

Review of EPPO's approach to Pest Risk Analysis

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1. Reasons for the review

One of the functions of EPPO set out in the Convention is to ‘*Develop technical measures necessary to prevent the introduction and spread of regulated pests, particularly measures for inspection and testing, certification, treatment, survey and eradication.*’ One important component of the EPPO Strategy to prevent the introduction and spread of pests is the analysis of the potential risks they might present for the EPPO region. This is done by conducting Pest Risk Analysis (PRAs).

Over the years different systems have been established to carry out this function (see section 3 *History of PRA in EPPO*).

In 2006, EPPO established a system of Expert Working Groups (EWG) to conduct PRAs valid for the EPPO region. The system has evolved progressively over the years and was regularly discussed at the Working Party on Phytosanitary Regulation.

The EPPO Secretariat considered that the experience acquired during the last 10 years should be reviewed in depth. At its meeting in June 2017, the EPPO Working Party on Phytosanitary Regulations agreed with conducting this review and suggested some additional issues to be considered. This review was first drafted by the Secretariat in early 2018 and presented to EPPO Panels involved in pest risk analysis. An earlier version of this document (under the reference 18-23916) was presented to the Working Party in June 2018 and included some questions and recommendations for improvement to EPPO's current PRA approach. The Working Party considered useful to publish this document as an EPPO Technical Document. This Technical Document is a slightly revised version which includes the outcomes of the discussion at the Working Party and the associated revised documents in Annexes.

This review does not consider the recently developed methodology for Regulated Non-Quarantine Pests (RNQPs)¹, and the process to assess biological control agents (EPPO PM 6/4 *Decision-support scheme for import and release of biological control agents of plant pests*, approved in 2018).

Findings and recommendations from this review will support the development of EPPO Strategy 2021-2025 in relation to the evaluation of pest risks.

2. Purpose of PRA

The International Plant Protection Convention (IPPC) was signed in 1951. It recognized ‘the usefulness of international co-operation in controlling pests and diseases of plants and plant products and in preventing their introduction and spread across national boundaries’. In 1995 the IPPC was recognised under the Sanitary and Phytosanitary (SPS) Agreement of the World Trade Organization (WTO) as the body setting global standards in the area of plant health, alongside the International Office of Epizootics (for animal health) and the Codex Alimentarius Commission (for food safety). When the IPPC itself was revised in 1997, in the context of the new World Trade Organization rules, it recognised that ‘phytosanitary measures should be technically justified, transparent and should not be applied in such a way as to constitute either a means of arbitrary or unjustified discrimination or a disguised restriction, particularly on international trade’. A more formal and elaborate process of ‘Pest Risk Analysis’ was developed (ISPM 2 and ISPM 11). PRA is defined as ‘*the process of evaluating biological or other scientific and economic evidence to determine whether a pest should be regulated and the strength of any phytosanitary measures to be taken against it*’ (ISPM 5). This form of PRA is intended not just to identify risks and recommend measures to manage those risks, but also to justify measures to trading partners who might otherwise regard the measures as ‘disguised restrictions’ on trade.

2.1. Recommendation for listing

A PRA provides the technical and scientific evidence to support the listing of a pest as a quarantine pest. PRAs produced and reviewed in the EPPO framework support the listing of pests as “recommended for regulation as quarantine pests”. It is then up to EPPO countries to decide to regulate them if they are part of the endangered area as described in the PRA (see also 4.3.1).

¹ A methodology for preparing a list of recommended regulated non-quarantine pests (RNQPs) <https://onlinelibrary.wiley.com/doi/abs/10.1111/epp.12420>

2.1. Identification and justification of risk management measures

The PRA allows the identification of phytosanitary measures at import to prevent the introduction of the pest with commodities, as well as measures to be applied in the case of a finding or an interception. A PRA for a pathway will justify measures (including prohibition) on this pathway. A PRA can also clarify why it was decided not to take measures against a specific pest, or for a specific commodity or pathway.

The IPPC and the principle of "transparency" (ISPM 1 *Principles of plant quarantine as related to international trade*) require that countries should, on request, make available the rationale for phytosanitary requirements.

It is worth noting that if a pest is not regulated or is eventually deregulated, the information which has been gathered and analysed as part of the PRA process may be very valuable in the development of routine control practices by growers. This benefit of applying thorough PRA to newly introduced pests or potential pests, whether or not a regulatory approach is followed and whether or not it succeeds, should not be overlooked.

Information gathered during the PRA process is useful to decide on action to be taken in the case of an outbreak or an interception.

Measures recommended for different pests for a given commodity may be assembled in a PM8 Standard (Commodity-Specific Phytosanitary Measures). These exist at present for potato, and for many forest tree species.

3. History of PRA in EPPO

Analysis of risks from plant pests has been an important role of EPPO since its foundation in 1951. One of the functions set out in EPPO Convention was to 'advise Member Governments on the technical, administrative and legislative measures necessary to prevent the introduction and spread of pests and diseases of plants and plant products.' This advice has always depended on an assessment of pest risks, and an analysis of the measures needed to reduce those risks. Following the SPS agreement, a more formal and elaborate process of 'Pest Risk Analysis' or PRA was developed (see point 2). EPPO started harmonizing PRA processes within the EPPO region by developing regional guidelines (see 4.1), then reviewing and conducting PRAs.

EPPO started to elaborate A1 and A2 Lists of pests recommended for regulation in the early 1970s and the first Lists were approved in 1975. Additions of pests to the A1 or A2 List were proposed by Member Governments and made on the basis of scientific documentation and expert judgement. From 2000 to 2006, the addition of a pest to the A1 or A2 List was based on the proposal of a Member Government which provided a Pest Risk Analysis (PRA) conforming to EPPO Standard PM 5/3 *Decision support scheme for quarantine pests*, and supported by compilation of data according to EPPO Standard PM 5/1 *Check-list of information required for Pest Risk Analysis*. The EPPO Working Party on Phytosanitary Regulations decided, after due consideration, whether to recommend to EPPO Council the addition of a given pest to the Lists. The Panel on Phytosanitary Measures reviewed PRAs submitted to it in relation to candidates for the EPPO lists, the Panel on Quarantine Pests Forestry itself performed PRAs on its pests of concern in the framework of a dedicated project between 2000 and 2005. For many years EPPO had operated mainly on the principle that the Organization provided the tools for PRAs to be carried out by NPPOs. However, it appeared that only a small number of NPPOs undertook such PRAs.

Since 2004 the role of EPPO in PRA has been discussed at meetings of the Organization both at the strategic level (Workshop for Heads of NPPOs on the Future of EPPO in 2004), and at the technical level (Working Party on Phytosanitary Regulations, Panel on PRA, Panel on Phytosanitary Measures in 2003, 2004 and 2005). They recognized that many countries do not have the resources to perform PRA

and consequently member countries wished that EPPO should now play an active role in organizing internationally conducted PRA in the region, in order to share costs and workload and to provide technical justification for the regulation of certain pests. They proposed that special EPPO expert groups should now carry out PRAs, as well as reviewing PRAs from other sources. They also considered that the creation of a specialized Expert Group would encourage collaboration between members and increase the quality of the PRAs produced. Finally, the EPPO Council formally approved in September 2005 the creation of special expert groups that will conduct PRAs, subsequently renamed the 'Expert Working Groups for PRA'. Member countries requested that Pest risk analyses performed through the EPPO system should include risk assessment as well as the identification of suitable risk management options. Each member country then decides which management options it wants to include in its legislation according to its level of protection. PRAs are done for a clearly defined area (EPPO region or a specific area on request) and the endangered part of the area is specified as a result of the PRA.

4. EPPO PRA activities

4.1. Existing EPPO Standards

Number	Title of Standard	First adoption	Last revision
PM 5/1(1)	Check-list of information required for pest risk analysis (PRA)	1992	
PM 5/2(2)	Pest risk analysis on detection of a pest in an imported consignment	1992	2001
PM 5/3(5)	Decision-support scheme for quarantine pests Also available in CAPRA (Computer Assisted Pest Risk Analysis) software	1997	2011
PM 5/4(1)	Pest Risk Management Scheme	2000	Merged with PM 5/3
PM 5/5(1)	Decision-Support Scheme for an Express Pest Risk Analysis Also available in CAPRA software	2012	-
PM 5/6(1)	EPPO prioritization process for invasive alien plants	2012	
PM 5/7(1)	Screening process to identify priorities for commodity PRA for plants for planting	2013	
PM 5/8(1)	Guidelines on the phytosanitary measure 'Plants grown under complete physical isolation'	2016	
PM 5/9(1)	Preparation of pest lists in the framework of commodity PRAs	2017	

Development of EPPO Standards on PRA started in the 1990's. While contributing to the development of the ISPMs on Pest Risk Analysis such as ISPM 11 *Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms* (IPPC, 2007), EPPO has also developed a regional scheme for PRA now called the *EPPO Decision-support scheme for pest risk analysis of quarantine pests*. Compared to ISPM 11, this scheme has the added value of guiding the assessor through a logical sequence of questions covering all elements mentioned in this ISPM. The scheme was revised in 2011 in the framework of the European Union 7th framework program project PRATIQUE. A piece of computer software named CAPRA has also been developed by the EPPO Secretariat in the framework of PRATIQUE and with the support of the EPPO Panels. This computer system assists pest risk analysts to run the EPPO decision-support scheme for PRA of quarantine pests and is freely available on the EPPO website (<http://capra.eppo.int>). EPPO has also recently developed a *Decision-Support Scheme for an Express Pest Risk Analysis* (PM 5/5(1)) which provides a simplified scheme for the rapid production of pest risk analyses (EPPO, 2012). PM 5/5 has a similar structure to PM 5/3 but has a much more limited number of questions. The Panel on PRA Development underlined during its development that it should be used mainly by experienced risk assessors and that, if it was not clear what information should

be provided in each question, assessors may refer to the same section in PM 5/3 where all factors to be considered are listed. As requested by the Working Party on Phytosanitary Regulations in 2016, the Express PRA scheme (PM 5/5) is now also available in CAPRA. During their meeting in 2014 core members also suggested that PM 5/5 should include additional guidance, tools and examples as it is the case in the computerized version of PM 5/3. This has not been done yet mainly due of a difficulty with the IT development as the CAPRA software dates to 2009 and is now unstable.

In addition to PM 5 Standards, Standards PM 9/18 *Decision-Support Scheme for prioritizing action during outbreaks*, and PM 9/10 *Generic elements for contingency plans* may be used as guidance when drafting the pest risk management part of the PRA.

4.2. Current EPPO PRA process

4.2.1. Identification of emerging pests or pathways

Numerous new or emerging pests are reported in EPPO countries or elsewhere in the world that may be of concern for the EPPO region and for which it may be needed to raise awareness or to evaluate the need for action based on a PRA.

The EPPO Secretariat established the Alert List in the 1990s. The main purpose of the Alert List is to draw the attention of EPPO member countries to certain pests possibly presenting a risk to them and achieve early warning. It is also used by EPPO to select candidates which may be submitted to a PRA. The pests in the Alert List are selected by the EPPO Secretariat, mainly from the literature but also from suggestions of NPPOs of member countries. Candidates for the Alert List may also be suggested by Panels. The development of network of sentinel plants such as IPSN² (developed within the Euphresco network) will also be a useful input to identify emerging pests in future.

All pests on the Alert List are selected because they may present a phytosanitary risk for the EPPO region. The reasons for considering inclusion to the Alert List can be of various nature: e.g. pests which are new to science, new outbreaks recorded in the EPPO region or in other parts of the world, reports of rapid spread. A short datasheet is prepared for each pest added to the Alert List and relevant data is maintained in EPPO Global Database.

For the moment the EPPO Secretariat is not trying to monitor emerging pathways, and this has not been suggested so far as a task for EPPO.

4.2.2. Selection of pests and pathways for PRA

For pests other than plants, the identification of priorities for PRA relies on expert judgment and is mainly based on the EPPO Alert List. To identify priorities, experts in the Panel on Phytosanitary Measures consider important factors such as current geographical distribution, importance of the crops concerned, rapidity of natural spread, potential pathways, impact, availability of data. The availability of a national PRA is also considered. The Panel ranks pests by priorities for PRA. Those priorities are reviewed by the Working Party on Phytosanitary Regulations which decides on the work programme for the year to come. However, if considered relevant by the Panel, an EWG may be organized before the approval of the Working Party to address an urgent need.

A prioritization process (PM 5/6 *EPPO prioritization process for invasive alien plants*) is applied to identify priorities for PRA for invasive plants. This was useful when the EPPO work on IAP was initiated in 2002 as numerous candidates were submitted by member countries and it was not possible to conduct PRAs for all candidates.

An *ad hoc* prioritization process was also designed in the framework of the EPPO Study on Pest Risks Associated with the Import of Tomato Fruit to select 5 pests from the 43 species identified during the study on which short PRAs should be conducted.

The identification of pathways for pathway studies has not been structured: the studies of plant for planting, tomato fruit and wood commodities were punctual proposals made by the Panel on

² <https://www.bgci.org/plant-conservation/ipsn/>

Phytosanitary Measures and the studies on other fruit resulted from the implication of EPPO in an EU-funded Project (DROPSA³).

