one.	Uncertainty on the host range of the small-spored AK-toxin producer *Alternaria* (Uncertainty 2) Absence of data on dormant host plants for planting imported from affected non-EU countries into the risk assessment area (Uncertainty 3) Uncertainty about the abundance/distribution of *Pyrus pyrifolia* in the EU28 and on the susceptibility of the grown cultivars (Uncertainty 4) Uncertainty about the maximum distance, the conidia of small-spored AM-/ AK-toxin producer *Alternaria* could travel by air currents (Uncertainty 5)
Potential for consequences in the EU territory (Section 3.5)	The introduction and spread of the pests in the EU could cause yield and quality losses in apple and pear production, but the magnitude of the impact is unknown.	The presence of the pests on host plants for planting could have a negative impact on their intended use	The contribution of small-spored AM-/AK-toxin producer *Alternaria* on the impact caused worldwide by small-spored *Alternaria* pathogenic to apples and pears is uncertain (Uncertainty 6)

Criterion of pest categorisation	Panel's conclusions against criterion in Regulation (EU) 2016/2031 regarding Union quarantine pest	Panel's conclusions against criterion in Regulation (EU) 2016/2031 regarding Union regulated non-quarantine pest	Key uncertainties
Available measures (Section 3.6)	Phytosanitary measures are available to prevent the entry of the pests into the EU (e.g. sourcing host plants for planting and fruit from pest-free areas or pest-free places of production). Inspection at the place of origin and at the EU entry point is not fully effective to prevent the entry of the pests. There are no fully effective measures to prevent establishment and spread	There are no fully effective measures to prevent the presence of the pests on host plants for planting	
Conclusion on pest categorisation (Section 4)	To the best of the Panel's knowledge, small-spored AM-/AK-toxin producer *Alternaria* are not under official control in those restricted areas where they have been found. As such, the pests do not meet all the criteria evaluated by EFSA.	Small-spored AM-/AK-toxin producer *Alternaria* can spread by movement of infected fruits, as well as by airborne conidia; therefore, they do not meet all the criteria assessed by EFSA.	There is uncertainty about the distribution of the pests in the risk assessment area, particularly where the presence of AM-/AK-toxin genes has not been tested (Uncertainty 1).
Aspects of assessment to focus on/scenarios to address in future if appropriate	Given that all the data available in the literature have been explored, the Panel considers that a survey could be carried out using appropriate pest identification methods (see Section 3.1.3) to define the current geographical distribution and impact of small-spored AM-/AK-toxin producer *Alternaria* in the risk assessment area before a full PRA is performed to reduce the uncertainty related to the conclusion of this pest categorisation.		

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Abbreviations

DG SANCO	Directorate General for Health and Consumers
EPPO	European and Mediterranean Plant Protection Organization
FAO	Food and Agriculture Organization
HST	host-specific toxin
IPPC	International Plant Protection Convention
MS	Member State
PLH	EFSA Panel on Plant Health
TFEU	Treaty on the Functioning of the European Union
ToR	Terms of Reference