The identification of priorities for pest-specific PRAs has not been a problem for the Panel on Phytosanitary Measures. It has never been suggested to develop a formalized prioritization system similar to the PM 5/6 used for plants. However, this has been done by several member countries in recent years (e.g. Finland, France, the Netherlands, Norway, and the United-Kingdom⁴). Pests identified as a priority for a PRA at national level are usually discussed by the relevant EPPO Panels to consider if they should be a priority at EPPO level.

Concerning the identification of emerging pathways, within the Euphresco project G-228 'Assessment and prioritisation of pathways'⁵ models used in the UK have been presented to identify emerging pathways.

4.2.3. Preparation of pest-specific PRAs by EWGs

Since 2006, a new system has been established and special expert groups have been created to conduct PRA (Expert Working Groups (EWG) for PRA). The document *Background information on EPPO and the system established to perform PRA in the EPPO framework* (Annex 3) describes in detail the structure and working procedures of the PRA EWGs and the document 18-23922 (Annex 4) describes the role and working procedures of core members. In general, a literature search is conducted, and a draft PRA is prepared in advance of the meeting (by the Secretariat or an expert of the EWG). The PRA is thoroughly reviewed and amended typically during one meeting of the EWG, with limited follow-up. It is then reviewed for consistency by core members, and by the relevant Panels to review phytosanitary measures (Panel on Phytosanitary Measures and Panel on Invasive Alien Plants, as well as specialized Panels if needed).

Initially, EPPO EWGs produced the PRAs according to EPPO Standard PM 5/3. Based on the recommendations of a meeting of core members (2014-06-03/04), the Working Party agreed in 2014 that the newly adopted PM 5/5 *Decision-Support Scheme for an Express Pest Risk Analysis* should preferably be used for EPPO PRAs. Outcomes were considered as sufficiently informative and much easier for risk managers to read and understand.

To constitute an EWG, a call for experts is sent to the Heads of NPPOs. In addition, the Secretariat may also contact relevant experts directly both from within the EPPO region and more globally. However, all EWG members from the EPPO region should be approved by their NPPO (which is generally a straightforward process). Typically, an EWG will involve 5-8 experts (including at least one expert with experience of the pest in the area of origin and one core member) and one or two members of the Secretariat. The participation of the core member(s) and the Secretariat aims to maintain consistency between different PRAs. The participation of experts from non-EPPO Countries has been considered very beneficial in all EWGs.

Calling for experts to NPPOs is considered an effective way to identify suitable experts. It is also considered a good way to raise awareness on pests of concern. However, the call for experts does not always allow the whole range of expertise needed in relation to a PRA to be covered. In particular few experts are nominated for invasive alien plants generally (and only a few core members have expertise on invasive plants), and also in relation to issues such as climate mapping or other modelling, production of host crops or economics.

The Secretariat will establish a database of possible experts and strengthen EPPO's network to better identify experts e.g. on invasive plants, modelling, plant production industry, national or

³ https://www.eppo.int/QUARANTINE/Pest_Risk_Analysis/dropsa.htm

⁴ See presentations made at the Joint EFSA-EPPO Workshop: *Modelling in Plant Health – how can models support risk assessment of plant pests and decision making?* http://archives.eppo.int/MEETINGS/2016_conferences/efsa-eppo_modelling.htm

⁵ The project runs from 06/2017 to 03/2018. A description is available at <https://zenodo.org/record/1188772#.Wp0-bujOXcs>

international professional networks specialized on a crop. The involvement of stakeholders in the PRA process may also help raising awareness and achieve early warning. This issue should be considered along with other stakeholders other EPPO work during the revision of EPPO Strategy.

4.2.4. Review (and amendment) of national pest-specific PRAs to support EPPO recommendations

As noted under point 3, national PRAs have been used to support EPPO recommendations since 2000. It was agreed by the Working Party in 2006 that, to be able to address urgent phytosanitary concerns, it was necessary to carry on using national PRAs as a basis of EPPO recommendations 'for a transitional period'. Since then, the Panel on Phytosanitary Measures confirmed that the consideration of national PRAs is useful, and the Working Party agreed to carry on adding pests to the A1/A Lists based on a national PRA if it is considered valid for the EPPO region. The process to review the PRAs has been established (see Annex 5), and point 5 Other PRA activities in the EPPO region). PRAs considered as relevant by NPPOs are submitted to the Panel on Phytosanitary Measures. In most cases, those national PRAs have been prepared for a pest recently found in the country. A first screening is made by the Secretariat, which may decide to send it for review to core members. Depending on the cases, the PRA is then either agreed without modification if it fulfils all criteria, or amended in coordination with the NPPO which drafted it, or an EPPO PRA report is prepared together with the Panel where relevant information from the PRA is summarized and additional information is added whenever relevant.

4.2.5. Preparation of pathway analyses

In recent years, EPPO produced several studies on risks associated with specific pathways (plants for planting⁶, tomato fruit⁷, wood commodities⁸ and, in the framework of the EU DROPSA project apples, vaccinium fruit, table grapes, orange and mandarin⁹). The study on plants for planting and on wood commodities aimed to identify the main pest risks associated with these commodities. The studies on tomato and fruits aimed to list pests from all over the world, that were not already regulated by EPPO countries, and not present in the EPPO region (or the EU) and could pose a risk for EPPO countries. They involved gathering information on pest distribution, host range and impact. The outcome is a short list of pests that could be introduced with the commodity and could threaten host crops in the EPPO region and for which short datasheets are prepared. However, these analyses are not commodity PRAs, as they do not include a section on management of the risk. This work was detailed in EPPO Technical Document No. 1074¹⁰ and supported the development of Standard PM 5/9 *Preparation of pest lists in the framework of commodity PRAs*.

It should be noted that some EPPO countries have expertise in producing pathway analyses, in particular to support export of their commodities to non-EPPO countries when a PRA is required to open markets.

These commodity studies were very labour intensive: as the EPPO region is large and the trade is versatile, the pathway analyses covered import for all countries in the world. The EPPO Secretariat cannot ask for pest lists or specific information on pest management directly to exporting countries

⁶ EPPO Study on the Risk of Imports of Plants for Planting Steps 1-3 EPPO Technical Document No. 1061 https://www.eppo.int/QUARANTINE/EPPO_Study_on_Plants_for_planting.pdf

⁷ EPPO Technical Document No. 1068 EPPO Study on Pest Risks Associated with the Import of Tomato Fruit https://www.eppo.int/QUARANTINE/DT_1068_Tomato_study_MAIN_TEXT_and_ANNEXES_2015-01-26.pdf; see also summary article in the EPPO Bulletin <https://onlinelibrary.wiley.com/doi/epdf/10.1111/epp.12180>

⁸ EPPO Study on wood commodities other than round wood, sawn wood and manufactured items. Technical Document no 1071. https://www.eppo.int/PUBLICATIONS/TD-1071_EPPO_Study_on_wood_commodities.pdf

⁹ https://www.eppo.int/QUARANTINE/Pest_Risk_Analysis/dropsa.htm; Suffert et al. 2018 <https://onlinelibrary.wiley.com/doi/10.1111/epp.12462>

¹⁰ EPPO Secretariat's approach for commodity studies. EPPO Technical Document No. 1074 https://www.eppo.int/QUARANTINE/DT1074_Secretariat_approach_for_commodity_studies.pdf

(whereas NPPOs of trading partners have the right to do so according to the IPPC). In general, it is difficult to retrieve information on industry practices to be able to describe the commodity and assess the role of current practices on pest survival.

These analyses gather a large amount of data but it is not fully retrievable for further use. At present, all short datasheets for pests identified during these analyses have been made available in Global Database. However, they are not linked to dynamic data in Global Database.

The development of commodity specific International Standards for Phytosanitary Measures has been strongly promoted by EPPO within the IPPC framework. One of the possible ways forward is the further consideration of regional commodity Standards, such as EPPO's PM8 series, as models.

The approach of pathway analyses conducted to-date is considered useful as it may help in develop management measures that can cover different pests, as well as not-yet identified pest risks.

The new EU Regulation 2016/2031 on protective measures against pests of plants, that should enter into force on 13th December 2019, allows the possibility to prohibit the introduction of high risk commodities based on a preliminary assessment pending a risk assessment being carried out (Article 42). These high-risk plants, plant products and other objects are now listed in implementing acts ¹¹.

Work to identify high risk pathways has also been done by many EU countries, often based on data extracted from Global Database. It should be noted however that not all pathways considered in PRAs are categories of 'host commodities' in Global Database. In addition, data on pathways is available only for regulated pests, and there is a backlog for some pests as this data could not be entered for several years in Global Database because of IT problems. The Panel on Phytosanitary Measures recommended at its meeting in 2018-03 that more resources are put into Global Database to help on pathway analysis.

However, for EU countries, the body in charge of performing commodity risk assessment will be EFSA (see point 5.2)

The Working Party on Phytosanitary Regulations agreed at its meeting in June 2018 that developing a commodity PRA scheme was not a priority for EPPO. However EPPO's work on pathway analysis should continue. Commodity PRAs prepared by EPPO countries may be usefully shared via the EPPO Platform on PRAs.

4.2.6. Preparation of analysis for group of pests for a specific pathway

A study is under way on bark and ambrosia beetles on non-coniferous wood. This approach is attempting to cover several pest species with a similar life cycle, for a commodity which may comprise any of several host plants. By identifying case studies, management measures should be identified that could cover all bark and ambrosia beetles. The Panel on Phytosanitary Measures was very appreciative of the work done and the evidence gathered. However, concerns were about raised whether such studies would be sufficient to make a case at WTO-SPS.

The Panel on Phytosanitary Measures suggested that a similar approach could be developed for other groups of pests such as tropical *Meloidogyne* species. The Working Party agreed that such studies on the risk posed by a group of pests for a specific pathway are useful and that this approach could be repeated for other groups of pests on other commodities.

4.2.7. Impact on the revision of the pest taxonomy

The revision of the taxonomy of an A1 or A2 pest may have consequences on the need for regulation. The process to evaluate these consequences and the need for a new (or revised) PRA is explained and illustrated with recent examples in Annex 6.

¹¹ Commission Implementing Regulation (EU) 2018/2019 of 18 December 2018 establishing a provisional list of high risk plants, plant products or other objects, within the meaning of Article 42 of Regulation (EU) 2016/2031 and a list of plants for which phytosanitary certificates are not required for introduction into the Union, within the meaning of Article 73 of that Regulation. http://data.europa.eu/eli/reg_impl/2018/2019/oj

4.3. Adoption of recommendations based on PRA

4.3.1. Listing in EPPO A1/A2 Lists

A PRA supports the listing of a pest as quarantine pest and defines the endangered area.

The purpose of EPPO A1 and A2 Lists is described in the introduction of EPPO Standard PM 1/2 *EPPO A1 and A2 Lists of pests recommended for regulation as quarantine pests* (available at <https://gd.eppo.int/standards/PM1/>), as revised in 2019.

After the adoption of the SPS Agreement in 1995, the EPPO Working Party discussed the relevance of the A1 and A2 Lists at regional level. According to a certain interpretation of the SPS Agreement, countries are only technically justified in protecting plant life and health on their own territories. Thus, quarantine pests only concern individual countries and RPPOs have no basis to draw up A1 and A2 Lists, but only to advise countries of a single list of recommended quarantine pests for their members, which will be A1 or A2 for each individual country according to its pest status.

However, it was agreed that EPPO should continue to recommend A1 and A2 Lists. Justifications were stated in a specific document drafted in 1995 (see Annex 1 EPPO Concept of A1 and A2 Lists and the Principle of Solidarity)

At its meeting in 2016, the Working Party raised the following questions on the implications of the listing as A1 or A2 pest:

- Is A1/A2 listing linked only to the pest distribution or to the type of measures recommended (i.e. all countries needs to take measures vs only some countries)?
- Should a pest be listed as a A2 when it is present in a potential EPPO country?
- Should EPPO make clear recommendations on which countries should regulate a pest?

When the document in Annex 1 was further discussed by the Panel on Phytosanitary Measures in 2018 in the framework of this review, they considered that the A1 and A2 concept are not linked to the strength of the measures applied against it. The Panel also considered that not all EPPO countries need to take measures against an A1 pest. The listing of a pest on the A1 or A2 EPPO List is based on its known distribution within the EPPO region: pests are recommended for regulation as quarantine pests, they are A1 pests for the EPPO region if they are not present in the EPPO region, and A2 if they are present in the EPPO region but not widely distributed there and being officially controlled. Consequently, a pest should be listed as an EPPO A1 pest if it is not present in an EPPO country even if it is present in a potential EPPO member country.

Of course, an A2 pest for the EPPO region, may be an A1 pest for most EPPO countries or may qualify as a Regulated Non-Quarantine Pest in some other countries. The geographical distribution of EPPO A1/A2 pests is provided in EPPO Global Database and in EPPO datasheets.

Outbreaks of A1 pests in EPPO countries are reviewed annually by the Panel on Phytosanitary Measures to consider whether they are eradicated or whether eradication is not possible, in the latter case the pest should be transferred to the A2 List. Transfer of pests from the A1 to the A2 list is submitted for approval to the Working Party on Phytosanitary Regulations and to Council. The information is then made available in Global Database, and in EPPO Reporting Service.

4.3.2. Endangered area

EPPO Standard PM 1/2 states that “it is accepted that certain pests appearing in the A1 and A2 Lists, though of concern to some Member Governments, may not be of concern to all the countries from which they are absent, and in particular that it may not be necessary or useful for all countries to take measures contributing to the protection of those countries which are at risk from these pests. Therefore, the Pest Risk Analysis process aims to identify the part of the EPPO region which is endangered”.

Since 2006, the endangered area is specified in PRAs conducted by EPPO. EPPO countries may decide on this basis to regulate the pest as a quarantine pest for their own territory or not, depending whether

their territory belongs to the endangered area or not (and whether they have free trade arrangement with countries within the endangered area, a reason to apply the “solidarity principle”).

PRAs on invasive plants conducted within the LIFE IAP – Risk project (see Box 1) explicitly list countries in the endangered area whereas PRAs on pests may be more general (e.g. *Massicus raddei* ‘could establish where oak (*Quercus* spp.) and chestnut (*Castanea* spp.) are grown’ in the EPPO region).

The endangered area is currently defined in the PRA¹². A difficulty may be that in practice the endangered area is not always easy to define precisely because of lack of data (e.g. climatic requirements of the pest, distribution of different host plants).

EPPO countries should decide on this basis whether they should regulate EPPO A1/A2 pests as quarantine pests on their territories.

4.3.3. Phytosanitary measures recommended to Member Countries

The PRA provides the identification of phytosanitary measures at import to prevent the introduction of the pest with commodities, as well as measures to be applied in the case of a finding or an interception. A PRA for a pathway will justify measures (including prohibition) on this pathway.

The IPPC and the principle of "transparency" (ISPM 1 *Principles of plant quarantine as related to international trade*) require that countries should, on request, make available the rationale for phytosanitary requirements.

Decision not to regulate a pest

A PRA is also useful to clarify why it was decided not to take measures against a specific pest. It is worth noting that if a pest is not regulated or is eventually deregulated, the information which has been gathered and analysed as part of the PRA process may be very valuable in the development of routine control practices by growers. This benefit of applying thorough PRA to newly introduced pests or potential pests, whether or not a regulatory approach is followed and whether or not it succeeds, should not be overlooked.

Adoption of measures for a pest

Up to 1999 EPPO pest-specific phytosanitary measures (PSPRs, formerly Specific Quarantine Requirements -SQRs) were adopted as Standards in series PM 2. Different Panels also drafted some PSPRs e.g. for forestry or potato pests. About 300 SQRs/PSPRs have been adopted over the years. Member governments were recommended by EPPO Council to align their regulations to the SQRs.

The work on these Standards was put on hold for several years because it was recognized that most EPPO countries operated on the basis of EU requirements (directly or indirectly). In 2006 the Working Party agreed that PM 2 Standards should be withdrawn, and that PRAs prepared by EPPO should propose several management options which countries can use to decide how they will regulate a quarantine pest. The Working Party agreed that these management options are comparable to the PSPRs.

The issue was raised recently while preparing Commodity-specific Phytosanitary Measures Standards (series PM8), on the status on recommendations for management measures defined in a PRA. Indeed, PRAs are not sent for country consultation and adopted, whereas Standards in series PM 2 were. It was also noted that PRAs for pests with a similar biology did not necessarily recommend a set of similar measures (but this was often due to recent research results influencing the newer recommendations).

The Working Party agreed that the set of recommended measures is agreed when a pest is added to the EPPO A1/A2 Lists.

Inconsistencies in measures identified during the drafting of PM 8 Standards will be highlighted by the Panel in charge. The Secretariat (together with the Panel on

¹² and summarized on the webpage https://www.eppo.int/ACTIVITIES/plant_quarantine/A1_A2_recent_add

Phytosanitary Measures) if needed should decide whether PRAs should be amended to solve those issues. This will help further harmonizing measures.

Consistency of wording for measures (tool kit vs tailored approach)

EPPO Standard PM 5/3 provides a structured analysis of the measures that can be recommended to minimize the risks posed by a pest or pathway. A set of questions explores options that can be implemented (i) at origin or in the exporting country, (ii) at the point of entry or (iii) within the importing country or invaded area. A summary table referring to these questions is used in PM 5/5. The EPPO Secretariat has worked with EFSA on a standardised checklist of risk reduction options. It is now part of the Guidance of the EFSA Plant Health Panel on quantitative pest risk assessment (EFSA, 2018, <https://doi.org/10.2903/j.efsa.2018.5350>). This document provides an Inventory of risk reduction options and a link to the corresponding information sheets both for the control and the supporting measures (<http://doi.org/10.5281/zenodo.1164805>). This experience showed that it is not easy to have a meaningful limited set of standardized phytosanitary measures.

In the development of phytosanitary measures for specific pests, the recommendation of the Panel on Phytosanitary Measures so far has been to recommend measures tailored for the pest: e.g. it should not be stated that an 'appropriate' heat treatment will be relevant (as was done in Standard PM 2), but during the PRA it should be checked that data is available to support that a heat treatment at a given temperature for a given time will provide a sufficient level of protection. *It is recognized that it may be difficult for the industry and the trade to comply with similar but different schedules for different pests on the same commodity.*

In EPPO datasheets, the measures are summarized succinctly.

An IPPC Standard on risk management is under development¹³ and may be taken into account to revise the risk management section of the PRA scheme.

The Working Party did not consider as a priority for EPPO to standardize the wording in the formulation of recommended measures.

Box 1. LIFE IAP – Risk project

The LIFE IAP-RISK project was coordinated by the EPPO, in collaboration with the UK NERC Centre for Ecology and Hydrology. The project was initiated in February 2016 and will finish in June 2018. The objectives of the project were to:

- To determine which species from the EPPO List of Invasive Alien Plants and the horizon scanning exercise (ENV.B.2/ETU/2014/0016) have the highest priority for a risk analysis,
- To assess 16 invasive alien plants by performing a risk analysis which is fully compliant with the Regulation (EU) no. 1143/2014,
- To facilitate knowledge transfer and capacity building in pest risk analysis within the EU.

From a list of 37 plant species, 16 species were identified as having a high priority for risk assessment using an updated prioritization scheme compliant with the Regulation (EU) No. 1143/2014. The 16 species (*Ambrosia confertiflora*, *Andropogon virginicus*, *Cardiospermum grandiflorum*, *Cinnamomum camphora*, *Cortaderia jubata*, *Ehrharta calycina*, *Gymnocoronis spilanthoides*, *Hakea sericea*, *Humulus scandens*, *Hygrophila polysperma*, *Lespedeza cuneata*, *Lygodium japonicum*, *Pistia stratiotes*, *Prosopis juliflora*, *Salvinia molesta* & *Sapium sebiferum*) were risk assessed using a modified version of the Express PRA Scheme (PM 5/5). Additional text was incorporated into the document to explain and detail the ecosystem services the user should consider along with a new section on climate change

¹³ Specification for this ISPM is available at <https://www.ippc.int/en/publications/81795/>. A short report of the EWG is available at <https://www.ippc.int/en/news/meeting-of-the-expert-working-group-on-guidance-on-pest-risk-management-successfully-held-in-malta/>

to capture the influence of climate change on the introduction, establishment, spread and impact of the invasive alien plant.

See the project's website for further details: <http://www.iap-risk.eu>

4.3.4. Development of EPPO Standards based on PRAs

Within the EPPO framework, information gathered during the PRA process is useful to decide on action to be taken in the case of an outbreak or an interception. It can be used to develop a recommendation for official measures to control the pest such as in a Standard in series PM 9 *National Regulatory Control System*. This was done for many invasive alien plants

Measures recommended for different pests for a given commodity may be assembled in a PM8 Standard *Commodity-Specific Phytosanitary Measures*. This exists for the moment for potato, and several wood products¹⁴.

Once a pest is recommended for addition to the A1/A2 Lists, other relevant Standards may be developed such as Standards on Phytosanitary Inspections (PM 3), or a Diagnostic Protocol (PM 7).

4.4. Dissemination of PRAs – EPPO Platform on PRAs

When agreed by the Panel on Phytosanitary Measures or the Panel on Invasive Alien Plants, PRAs are presented to the Working Party on Phytosanitary Regulations to approve the addition of the pest to the A1/A2 list, and to agree on the proposed management measures. Once the addition of the pest to the A1/A2 List is approved by Council, EPPO PRAs (or national PRAs used to support EPPO recommendation) are made available in EPPO Global Database and the EPPO Platform on PRAs. Data on distribution and host plants is entered (and then updated) in Global Database.

EPPO PRAs concluding that a pest should not be recommended for regulation are also available in Global Database and the EPPO Platform for PRAs.

In September 2018 EPPO launched the EPPO Platform on PRAs (<https://pra.eppo.int/>) where EPPO member countries may made their national PRAs available (see point 5.1). The objective is to share PRAs that are completed, as well as plans to conduct PRAs in the EPPO region. EFSA also agreed to share their PRAs in this Platform. As of March 2019, more than 700 pest risk assessment documents were available in the Platform.

4.5. Training on PRA

EPPO has organized workshops to train experts on EPPO PRA methodology during the development of successive versions of Standard PM 5/3. Training on PRA methodology for pests slowed down after 2012 and training was then more focused on prioritization process for invasive plants. In recent years, the Better Training for Safer Food initiative (http://ec.europa.eu/chafea/food/calendar.html#Risk_Assessment) organized (free) training for dozens of experts (of EU countries as well as candidate, acceding, and associated countries) training on PRA concept and methodology (based on ISPM 11). In the last three years, EPPO staff contributed as tutors in BTSF trainings, or conducted dedicated training at the request of EPPO countries in Eastern Europe and Central Asia. Training workshops were organized on prioritization and pest risk analysis for invasive alien plant species¹⁵ in 2016 and 2017.

Finally, on request, experts involved in risk assessments in their countries can also attend an EWG as observers to become familiar with EPPO methodology. It should be underlined that most scientists taking part in EPPO EWGs are not familiar with the PRA methodology and the EWG itself provides a form of training. Feedback forms collected after EWGs have showed that experts are very satisfied with this experience and gain a better understanding of the purpose a PRA, the complexities involved with compiling a PRA and the need for phytosanitary regulations.

¹⁴ <https://gd.eppo.int/standards/PM8/>

¹⁵ http://archives.eppo.int/MEETINGS/2016_conferences/ias_workshop1.htm

During the LIFE project (see Box 1) as 16 PRAs were conducted in a short time frame, some experts were involved more than one EWG. One modeller from the UK Centre of Ecology and Hydrology was involved in every EWG either in person or remotely allowing for a greater understanding in what was required from the experts following the initial EWGs. This allowed time saving in terms of explaining the PRA process and improved consistency of assessments. The Secretariat will try to organize webinars in advance of the EWG meeting to explain the methodology, as was done during the EPPO project on RNQPs.

4.6. Resources and timelines

4.6.1. Budget

In the EPPO Secretariat, 4 staff members and a consultant are working part time on PRA, and two on early warning. The full-time equivalent is about 2 persons.

The budget for EWGs covers expenses of invited experts (travel and substance for the meeting of the EWG) but experts are not paid for their work before, during and after the EWG. They may only be paid a fee if they prepare the draft PRA (1250 Euros) or draft a datasheet (250 Euros).

Since the system of EWGs for PRA has been established in 2006, the Working Party has expected that 5 pests (including 1 invasive alien plant) are evaluated by expert working groups every year. Including the expenses reimbursed to EWG participants and associated preparation and staff time, each PRA costs EPPO in the order of 10 000 - 20 000 Euros to produce. Experts are not paid for their work before, during or after the meeting (altogether about 5-10 days for each expert for a PRA following PM 5/5). Core members spend about 0.5 to 1 day reviewing a PRA prepared according to PM 5/5 (it was twice as long when following PM 5/3). It is considered that time spent by the EPPO Secretariat is 22 to 30 days (including the preparation of the draft PRA, and the management of comments after the EWG). Members of the Panel on Phytosanitary Measures (or the Panel on Invasive Alien Plants) will also spend at least half a day to review each PRA (as part of their preparation and during the Panel meeting). Depending on the comments made during the Panel, an additional 0.5-2 days may be spent by the Secretariat to finalize the PRA for the Working Party on Phytosanitary Regulations.

Pathway analyses for tomato and fruit were conducted on specific budgets and needed about 60 days of work by the Secretariat for each commodity.

4.6.2. Timelines (from preparation to use by EPPO Member countries)

The timeline between the identification of a pest as a priority for PRA to the use by Member countries is outlined in the table below. It should be noted that the time indicated does not represent the working time, but the time needed to make the necessary arrangements and data collection.

Steps of development of the PRA	Time
Identification of a pest as a priority for PRA, and setting up the EWG	About 6 months (during which a first draft PRA is prepared and relevant experts are identified and contacted)
Conducting the PRA by the EWG	3.5 days for one pest (5 days for 2 invasive plants in LIFE IAP – Risk project)
Finalisation of the PRA after the EWG	About 1 month (in consultation with the EWG)
Consultation of core members and review of the draft taking into account core member comments	About 6-8 weeks (consultation of the EWG may be needed)
Review of the PRA to the relevant Panels	Panel on Phytosanitary Measures meets twice a year (in March and December). Panel on Invasive Alien Plants meets once a year in June. Depending on the subject and the other documents on the agenda of the Panel, 2 meetings may be

	necessary (consultation of the EWG may be needed)
Presentation to the Working Party (June) to approve recommendation for listing and risk management options	Annual meeting in June
Recommendation for listing by Council (September)	Annual meeting in September
Publication of the PRA	Usually in October
Consideration of the PRA by risk managers leading to regulation of the pest (based on the experience with pests listed by the EU)	2 to 4 years

When a EWG is organized in September-December, the PRA can be presented to the Panel on Phytosanitary Measures in March of the following year, and for approval by the Working Party on Phytosanitary Regulations in June, so the shortest time between the EWG and the recommendation for listing is 9-12 months. However, this time can increase up to 18-24 months for EWGs meeting between January and August (e.g. if a pest is identified as a priority for PRA by the Panel on Phytosanitary Measures in October 2017, the EWG is organized in March 2018, the PRA is reviewed by the Panel on Phytosanitary Measures in October 2018, and the recommendation for listing is made in September 2019).

The situation has been improved since 2011 because the Panel on Phytosanitary Measures now meets twice a year (instead of only once a year). In specific cases, PRAs have been discussed by teleconference to help speed up the process. However, the Panel on Phytosanitary Measures prefers discussing PRAs in face to face meetings.

During the Working Party in 2018, EPPO Countries considered that this timeline between the identification of a pest as a priority for PRA to its regulation was acceptable.

5. Other PRA activities in the EPPO region

Within the EPPO region, PRAs are performed at national level (by the NPPO or a dedicated agency), by EFSA for the EU territory and by EPPO for the EPPO region. In addition a number of PRAs are conducted by researchers, or within research projects as well as by technical institutes.

5.1. Production of PRAs by NPPOs or associated agencies

The production of national PRAs are presented in detail in the document on outcome of the EPPO survey on the use PRA schemes in the EPPO region (see Annex 7).

Although one of the reason to establish the EPPO EWGs for PRA was the idea that EPPO member countries did not have the resources to perform PRA themselves, the survey conducted at the end of 2015 showed that many countries do perform PRAs and have recently established PRA teams.

Among the 24 EPPO countries that completed the questionnaire, 16 countries declared that they prepare PRAs or other analysis of pest risk, and 16 declared that they contribute to EPPO or EFSA PRAs. The EU report 'Identification and response to new plant health risks'¹⁶ identifies 2 additional EU countries that prepare PRAs.

Most countries preparing PRAs nationally also contribute to other PRAs (EFSA or EPPO). Between 2014-2015, the most common circumstances for use of risk assessment schemes were the finding of an infestation/incursion, the detection of a pest at import, the re-evaluation of phytosanitary measures (in particular in the framework of harmonization of pest lists in the Eurasian Economic Union, and the identification of priority pests in the EU) and horizon scanning.

¹⁶ Report available at <https://publications.europa.eu/en/publication-detail/-/publication/a21fa318-8c64-11e7-b5c6-01aa75ed71a1/language-en>; doi:10.2875/72108

A majority of countries (16) perform PRAs only for their country, 8 countries for their country or a group of countries such as the EU or the Eurasian Economic Union, and only 2 for their country or the EPPO region (ES, GB). In some cases, the PRA is conducted only for the country but with an indication of the potential risk for other countries in the region.

14 countries have a dedicated team or person performing PRA (within the NPPO or within an agency working for the NPPO) whereas 10 countries do not have any dedicated team and involve experts depending on the pests of concern. The situation is very diverse within the EPPO region, with for example, a recently established team of 27 persons in Poland working on PRAs, producing about 20 PRAs per year, and in other countries the equivalent of 0.1 full-time person working on PRA.

At present, most NPPOs use a national scheme, several of them using a scheme which is similar to Standard PM5/5¹⁷ but in their national languages. EPPO Standard PM 5/3 is also used occasionally.

Time to complete a PRA is between 1 day and 1 year depending on the circumstances (e.g. more rapid for an interception but longer for new trade, re-evaluation of measures, and release of a biological control agent).

National PRAs may be used as a trigger for an EPPO PRA or may be the basis of EPPO recommendation if considered suitable by the Panel on Phytosanitary Measures (see document on review of national PRAs 18-23710 in Annexes). If necessary, the Panel may complement the PRA with additional information to cover the entire EPPO region. The Panel always review management measures to check that they are relevant and consistent with measures recommended for similar pests.

The survey on the use of PRA schemes showed that a large number of national PRAs are produced (several hundred over the last years). The Working Party agreed in 2017 that it would be interesting to share them (publicly or with a restricted number of identified users). The EPPO Secretariat released the EPPO Platform on PRAs in September 2018 (<https://pra.eppo.int/>) Both pest-specific and pathway PRAs are posted and that the database will also include PRAs concluding that no action should be taken for a pest. The Platform already includes more than 700 risk assessments produced by EPPO, EFSA, and some national authorities. EPPO Member Countries are encouraged to share their national PRAs on the EPPO Platform.

5.2. EFSA

5.2.1. EFSA methodology in plant health

Between 2010, when it started performing PRA and 2018, the EFSA PLH Panel used an adapted version of the EPPO PRA scheme for quarantine pests (Standard PM 5/3, version 2007). The version was adapted in order 'to follow the fundamental principles of risk assessment as laid down in Regulation (EC) No 178/2002, most importantly the independence and transparency of risk assessments carried out by EFSA'. In particular the assessment of economic impacts and expressing environmental impacts in economic terms is explicitly outside the remit of EFSA. It should be noted that the EFSA guidance was not revised after the revision of the EPPO scheme in 2011 (in particular the section on risk management, and the new section on environmental risk assessment).

Therefore, for the period 2010-2017, EFSA and EPPO have worked on slightly different but similar qualitative PRA schemes.

EFSA decided in 2016 to develop a "quantitative" methodology to be more consistent with what is done in other areas of work of EFSA. This methodology has been developed between 2016 and 2018 and has been applied so far to 8 case studies. These PRAs have been conducted for pests already regulated in the EU. They are currently under review by the EU annexes working group and the Standing Committee on Plant Health. It is not possible to know for the moment whether this approach is more helpful for the decision makers. However, it is underlined in the new methodology that it "involves a terminology which risk assessors and risk managers are perhaps unfamiliar with. Therefore, a glossary of terms is provided to facilitate learning and understanding."

¹⁷ EPPO Standard PM 5/5 was elaborated on the basis on the German and UK Express PRA scheme

The new methodology was submitted to stakeholders for comment (was published in August 2018¹⁸).

In early 2018, EFSA received a mandate¹⁹ of the EU Commission to produce a Commodity PRA scheme. This should be available by the end of 2019. EFSA is requested to support the process and perform commodity risk assessments for the EU.

5.2.2. EFSA Panel and working groups

In 2017, the EFSA Plant health (PLH) Panel was composed of 21 experts who are selected for a mandate of 3 years. Their mandate may be renewed up to 3 times. They are mainly scientists working in academia. They carry out scientific assessments and develop related assessment methodologies.

The EFSA PLH Panel is supported by the ALPHA (Animal and Plant Health Unit) team in the secretariat of EFSA.

EFSA usually sets up a Working Group of experts to carry out the risk assessment. The Working Group is typically comprised of 2-5 members of the Panel plus 1-2 additional experts if considered needed. EFSA WG are usually smaller than EPPO ones and are mainly constituted of members of the Panel, they do not necessarily involve experts from the country of origin of the pests. The working group develops a draft and submits it to the Panel for discussion. The assessment is adopted by a majority of Panel members – with any minority opinion recorded – at a plenary meeting of the relevant Panel. If the Panel does not adopt it, the document is sent back to the working group for further examination and to prepare a revised draft for adoption at a following plenary meeting.

The output – which is usually a Scientific Opinion, but may be a Statement, Guidance Document or another type of output – is then published on the EFSA website in the EFSA Journal, a open-access, online scientific journal.

EFSA documents are generally not reviewed by external experts. However public consultations may be organized on draft outputs²⁰, and comments are considered in a revised document. This was done in 2014 for the PRA on *Phyllosticta citricarpa*.

The establishment and operations of the Scientific Committee, Scientific Panels and of their Working Groups are described in a document available at <https://www.efsa.europa.eu/sites/default/files/paneloperation170601.pdf>

5.2.3. Production of EFSA PRAs

Identification of priorities for PRA is made by the EU Commission which send mandates to EFSA. Up to now, EFSA has mainly worked on the re-evaluation of regulated pests, and not on emerging pests (whereas EPPO is focusing on emerging pests).

The drafting of PRAs is made by the members of the EWG (not the ALPHA team). The collection of data may be outsourced and often include a 'extensive literature search'.

Unlike the EPPO system, where PRAs are performed during one week by the EWG, EFSA EWG meets for 1-2 days at regular intervals by physical or webmeeting. The draft PRA is elaborated by experts during their meetings. Typically, a PRA is produced in 5 meetings of 2 days over 6 to 12 months, plus intermediate webmeetings. The new "quantitative" methodology developed between 2016 and 2018 has been noted to be more labour intensive, requiring between 15 and 20 meetings of each EWG. However, the Panel considered that, now that experts have more experience of the methodology and the tools have been developed, PRAs will not need as long to be produced, and quantitative PRAs may only need about 20% more resource than qualitative PRAs.

¹⁸ EFSA 2018 Guidance on quantitative pest risk assessment <https://doi.org/10.2903/j.efsa.2018.5350>

¹⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/wicket/page?6>

²⁰ as described in

https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/consultationpolicy.pdf

For most mandates for pest specific PRAs, the first output is a 'categorisation' where basic information on the pest is assembled, and which help the risk managers decide whether a full risk assessment is needed. Such categorisations are typically produced by a small EWG (2-5 experts) over 1-3 meetings equivalent to 5 days. Following the adoption of Regulation (EU) 2016/2031 on protective measures against pests of plants, EFSA was 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. Therefore 133 pest categorisations should be produced before 2020 for pests or groups of pests.

Similar to EPPO, EFSA has up to now mainly worked on pest-specific PRAs. However recently, they have also been asked to work on risk assessment (categorisation) for groups of pests (e.g. Non-European Scolytidae), and have received a mandate to elaborate a scheme for a commodity risk assessments.

5.2.4. EFSA resources on PRA in plant health

EFSA resources for plant health PRAs are much higher than EPPO: in 2017, 10 FTEs were dedicated only to plant health, and the budget for the production of 'PLH generic opinions' alone was 2 036 000 Euros (https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/amp1719.pdf). In addition, part of the resources for 'ALPHA general scientific and technical assistance' (2.4 FTE and 545 000 Euros) and 'ALPHA internal projects' (2.4 FTE and 1 528 000 Euros) also support work on plant health. It should be noted however that EFSA has also recently been asked to work on areas beyond PRAs such as pest surveillance, or media and literature monitoring for early warning. The PLH may also benefit from the help of the AMU unit (Assessment and Methodological Support Unit) on issues such as modelling.

A major difference between EFSA and EPPO is that EFSA pays experts for their time (in addition to reimbursement of travel and subsistence).

5.3. Others

A number of PRAs are conducted by researchers, or within research projects as well as by technical institutes. Past examples include PEPEIRA²¹ on *Pepino mosaic virus*, RAPRA on *Phytophthora ramorum*²², Prima Phacie PRA on *Acidovorax citrulli*.²³ These PRAs followed EPPO PRA scheme PM 5/3 and were further considered in the framework of EPPO to make recommendations. PRAs produced in the framework of research projects can only be used by EPPO if they follow an internationally agreed PRA scheme (see document on review of national PRAs in Annex 5).

Other organizations may also produce PRAs for specific purposes, such as CABI for biological control agents.

Risk assessment of invasive alien species attract a lot of attention from EU research teams as there is a need (and funding available) to produce PRAs to add high risk damaging species to the EU List of Invasive Alien Species of Union concern.

6. Analysis of the system

6.1. PRA as a core activity of EPPO

Analysis of risks from plant pests has been an important role of EPPO since its foundation in 1951 (see point 3). One of the strength of EPPO is that the work on PRA is linked to the work on information

²¹ Pest Risk Analysis for *Pepino mosaic virus* <https://pra.eppo.int/pr/595150d8-ff08-4a96-90ed-4995fc4cb58d>

²² Risk analysis for *Phytophthora ramorum*, a newly recognised pathogen threat to Europe and the cause of Sudden Oak Death in the USA (Acronym - RAPRA) <https://pra.eppo.int/pr/cd930f6c-6598-49de-a2f7-cecf896e5293>

²³ Pest Risk Assessment (two different formats) are available at: <http://www.efsa.europa.eu/en/supporting/pub/319e.htm>

services. Information collected for the Reporting Service and Global Database is used to support PRAs, and information gathered during PRAs is entered in Global Database and may be easily retrieved for further use. As noted under point 4.3.4, pest-specific Standards are developed after pests are added to the EPPO A1/A2 Lists. Concise datasheets are also prepared for pests recommended for regulation.

6.2. Resources available for PRA

The major resources for PRA in the EPPO region are in the Secretariats and Panels of EPPO and EFSA. This makes it particularly important that the resources continue to be used in a complementary and co-ordinated way. It is difficult to make a direct comparison between the two because EFSA pays for expert input whereas EPPO benefits from substantial “in kind” contributions from national expertise. Both teams do other work than PRA. However, it is likely that EFSA has a significantly larger overall budget for PRA related activities.

It should be noted that in recent years part of EPPO work on PRA has been financed by projects (in particular LIFE for invasive plants, and DROPSA for fruit pathway analysis). This allowed increasing activity on certain aspects: for example 16 PRAs for invasive plants have been produced (instead of 2) in 2 years. However, it may also challenge the production of PRAs in future when such funding is no longer available.

6.3. Pests recommended for regulation in EPPO countries based on EPPO PRAs

All pests recently added to the EU Directive 2000/29 were based on EPPO PRAs, as well as a number of pests for which emergency measures were taken. For invasive plants, 15 species out of the 23 added to the Invasive alien species of Union concern (as defined by EU Regulation 1143/2014) were based on EPPO PRAs, but other bodies have also submitted PRAs. See Annex 2 Consideration of EPPO PRAs for regulation by EPPO countries for details.

Several new pests added to the list of the Eurasian Economic Union are also pests for which EPPO PRAs were recently produced but it is not known whether EPPO PRAs were used as such or complemented with additional information.

The time taken for action based on EPPO (or other) PRAs is quite long: 2 to 7 years between the publication of the PRA and the pest addition to a quarantine list. It is considered that this delay is mainly due to the constraints existing at national level for amending quarantine lists, and not to problems in interpreting the EPPO PRAs. The timeline for listing of invasive alien species is much shorter and the procedure is different (it is described at http://ec.europa.eu/environment/nature/invasivealien/index_en.htm).

The Working Party noted that the fact that EPPO PRAs may wait several years before being considered to support national regulations was inherent to the regulatory process.?

6.4. Pests recommended for regulation by EPPO based on national PRAs

Reviewing national PRAs helps more pests of concern for the EPPO region to be considered than the 5 pests allowed by the current EPPO budget for EWGs. National PRAs are generally good quality (in particular when they are first reviewed by an established PRA team in the country). However, some difficulties are as follows:

- data cannot be thoroughly checked as is done during an EWG
- the assessment does not involve experts from the area of origin of the pest
- collecting additional data to assess the risk for the whole of the EPPO region is demanding and the Secretariat does not always have the resources to do it rapidly
- the agenda of the Panel on Phytosanitary Measures does not always allow the necessary time to define risk management measures during the meeting
- the final document is not always as ‘polished’ as an EPPO PRA, in particular for editing of the English
- some EPPO countries do not want to share their PRAs with the Panel.

Member Countries are currently satisfied with the use of national PRAs to support EPPO recommendations. However, the Panel on Phytosanitary Measures agreed that the process may be improved, and this will be discussed in 2019.

6.5. Geographic coverage of EPPO PRAs

Data availability in the region is unbalanced, with much more information available for the EU than for most EPPO non-EU countries. Although some information on trade and crop production may be available from FAOSTat for the non-EU countries for some commodities, data is often not detailed enough (as several commodities may be grouped) and there are often inconsistencies between import and export data. Little information is generally available for certain aspects (e.g. detailed import data, pest management, production practices, distribution of some host plants within the region, and even existing phytosanitary regulations). Experts from non-EU countries participating in EWGs or Panels can provide such information mostly for their countries or area, but not for the whole region. In addition, in the framework of an express PRA, it is simply not possible to consider certain aspects for the whole EPPO region, such as production practices that may mitigate establishment and impact, and there is an expectation that countries consider how the PRAs apply to their own conditions.

6.6. Quantitative and Qualitative PRAs

As noted under point 5.2.1 EFSA intends to perform quantitative PRAs whereas EPPO PRAs are qualitative. It should be underlined that although the scores given for the different steps of the analysis in qualitative PRAs are verbal phrases, they are always supported by quantitative data if available. No EPPO country currently produces quantitative PRAs. It is not clear for the moment whether groups other than EFSA will want to follow their draft guidance or be able to do so. According to the EPPO survey on the use of PRA schemes in the EPPO region (doc 16-21772), 10 countries declared to have the capacity within their team to conduct quantitative risk analysis, whereas 8 countries answered they do not. It was noted that specific skills (e.g. modelling) are needed and that enough data should be available. Such quantitative analyses may only be performed when projects are funded.

The limited availability of data for the entire EPPO region and the diversity of plant production practices and environmental conditions are the main reasons why a fully quantitative approach has been considered impossible for EPPO PRAs. This situation may partly evolve in future: in 2015, the Working Party underlined the need for dynamic databases on imports and encouraged NPPOs to establish databases or use existing databases that can provide the relevant risk-based information and make summary information available e.g. for PRA purposes.

All PRAs produced within the LIFE IAP – Risk project (see Box 1) included modelling for pest establishment. PRAs for pests other than plants do not often include detailed modelling. This is mainly due to the lack of data on the pest, but also on the distribution of host plants in all EPPO countries. Modelling should be considered carefully depending on the quality and quantity of data available.

EPPO member countries need to make rapid decisions on the wide range of pests which they find on imported consignments and during surveillance of their national territory. The number of plant pests which would justify regulatory action across Europe is large. Supporting those decisions by member countries requires a PRA system which can maintain up to date advice for species known to present a risk and can also develop new recommendations quickly when evidence of risk from other species emerges. So there is generally a need for more and quicker PRAs, as well as the need identified by EFSA for more quantification. Because quantitative PRAs take more time and resources than qualitative, there is a balance to be achieved between those two objectives.

The EPPO Secretariat considers two possible scenarios in which a quantitative PRA could be particularly beneficial: when the results of a PRA are likely to be challenged, for example by trading partners, and when the risks from the pest or the costs of measures are likely to be high and outputs from a quantitative PRA can feed into a cost benefit analysis of options. We could also envisage occasional quantitative PRAs being used to calibrate results obtained from qualitative approaches, to see how much difference results in practice between the two approaches.

While discussing this review in 2018, the Working Party supported that EPPO should generally not conduct quantitative PRAs: although these PRAs seem more precise, data is often lacking, and most assessments are finally based on expert judgements. In addition, more time is needed for their preparation. Finally, several participants commented that quantitative assessments are difficult to read and understand. As a conclusion the Working Party agreed that quantitative PRAs should be the exception rather than the rule but that EPPO should continue to study and learn from EFSA's experience with quantitative PRAs.

6.7. Collaboration with EFSA

EPPO and EFSA management have regular meetings to keep each other informed of PRAs to be conducted in order to avoid any overlap. For the moment EFSA has been mainly requested to produce PRAs for the re-evaluation of regulated pests or for the revision of existing phytosanitary measures whereas EPPO PRAs mainly focus on emerging pests. EFSA has not produced PRAs on invasive plants. The only EFSA PRA on emerging pests (Apple snails) was considered by the Panel on Phytosanitary Measures to support the addition of these pests on EPPO Lists.

EFSA PRAs are regularly used to update EPPO information in Global Database. However, discussion should continue to see how data can be better exchanged.

The Working Party agreed that the collaboration with EFSA should be continued, in particular to better define the area of work of each organization and improve data exchange.

6.8. Interaction between NPPOs and EPPO

EPPO countries need to conduct PRAs to evaluate the need for action on their territories on pests found during import inspections or for new pest outbreaks. It is likely that they will carry on conducting PRAs in future. It is not known whether EPPO countries use EPPO PRAs to further develop a PRA for their own territory.

As noted under 4.2.4 and 5.1, national PRAs are useful for EPPO work and sharing them is of benefit for all EPPO countries. It has already been agreed to share national PRAs in a dedicated EPPO Platform.

6.9. Evolution of the EPPO PRA schemes and expectation of risk managers

Following the recommendation of the core members, the Express PRA scheme (Standard PM 5/5) is now used with ratings using a 5-level scale instead of a 3-level scale. It has been suggested by core members and other experts that more guidance should be available in PM 5/5 to help assessors answer questions and to improve consistency, in particular when they have to perform PRAs on their own without having been trained on the EPPO scheme. For the moment detailed guidance is not available for all questions. Good practice has been developed, for example by using a table to review possible risk management measures.

During the LIFE IAP – Risk project (see Box 1) on invasive alien plants, the scheme was amended to explicitly mention the evaluation of the impact of climate change in the PRA, and the evaluation of the impact of the plant on biodiversity and ecosystem services to be compliant with the requirement of the [Regulation \(EU\) 1143/2014](#).

An amended version of PM 5/5 covering both plants and pests is under development with additional guidance to help assessors. A preliminary version is presented in Annex 8. However, it may be needed to propose 2 levels of guidance: one for a 'emergency' express PRA to be produced in a few hours for urgent situation, and guidance to produce a more complete PRA to support permanent regulation.

During the survey on the use of PRA schemes conducted in 2015-2016, a question was asked on the maximum lengths of PRAs. Countries considered that the appropriate length for a PRA depends on the context (interception and quick decision needed, to decide permanent measures, deregulation) and on the subject of the PRA (single organism or not, complexity of the subject, amount of information available, weight of proof and uncertainties associated to the risk, if this is a pest- or a pathway-analysis). Several countries proposed a stepwise approach with a first PRA limited in size (only the most important questions regarding potential establishment, impact and control) which may be extended later if needed. The size for a PRA to allow prompt decision or support emergency measures is estimated between 5 and 30 pages. The size for a PRA to decide on permanent phytosanitary measures should be 20-70 pages, but some recommended that it should be "as long as necessary", with a short executive summary.

Since 2013, most EPPO PRAs are produced following EPPO Standard PM 5/5, and no longer following EPPO Standard PM 5/3. The size of EPPO PRAs fits with the size recommended by EPPO countries. The core members and the EPPO Panels reviewing PRAs as well as the Working Party welcomed this change as the PRAs include an executive summary, they are shorter and easier to read while being still high quality and fit for purpose. Positive feedback is also received by the Secretariat from the EU Annexes Working Group and the EU Standing Committee.

6.10. Knowledge gaps and needs for research

When knowledge gaps are identified, they are listed in the PRA with needs for research. Issues may be further discussed in EPPO Panels, and/or included in the call for topics for Euphresco, and may then result in research projects (e.g. this was done for *Epitrix* species²⁴, *Thekopsora minima*²⁵).

7. Conclusions and recommendations

Assessment of pest risk has been a core activity of EPPO since its creation. The PRA process within EPPO is integrated together with the early warning process, information services, and Standard setting process for Standards such as Diagnostic Protocols, Phytosanitary Inspections or National Regulatory Control Systems.

Currently about 5 pest specific PRAs are produced every year, and pathways analysis or PRAs for groups of pests on a commodity. Feedback from Panels and Working Party so far suggests that PRA documents are fit for purpose. It is noted that EPPO countries take several years before taking actions based on the PRAs.

PRAs on which EPPO bases its recommendations to regulate pests for regulation are qualitative, as it is considered that obtaining the sufficient data to conduct quantitative PRAs for the whole of the EPPO region would be difficult, in particular for new and emerging pests and would considerably slow down the evaluation process and therefore postpone adequate risk management to be applied.

²⁴ *Epitrix* (flea beetle) species, life cycles and detection methods (project Epitrix and EpitrixII)
<https://zenodo.org/record/1163656#.WwvOO6FOHt>

²⁵ Blueberry rust caused by *Thekopsora minima* – improved risk assessment by supplying quick and reliable identification tools and by performing infection studies.
https://www.euphresco.net/media/topic_descriptions/euphresco_topic_2017-g-263.pdf

Annex 1 EPPO Concept of A1 and A2 Lists and the Principle of Solidarity

*Document agreed in 1995. It was published in EPPO Reporting Service 2003/176
Note that the principles stated in this document will be rediscussed in 2019-2020 by the Panel on
Phytosanitary measures*

The EPPO concept of A1 and A2 lists and the associated principle of solidarity were discussed by the Panel and Working Party on Phytosanitary Regulations at several occasions, but results of the discussions were never published as such. As discussions about these concepts are continuing among the EPPO member countries, it was felt useful to publish them in the EPPO Reporting Service.

EPPO Concept of A1 and A2 Lists and Principle of Solidarity

According to a certain conception of the SPS Agreement, countries are only technically justified in protecting plant life and health on their own territories. Thus, quarantine pests only concern individual countries: A1 pests for an individual country are those that are absent (though they might be present in that country's immediate neighbours), while A2 pests are those which are present but not widely distributed and subject to official control. In this conception, RPOs have no basis to draw up A1 and A2 lists, but only to advise countries of a single list of recommended quarantine pests for their members, which will be A1 or A2 for each individual country according to its pest status.

However, EPPO continues to recommend regional A1 and A2 lists. These are justified by considerations that go beyond those of the above paragraph:

- 1) A1 pests are 'exotic' to the region. Their potential in EPPO countries is relatively uncertain, since there is absolutely no experience of it, so the measures recommended to EPPO members are relatively strong. EPPO thus implies that the appropriate level of protection for such exotic pests should be high. On the other hand, A2 pests are known in the region, and there is shared experience of what they can do. There is also experience of measures taken against them. The measures which EPPO recommends for A2 pests should thus be in line with the principle of 'managed risk', and it is easier to determine what are the measures that are not more stringent than necessary. In practice, this means that these measures are generally less stringent than those for A1 pests. Because EPPO knows the risks from A2 pests better than those for A1 pests, it can better establish what is an acceptable risk.
- 2) The A1 list is also underlain by a principle of regional solidarity.

EPPO members cooperate in preventing the introduction of A1 quarantine pests into any part of the EPPO region by regulating all A1 pests as quarantine pests in their national legislation. Since the pests concerned present greater risks to some Members than others, the countries facing the lesser risks act 'in solidarity' by taking the EPPO recommended measures. The EPPO Working Party on Phytosanitary Regulations maintains the view that such measures are justified in appropriate cases, but notes that the appropriate circumstances have to be established.

The Panel on Phytosanitary Regulations examined various scenarios and concluded that taking measures against a 'lesser risk' is adequately covered by existing principles in many cases. In particular, taking the EPPO A1 list as an example, if the entry or establishment of an A1 pest into one EPPO country presents a low direct risk to that country, but could affect its trade to other EPPO countries where the pest would be more important, then appropriate measures are justified. The restrictions on trade may not yet exist as such, but it may be supposed that they would be imposed.

In a second scenario, there is no obvious risk to trade, but establishment of an A1 pest in the first country presents a risk of natural spread to the second. This is where an explicit solidarity principle is needed and the Panel proposes that: 'Phytosanitary considerations may include the prevention of introduction of quarantine pests into other countries with which cooperation has been established, provided that PRA methods based on biological and economic evidence have been used to demonstrate the risk of such introduction'.

A third scenario is represented by the wording 'Phytosanitary considerations may include the prevention of introduction of quarantine pests into any of a group of countries which have agreed to form a single market, with no or limited phytosanitary measures between its members'.

In the fourth scenario, there is little or no risk to the importing country, no possible effect on trade, and no risk of natural spread to a country where there is a risk. Phytosanitary measures would not be justified.

Annex 2 Consideration of EPPO PRAs for regulation by EPPO countries

Table 1 Pests for which EPPO PRAs were produced, and time for consideration and listing in EPPO countries

Pests (links EPPO Global Database)	PRA Scheme	Date of EWG	EPPO decision	Review by EU	EU decision	Regulation by other EPPO countries
<i>Insects and mites</i>						
Agrilus anxius	PM5/3	2010-09	A1 - 2011	Started in 2012-05, final in April 2013-04	2014	Norway (2013); EAEU (2016); Turkey (2016)
Agrilus planipennis	PM5/5	2013-01	A1-2004	Started in early 2013 (PRA provided before final endorsement of WP to facilitate early action at EU level)	Revision of measures 2014	EAEU (2016); Turkey (2016)
Apriona germari, A. rugicollis (A. japonica), A. cinerea	PM5/3	2011-12	A1 - 2013	Under review		Turkey (2016)
Aromia bungii	PM5/3	2013-11	A1 - 2014	In 2017-2018, under consideration for emergency measured	Listing and Emergency measures in 2018	EAEU (2018); Turkey (2016)
Aulacaspis yasumatsui	PM5/3		Not added			
Bactericera cockerelli	PM5/3	2010-11	A1 - 2012	Started in 2013-07, presented to Standing Committee in 2016-01, Added to EU list in 2017-08	2017	Turkey (2016)
Bactrocera invadens	PM5/3	2009-12	A1 - 2010	From 2014 considered as a synonym of B. dorsalis, already regulated		
Diocalandra frumenti	PM5/3	2008-12	Not added	Under review in 2019		
Drosophila suzukii	PM5/3	2010-07	A2 - 2011		Not quarantine pest	EAEU (2016)
Epitrix cucumeris, E. subcrinita, E. tuberis, E. papa	PM5/3	2010-01 & 2010-04	A1/A2 - 2010		Emergency measures	EAEU (2016) (E. cucumeris, E. tuberis); Turkey (2016) (E. similis, and E. tuberis)
Keiferia lycopersicella	PM5/3	2011-09	A1 - 2012	Started in 2013-12, Presented to Standing Committee in 2016-01.	2017	Turkey (2016)
Lycorma delicatula	PM5/5	2016-02	A1 - 2016	To start in June 2019		
Megaplatypus mutatus	PM5/3	2007-01	A2 - 2007			Turkey (2016)
Metamasius hemipterus	PM5/3	2008-12	A1 - 2009			
Neoleucinodes elegantalis	PM5/5	2013-04	A1 - 2014	Presented at Standing committee in 2017-10	2019	Turkey (2016)
Oemona hirta	PM5/3	2012-05	A1 - 2013	Presented at Standing committee in 2017-10	2019	Turkey (2016)

Annex 2 Consideration of EPPO PRAs for regulation by EPPO countries

Polygraphus proximus	PM5/3	2012-12	A2 - 2014	Started in 2017-09		EAEU (2016); Turkey (2016)
Raoiella indica	PM5/3	2008-05	Not added			
Saperda candida	PM5/3	2009-11	A1 - 2010	Started in 2012-06	2017	EAEU (2016); Turkey (2016)
Tetranychus evansi	PM5/3	2007-08-27/30	A2 - 2008			EAEU (2016); Turkey (2016)
Thaumatotibia leucotreta	PM5/3	2011-11 & 2012-06	A2 - 2013		2017	Israel (2009), Jordan (2007); Turkey (2016)
Nematodes						
Bursaphelenchus xylophilus	PM5/3	2009-05	A1 - transferred to A2 in 2010	Already listed, PRA produced to support modification of measures	Emergency measures in 2012	EAEU (2016); 9 EPPO countries
Meloidogyne enterlobii	PM5/3	2009-05	A2 - 2010			EAEU (2018), Russia (2014)
Fungi (and fungus-like)						
Geosmithia morbida and Pityophthorus juglandis	PM5/5	2014-08	A2 - 2015		2019	
Heterobasidion irregulare	PM5/5	2014-12	A2 - 2015	??		
Phytophthora kernoviae and Phytophthora ramorum	only risk management PM5/3	2012-02 & 2012-03	A2 in 2013	Started in 2012 (also consideration of EFSA PRA). Not finished in 2017-09	Emergency measures for <i>P. ramorum</i> in place since 2002	EAEU (2016); Israel (2009); Kazakhstan (2017); Turkey (2016)
Phytophthora lateralis	PM5/3	2006-02	A1 - transferred to A2 in 2011			
Bacterium						
Candidatus Liberibacter solanacearum	PM5/3	2010-11	A1 - 2012	Started in 2013-07	No regulation decided in 2016 (but regulation of vector <i>B. cockerelli</i>)	EAEU (2018), Turkey (2016)
Pseudomonas syringae pv. actinidiae	PM5/5	2011-09	A2 - 2012		Emergency measures 2012	No other countries
Xanthomonas axonopodis pv. allii	PM5/3	2008-09	A1 - 2009			EAEU (2016); Kazakhstan (2017)
Viruses						
Iris yellow spot virus	PM5/3	2007-01	Not added			

Table 2. Invasive alien plants added to the EU List of Invasive Alien Species of Union concern (list updated in 2018, note that the review of PRAs on invasive alien species by the EU Scientific Forum on IAS started in 2016).

Species	PRA scheme	Year	Comments	added to EU list
<i>Alternanthera philoxeroides</i>	EPPO	2015		2017-08
<i>Asclepias syriaca</i>	NAPRA EU amendment Final 30/11/2015			2017-08
<i>Baccharis halimifolia</i>	EPPO	2013		2016-08
<i>Cabomba caroliniana</i>	EPPO	2007		2016-08
<i>Eichhornia crassipes</i>	EPPO	2008		2016-08
<i>Elodea nuttallii</i>	EU amended template (Ireland)			2017-08
<i>Gunnera tinctoria</i>	EU amended template (Ireland)		considered lower priority for PRA by EPPO in 2014	2017-08
<i>Heracleum mantegazzianum</i>	EU non-native organism risk assessment scheme			2017-08
<i>Heracleum persicum</i>	EPPO	2009		2016-08
<i>Heracleum sosnowskyi</i>	EPPO	2009		2016-08
<i>Hydrocotyle ranunculoides</i>	EPPO	2009		2016-08
<i>Impatiens glandulifera</i>	Poland			2017-08
<i>Lagarosiphon major</i>	GB Non-native Species Risk Assessments			2016-08
<i>Ludwigia grandiflora</i>	EPPO	2011	together with GB NNRA	2016-08
<i>Ludwigia peploides</i>	EPPO	2011		2016-08
<i>Lysichiton americanus</i>	EPPO	2009	(no longer listed by EPPO after review of PRA by EFSA)	2016-08
<i>Microstegium vimineum</i>	EPPO	2015		2017-08
<i>Myriophyllum aquaticum</i>	GB Non-native Species Risk Assessments			2016-08
<i>Myriophyllum heterophyllum</i>	EPPO	2015		2017-08
<i>Parthenium hysterophorus</i>	EPPO	2015		2016-08
<i>Pennisetum setaceum</i>	EU non-native organism risk assessment scheme			2017-08
<i>Persicaria perfoliata</i>	EPPO	2007	under <i>Polygonum perfoliatum</i>	2016-08
<i>Pueraria lobata</i>	EPPO	2006		2016-08

Annex 3 Background information on the system established by EPPO to perform PRA

19-24967

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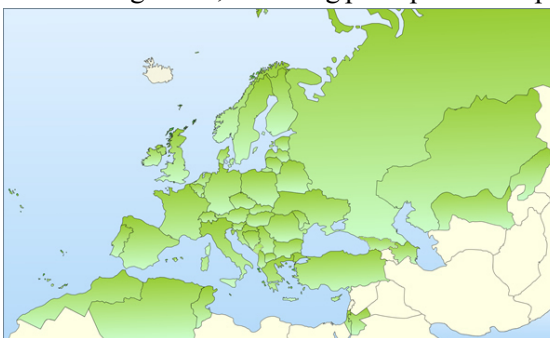
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What is EPPO?

The European and Mediterranean Plant Protection Organization (EPPO) was created in 1951 by 15 European countries. After World War II, European agriculture was faced with a great many difficulties, and in particular a significant food crop, potato, was threatened by the spread of Colorado beetle (*Leptinotarsa decemlineata*). These 15 countries considered that by creating an international organization, they would be able to control this pest more efficiently. EPPO’s work subsequently extended to preventing the introduction of other dangerous pests from other parts of the world, and limiting their spread within Europe if they were introduced. These activities which can broadly be labelled as ‘plant quarantine’ have been EPPO’s main priority in its 60 years of existence. Later, EPPO activities extended to plant protection in general, including plant protection products.

Today, 52 European and Mediterranean countries are members of the Organization. Our partners are the National Plant Protection Organizations, i.e. the official services which are responsible for plant protection in each country (usually within Ministries of Agriculture).



EPPO is a standard-setting organization, in two main fields of activity: plant quarantine and plant protection products. Technical documents are developed by 20 Panels of experts nominated by countries. A Secretariat of 15 persons based in Paris is in charge of facilitating the work of the experts by preparing documents, ensuring their quality and organizing meetings. The results of EPPO's work are technically based recommendations officially approved by EPPO’s Council where all member countries are represented. These recommendations are now considered at international level as 'regional standards'. So far, hundreds of EPPO standards have been published on various subjects: lists of pests recommended for regulation, pest risk analysis, diagnostic protocols, production of healthy planting material, efficacy evaluation of plant protection products, good plant protection practice, etc. Exchange of information within the Organization is also an important task. Numerous publications are prepared by the EPPO Secretariat. A Website and databases are also maintained. For more information, visit www.eppo.int.

EPPO and Pest Risk Analysis (PRA)

In recent years, the international plant health framework has changed and a striking acceleration in EPPO activities has taken place, which is a reflection of the increase in the tasks and duties attributed to the National Plant Protection Organizations. International trade patterns have expanded and diversified, thus increasing the risks of introducing new pests into new geographical areas. On the other hand under World Trade Organisation rules, Phytosanitary measures adopted by countries should be technically justified and should not be disguised barriers to trade. International Standards for Phytosanitary Measures on Pest Risk Analysis have been developed in the framework of the international Plant Protection Convention to provide technical justification for measures

Role of EPPO in the development of regional Standards on PRA

Since the 1990s, the EPPO Panel on PRA has been involved in developing schemes for pest risk assessment and pest risk management. Since 2002, International Standards for Phytosanitary Measures have been adopted (e.g. ISPM 11 *Pest risk analysis for quarantine pests*). these international standards are the international reference for the WTO Sanitary and Phytosanitary agreement (SPS agreement), which is the basis in case of disputes. Nevertheless EPPO Standards have been maintained as they have an added value in particular with a presentation in a logical sequence of questions addressing all the elements mentioned in ISPM 11. The EPPO Schemes also cover potentially invasive alien plants. The EPPO *Decision-support scheme for PRA on quarantine pests* (PM 5/3) and the *Decision-Support Scheme for an Express Pest Risk Analysis* (PM 5/5) are available on the [EPPO website](#).

Role of EPPO in performing PRA

Many EPPO member countries do not have the resources to perform PRA themselves. They have therefore asked EPPO to play an active role in organizing internationally conducted PRA in the region. In this way costs and workload are shared. The creation of special *Expert Working Groups for PRA* was formally approved in September 2006, with a budget for paying expenses of invited experts. It is expected that 5 pests (including 1 invasive alien plant) are evaluated by expert working groups every year.

EPPO Expert Working Groups for PRA

Terms of reference of the Expert Working Groups for PRA (doc 17-22854)

Scope

The Expert Working Groups for PRA conduct PRA on selected pests to provide technical justification for recommendations made to the EPPO Council for addition to EPPO Lists of pests recommended for regulation.

Tasks

The Panel shall:

- perform pest risk assessment on selected pests to determine whether they present a significant risk for the PRA area (usually the EPPO region) and to identify the endangered area within that area,
- perform pest risk management on these pests by identification and evaluation of options for phytosanitary measures and by selecting a range of options that provide a significant reduction in the risk of introduction and spread of the pest,
- deliver a report of this pest risk analysis, making appropriate recommendations on the need for regulation. This PRA be supported by scientific and/or technical references, in particular on the efficacy and practicability of the options, to provide technical justification of the phytosanitary measures which may be taken, as appropriate. The report should be of high quality (suitable for publication on the EPPO website).

Structure of an Expert Working Group for PRA

Membership of an Expert Working Group for PRA

- Core expert membership

A core group of PRA experts should be established. The EWG for PRA should include one or more of EPPO's core group of PRA experts to provide consistency. These core experts should preferably be drawn from existing Panels with experience in performing or reviewing risk assessment and determining risk management options: Panel on Phytosanitary Measures, Panel on Quarantine Pests for Forestry, Panel on Invasive Alien Plants. Core members do not attend all Panel meetings; their participation will depend on the pests studied. Usually 1 or 2 core members attend a specific EWG for a pest. Core members do not have to review all PRAs prepared every year, but are expected to review at least 2 PRA per year.

- *Ad hoc* membership

A list of *ad hoc* experts should be established by the EPPO Secretariat, who can be consulted or called upon to participate in meetings on specific pests or group of pests. The experts will be selected by the EPPO Secretariat on the basis of their declared expertise. This list should include members of other EPPO Panels (e.g. Panels on Diagnostics).

- Specific PRAs

The specific group of experts convened to conduct a PRA on a given pest will have an identity which may be maintained for one meeting and/or through e-mail consultation. The suggested expertise for such a group is:

- 2 experts with expertise on the pest or pest group
- 2 experts in risk management
- 1 expert on the crop concerned
- 1 expert with experience of the EPPO decision-making scheme
- 1 expert on species distribution modelling (GIS, Climex, BIOMOD, R, etc.)
- 1 expert in socio-economics

The expertise should be representative of the region (in particular if crop husbandry and other key element differ substantially across the region). Experts may be able to play more than one role.

Selection of potential members

Nominations should be made by NPPOs for the core group of experts and for specific pest expertise. Each year the Working Party on Phytosanitary Regulations will select pests on which PRAs should be performed. Usually two to three months before the meeting, the EPPO Secretariat will request nominations from NPPOs to constitute a list of experts from which the Secretariat selects the members for each specific pest for which a meeting is scheduled in the year to come. The EPPO Secretariat will also invite experts from outside the EPPO region who are leading experts on the particular species to be evaluated. Nominations are not restricted to just experts from NPPOs, and nominations by NPPOs of experts from institutions outside the NPPOs or from universities would be welcomed.

The list of core members and proposals for addition to this list is presented to the Executive Committee (in April and September) for approval.

Timing of meetings

In principle 5 meetings are organized per year and work also continues through e-mail consultation after each meeting. Each meeting will last 3,5 days on average.

Working procedures

Selection of candidate pests for performing PRA

The candidate pests should either be proposed by an EPPO member country or by the Panels on Phytosanitary Measures and Quarantine Pests for Forestry. For invasive plants the Panel on Invasive Alien Species should also make proposals. The Working Party on Phytosanitary Regulations should decide on priorities, but there should be enough flexibility to ensure that a PRA can be conducted on a new emerging pest even if it is not on the priority list.

Gathering documentation for conducting PRA

The necessary information, as described in EPPO Standard PM 5/1 on a checklist of information for PRA, will be gathered by the EPPO Secretariat or an expert. A pre-PRA (usually following PM 5/5 *Decision-Support Scheme for an Express Pest Risk Analysis*) is prepared (by the EPPO Secretariat or by an expert). The documentation gathered is provided in advance to the experts attending the meeting. Documentation includes any existing PRAs, even those prepared by individual members that cover restricted PRA areas. The pre-PRA is circulated in advance to the EWG to gather comments and a revised version is produced.

Production of PRAs

The PRA document prepared before the meeting, is reviewed and amended during the EWG.

Reviewing the PRAs

The PRA prepared by the EWG is sent by email to all confirmed core members for review.

The PRA is amended following core members comments, in consultation with the EWG if needed.

The PRA is presented to the Panel on Phytosanitary Measures or the Panel on IAP for plants. PRAs may be presented to other relevant EPPO Panels, e.g. Panels on Quarantine Pests for Forestry, on Measures for potatoes. The Panel reviews in particular the section on pest risk management. The PRA is amended following Panel's comments in consultation with the EWG if needed. The Panel makes appropriate recommendations to the Working Party on Phytosanitary Regulations.

Outcome

The PRAs are submitted to the Working Party on Phytosanitary Regulations, which will make appropriate recommendations on regulation to the Executive Committee and Council. The PRAs will finally be published in the EPPO Global Database in support of the recommendation. The PRAs should specify the endangered area within the PRA area and include options for management. The selection of management options is made by the NPPOs.

What is the role of an expert in an Expert Working Group for PRA?

Experts are called upon as individuals because of their specific expertise and are not expected to represent interests of their country or organization.

Examples of documents produced by previous EWGs are provided on the EPPO website: https://www.eppo.int/ACTIVITIES/plant_quarantine/pr_a_activities.

Role of the expert before the meeting

- Preparation of the documentation for conducting PRA

The necessary information to perform the PRA is gathered by the EPPO Secretariat with the help of the experts. A draft PRA (usually prepared by the Secretariat or one expert) and all references used are provided in advance to the experts called to attend the meeting of the Expert Working Group. One of the experts may be asked to prepare a pre-PRA and a datasheet, or to support the Secretariat for their preparation. All experts of the EWG are kindly requested to provide comments in advance of the meeting, as well as any relevant additional reference(s) that the group should be aware of.

Documentation includes any existing PRAs, even those prepared by individual member countries that cover restricted PRA areas.

Based on experience with previous Expert Working Groups, information that is often missing during meetings is data on trade of potential pathways (e.g. any means that allow the entry or spread of the pest), types of potential pathways, host plant distribution and cultural practices for host plants across the EPPO region. Data on damage and costs of control is also often lacking. The PRA performed should be valid for the EPPO region (this means that evaluation should take into account the different zones of the region).

- EPPO decision-support scheme for PRA on quarantine pests (PM 5/3) or EPPO Decision-Support Scheme for an Express Pest Risk Analysis (PM 5/5)

It is important that experts familiarize themselves before the meeting with the scheme (or combination of) which will be used and try to answer the questions of the scheme for the pest to be evaluated. The scheme used (or combination of) is specified in the draft PRA.

We also recommend those not familiar of the International Plant Protection Convention terminology to consult the ISPM 5 *Glossary of Phytosanitary Terms* (available on IPPC website <https://www.ippc.int>)

Role of the expert during the meeting

- Production of Pest Risk Analyses

During the meeting, the Expert Working Group performs the pest risk analysis. The Expert Working Group goes through each individual question of the scheme and finalizes answers in the PRA. Each answer should be justified and justifications are recorded in the PRA. For most questions, in addition to the justification, a rating and a level of uncertainty are given. All answers are based on the evidence and documentation gathered in advance of the meeting and the experience brought by experts.

The Expert Working Group usually works from a draft PRA, revised by the Secretariat taking account of the comments sent by experts in advance of the meeting.

Role of the expert after the meeting

The Expert Working Group is consulted by email, when needed, to answer specific comments at any stage of the review process within EPPO. At all stages, comments are processed by the Secretariat, who contact the Expert Working Group or individual experts as appropriate.

- Review process of the PRA within EPPO
 - The PRA is sent by email to the core members (see footnote above) and their comments are processed by the EPPO Secretariat.
 - A summary of the PRA (the PRA report if the scheme PM 5/3 was used; a summary table if the scheme PM 5/5 was used) is also prepared once the PRA is finalized. It summarizes the phytosanitary risk, the endangered area within the PRA area and includes options for management.
 - The PRA and its summary are presented to the Panel on Phytosanitary Measures, which will make appropriate recommendations to the Working Party on Phytosanitary Regulations. If comments are raised on management options, the EWG may again be consulted to provide clarifications.
 - The PRA or its summary is submitted to the Working Party on Phytosanitary Regulations (in June), which will make appropriate recommendations on regulation to the Executive Committee and Council (both in September).
 - PRA documents will finally be published on the EPPO website in support of the recommendation.

The final selection of management options is made by the NPPOs when preparing phytosanitary regulation for their countries.

Information gathered in the PRA may be used further to prepare a datasheet on the pest, or specific EPPO Standards, in particular in the series PM 9 National Regulatory Control Systems (<https://gd.eppo.int/standards/PM9/>). These documents may be provided to the EWG for comments.

Annex 4 Core members in EPPO Expert Working Groups for PRA: role, working procedures

19-24989

The role of core members and the working procedures are described generally in the Terms of reference of the Expert Working Group for PRA on specific pests (see Annex 3). This document was written by the Secretariat to provide specific guidance to new core members. It was amended based on the comments made during the meeting of the core members in 2014.

Nomination of core members

When the group of core members was first created in 2006, the Secretariat sent a circular requiring nominations, as well as two years later to try to involve more experts from the Panel on PRA Development or of the Panel on Phytosanitary Measures.

The list of nominated core members is included in the document listing all Panel members which is presented to the Working Parties, Executive Committee and Council (and is available at https://www.eppo.int/ABOUT_EPPO/panel_composition/pm_pra_core). Every year, NPPOs may decide to nominate new core members, as for other EPPO Panels. This is done by sending an official letter or e-mail to the EPPO Secretariat. The composition of Panels is agreed by the Executive Committee.

Withdrawal of core members

Panel members may withdraw at any time by simply informing the Secretariat (or the NPPO concerned may at any time withdraw its agreement).

Participation in EWG meetings

Core members do not have to attend all EWG meetings. In fact, given the number of nominated core members, and that 5 EWGs are organized per year (with 1 or 2 core members in each EWG), and the Secretariat tries to rotate core members, a core member may on average take part in one meeting every year.

Participation of core members depends on their availability, and the required expertise in the EWG (e.g. a core member with a training in background training in pathology may be preferred for a PRA on a pathogen, a core member with expertise in forest management may be preferred for a PRA of a forest pest, a core member with knowledge of a specific language...). It is also tried to have participation of experts that is representative of the region (in particular if crop husbandry and other key element differ substantially across the region).

In practice, when an EWG is announced, the Secretariat send an e-mail to core members to ask who is interested to take part and select 2 core members by EWG.

Role of core members during the meeting: the core members should help the Secretariat using the PRA schemes consistently, and provide guidance to *ad hoc* members on the PRA process. They should assess the supporting literature, check if the rating is supported by the answer given, and if the uncertainty level corresponds to the answer provided.

Review of PRAs

Core members receive the PRAs prepared by each of the Expert Working Groups (on average 5 per year) in order to review them. This review involves at least 1-3 days of work per PRA following PM 5/3 and 1 day of work for a PRA PM 5/5. Usually, the commenting period is 6-8 weeks.

If possible, the Secretariat provides the list of species to be assessed in the coming months so that core members can plan their work.

Core members do not have to review all 5 PRAs every year but it is expected that they review at least 2. The objective is to have at least 4 core members reviewing each PRA (in addition to core members who took part in the meeting). In order to better organize the review, it is good practice to inform the Secretariat if you would be able to review the PRA or not when you receive the document.

It is noted that currently the PRAs on invasive alien plants have less reviewers and less comments than PRAs on other type of pests.

The objective of the review is to provide consistency between PRAs and also note any inconsistencies or lack of supporting data in the PRA. Core members are expected to provide both general and detailed comments. Core members should check if the rating is supported by the answer given, and if the uncertainty level corresponds to the answer provided. It should also be checked if the statements given in the PRA are sufficiently justified by scientific evidence and logic arguments. Core members are only expected to review the draft PRA, and not to assess the supporting literature (but they are expected to do so if taking part in an EWG). However it was agreed that core members can be given access to the literature on request in case they would want to check some of references.

In practice, detailed comments are generally provided as track changes in the text whereas general comments (e.g. explaining the good and bad points of the PRA) are mentioned at the start of the draft PRA, in an e-mail, or in a new document.

If specific points should be checked during a review, the Secretariat mention it in the e-mail accompanying the draft PRA.

When all comments have been received, the Secretariat prepares a new version of the PRA including all comments received from core members, and addressing them (or indicating why the comment cannot be taken into account). This can be done in consultation with the EWG if needed. This working version is circulated to the core members for information as well as 'clean' revised version of the PRA that will be presented to the Panels on Phytosanitary Measures or on Invasive Alien Plants.

The Secretariat may ask the core members how to address specific comments.

If the draft PRA is modified significantly by the Panels the Working Party on Phytosanitary Regulations, the EWG and core members are informed.

Partial review

In 2012, it was suggested that core members may review only part of the PRA. The core member should indicate which part then intend to review so that the Secretariat can be sure that all parts are reviewed. This has worked fine for some PRAs following PM 5/3. However the Secretariat considers that partial review should only be done by experienced core members. As PRAs following PM 5/5 are shorter, this is generally not needed for them. It is considered preferable that core members review in depth a limited number of PRAs during the year rather than providing a superficial review of many.

Acknowledgment of the work of core members

In the final version of the PRA, core members who have commented on the draft are listed.

Revision of the EPPO PRA schemes

The Panel on Phytosanitary Measures considered that the core members will be the relevant persons to be consulted on the need of revisions of PRA schemes (PM 5/3 and PM 5/5) based on their experience by EWGs.

Appendix *Guidelines to help review of PRA* [still to be developed]

A standard form with key points to tick will help the review.

The rating guidance included in CAPRA which is not part of PM 5/3 should be made available to the core members as a Word document.

A table with the ratings and uncertainties given in previous PRAs would facilitate the review of consistency between PRAs.

Annex 5 Guidelines to review national Pest risk analysis ²⁶

19-24782

Background:

In addition to the system of Expert Working Groups for PRA described in document 17-22854, national PRAs or PRAs produced by other bodies than EPPO (e.g. EFSA) are also used as a basis for EPPO recommendations.

Process: a member of the Panel²⁷, or the Secretariat identify a national PRA on a pest of interest for recommendation for regulation. The PRA is considered by the Secretariat who decides either to send the PRA to core members²⁸ for review, or to present it directly to the Panel on Phytosanitary Measures if it is considered of good quality.

Scope:

When reviewing the national PRA, the Panel on Phytosanitary Measures or the Panel on Invasive Alien Plants should identify whether the PRA is sufficiently detailed to support the conclusions drawn and whether the PRA, as it is, can be extrapolated to make a recommendation for the entire EPPO region. This document provides guidelines for this review.

General questions

- Does the PRA follow ISPM 11 *Pest risk analysis for quarantine pests*?
- Is the PRA area (part of) the EPPO region or only the country that prepared the PRA?
 - If the PRA area is not the EPPO region, the review should determine:
 - whether the information provided in the document is valid for a wider area.
 - determine what additional information is needed to make the PRA valid for the whole EPPO region and define the endangered area within the EPPO region
- Has an EPPO-style datasheet been provided? If not, is a CABI datasheet available?
- Have all possible pathways been identified and those that are not relevant clearly stated?
- Is the document clearly written?
- Is the information used in the PRA up-to-date?
- When information is missing, is it clearly stated that it is because of a lack of data or because this data is not available?
- If specific prediction tools have been used, what are these and were their applications correct?
- For the section on economic damage has quantitative data been provided (when available)?
- Are the conclusions consistent with the answers provided?
- Is uncertainty noted (including its level) and correctly summarised?
- Are elements mentioned in the PRA adequately justified, documented & referenced (including personal communications)?

National PRA following an EPPO decision-support scheme (either PM 5/3 or PM 5/5)

- Are all sections, including risk management (if relevant), completed?
- Are all relevant questions answered?
- Are all questions correctly interpreted?

If yes, the PRA can be used directly to make EPPO recommendations.

If not, the Secretariat should contact the authors to see whether the PRA can be amended. If this is not possible, the PRA cannot be used as a basis for an EPPO recommendation.

²⁶ A national PRA is a PRA prepared by a NPPO or another body, either for its own territory or a wider area.

²⁷ Panel on Phytosanitary Measures, Panel on Invasive Alien Plants, Panel on Phytosanitary Measures for Potato, Panel on Quarantine Pests for Forestry, Panels on Diagnostics

²⁸ See document 17-22854 *Terms of reference of the Expert Working Groups for PRA on specific pests* in Annex 3

If the Panel considers that additional information are needed to make the PRA relevant for the whole EPPO region, a PRA report (see appendix) is prepared where both information from the national PRA and additional information are included.

PRA not following an EPPO decision-support scheme (either PM 5/3 or PM 5/5)

Are all main sections of ISPM 11 answered (i.e. does this PRA answer all relevant sections of the PRA report (see Appendix) including risk management (if relevant))?

If yes, the PRA can be used to make EPPO recommendations. If the document includes only risk assessment but not risk management, the Panel should define risk management measures for the relevant pathways. A report of PRA (see appendix) should be prepared, either by the Secretariat, the authors of the PRA or a member of the Panel.

If not, the PRA cannot be used as a basis for an EPPO recommendation.

Appendix: Format for a Report of a PRA (proposed amendments to be updated)

Report of a Pest Risk Analysis for *name of pest*

This summary presents the main features of a pest risk analysis which has been conducted on the pest. *Specify which PRA scheme has been used, and indicate the reference to the PRA under the section “References”*

Pest:

PRA area: *Specify EPPO region or another area*

Assessors: *For a national PRA used as a basis of EPPO recommendation, specify the authors of the original PRA, as well as the persons/panels who have completed it if relevant*

The risk management part was reviewed by the EPPO Panel on Phytosanitary Measures

Date: *Mention the date of the PRA and the subsequent reviews if relevant*

STAGE 1: INITIATION

Reason for performing the PRA: *Explain the reason for doing the PRA. If additional information was included in the report, explain why.*

Taxonomic position of pest:

Pest overview

STAGE 2: PEST RISK ASSESSMENT

Geographical distribution of the pest: *If additional references to the original PRA have been added so that the PRA covers the whole EPPO region, they should be listed*

Major host plants or habitats: List host plants/habitats in current area of distribution

Introduction

Likely pathway(s) of introduction:

Establishment

Plants or habitats at risk in the PRA area:

Climatic similarity of present distribution with the PRA area (or parts thereof):

Characteristics (other than climatic) of the PRA area that would favour establishment:

Area of potential establishment within the PRA area:

Spread

Likely pathway(s) for spread:

POTENTIAL ECONOMIC CONSEQUENCES

Nature of the damage *This is a description of symptoms*

Impact in the current area of distribution: (including environmental and social impact)

Potential impact in the PRA area:

CONCLUSIONS OF PEST RISK ASSESSMENT

Summarize the major factors that influence the acceptability of the risk from this pest:

Probability of introduction:

Probability of establishment:

Magnitude of spread:

Potential economic impact:

Identification of the endangered area

Degree of uncertainty

Summarize the main uncertainties of the PRA, and give an overall estimate of the uncertainty (low/medium/high)

OVERALL ASSESSMENT OF RISK

STAGE 3: PEST RISK MANAGEMENT

IDENTIFICATION OF THE PATHWAYS

Pathways studied in the pest risk management List pathways in order of importance

IDENTIFICATION OF POSSIBLE MEASURES

Possible measures for pathways

*List possible measures and explain why they are acceptable or not
Measures related to the crop or to places of production*

Measures related to consignments:

Possible measures for eradication and containment if the pest is introduced in the PRA area

Degree of uncertainty

IDENTIFICATION OF POSSIBLE MEASURES

PC= Phytosanitary certificate

<i>Name of the pathway</i>	<i>List of measures considered relevant to reduce the risk of introduction</i>
Plants for planting	PC and PFA Or Pest-free place of production
Cut branches	

References

List original PRA and additional references

Annex 6 Consequences of changes in Taxonomy of EPPO-listed pests

19-24782

Changes in taxonomy may result in pest names being changed, species being synonymized or split into different species. These changes have consequences for EPPO recommendations and on the names to be used in EPPO Standards, documents and databases. As a baseline, changes in taxonomy should be recognized by the relevant taxonomic entities.

An evaluation of the changes will usually be conducted by the EPPO Secretariat and the conclusions presented for feedback to the Panel on Phytosanitary Measures. The process to be followed for the different situations is presented below.

1. Change of name only (e.g. *Davidiella populorum* (EPPO A1 List) has been renamed as *Sphaerulina musiva*):

No change in EPPO recommendation. The Panel on Phytosanitary Measures and the Working Party should be informed (it was not always the case in the past, but it has been agreed in 2017 that this should be systematically done from now on). EPPO countries are encouraged to use the new agreed preferred scientific name. Ideally, EPPO Standards and documentation (including PRA) should be updated or amended to mention the new name.

2. Confusion of one species with another (e.g. a PRA was conducted on a pest present in Portugal first identified as *Epitrix similaris* (present in the USA), but it appeared later that the pest was a new species subsequently named *Epitrix papa*):

The information used to make the recommendation should be critically reviewed by the EPPO Secretariat to try to identify if the recommendation is still valid. In the above example, as very limited data was available for *E. similaris* in USA, most of the data used was related to the species present in Portugal (now known to be *E. papa*). If the area of distribution of the new species is different from the area of the species assessed, the entry section may be amended. The conclusions of the PRA are still relevant (as measures at import apply from all origins). Documentation should be provided for the new species. Documentation for the other species should be revised to remove any information related to the new species.

3. Disease of unknown aetiology (e.g. Elm phloem necrosis, then discovered to be due to *Phytoplasma ulmi*):

When the aetiology of a disease is discovered, the information used to make the recommendation should be critically reviewed by the EPPO Secretariat to try to identify if the recommendation is still valid (e.g. whether a vector is found and additional measures should be taken, whether there is more information on spread (e.g. seed transmission), etc.)

4. Several species are merged (e.g. *Bactrocera invadens*, *B. papayae*, *B. philippinensis* with *Bactrocera dorsalis*):

Only the new valid name should be used in EPPO Lists, data on pest distribution, host range are merged.

5. One species is split into different species (recent examples include *Ralstonia solanacearum*, *Xanthomonas citri*, *Leucinodes orbonalis*):

When a pest which was listed as a single entity is split into different species this always raises the question about what should be the phytosanitary categorization of the new split species.

Such changes also have consequences on the EPPO documentation system (datasheets, geographical distribution) which should be examined.

5.1 Listing of the pest on the A1 and A2 EPPO Lists

Do all the “split species” qualify to be recommended for regulation? What level of justification is needed for the addition of a “split species” on these lists? This is important for species that are currently included in EPPO member countries legislation.

When a single entity is split into two or more different species

- Consider whether the distinction between the species was triggered by a difference of impact or different host ranges which could lead to different conclusions regarding the quarantine status (e.g. no impact on certain hosts or hosts of minor agronomic or environmental importance). Consider if there are any differences in the epidemiology (e.g. difference of vector).
 - **If yes**, individual species should be evaluated,
 - **If no**, then all the “split species” could be considered to deserve a similar status with no individual assessment being performed. This should be documented for example in a PRA report.

(this approach was followed by the Panel on Phytosanitary Measures when TSWV was split into TSWV and INSV)

- Does the splitting of the species result in species being present in the EPPO region and other(s) not?
 - **If yes**, consider the criteria given above and assign the A1 and A2 list phytosanitary categorization according to the revised geographical distribution (see 0),
 - **If no**, then all the “split species” could be considered to deserve a similar status.

5.2 Geographical distribution of the species

The geographical distribution of both “split species” is often not easy to establish, given that in most cases reports date from before the new classification. The Panel on Phytosanitary Measures and the Working Party recognized that for some species it will be extremely difficult to revise the geographical distribution according to a new taxonomy.

For pests present in the EPPO region, countries should be encouraged to make surveys taking into account the new taxonomy.

Annex 7 Survey to determine the use of different Pest Risk Analysis (PRA) schemes and the needs of NPPO risk managers in EPPO countries

16-21772

This document was presented at the Working Party on Phytosanitary Regulations in June 2016.

In 2015, the EPPO Working Party on Phytosanitary Regulations discussed the process for conducting PRAs (Pest Risk Analyses) in the EPPO framework. It requested that the EPPO Secretariat should conduct a survey in order to better understand the different levels of PRA which may be required either at EPPO or national level – what triggers them, what their purpose and audience is, how much time and resources are needed to complete them. This survey aimed at establishing the current use of different Pest Risk Analysis schemes and the needs of practitioners and risk managers in order to better evaluate the capacity for pest risk analysis in the EPPO region and consider the need for new or revised Standards on PRA and any further work by EPPO. The draft analysis was presented to the Panel on Phytosanitary Measures, and amended according to the comments made during the meeting.

Out of 50 Member Countries, 24 answered (48%): including 19 EU countries, Bosnia-Herzegovina, Norway, Switzerland, Turkey and Russia.

ISO code	Name
AT	Austria
BA	Bosnia-Herzegovina
BE	Belgium
CH	Switzerland
CY	Cyprus
CZ	Czech Republic
DE	Germany
DK	Denmark
ES	Spain
FI	Finland
FR	France
GB	United-Kingdom
IE	Ireland
IT	Italy
LT	Lithuania
LU	Luxembourg
LV	Latvia
MT	Malta
NL	The Netherlands
NO	Norway
PL	Poland
RU	Russia Federation
SI	Slovenia
TR	Turkey

PART I Production of PRAs or other types of analysis of pest risk

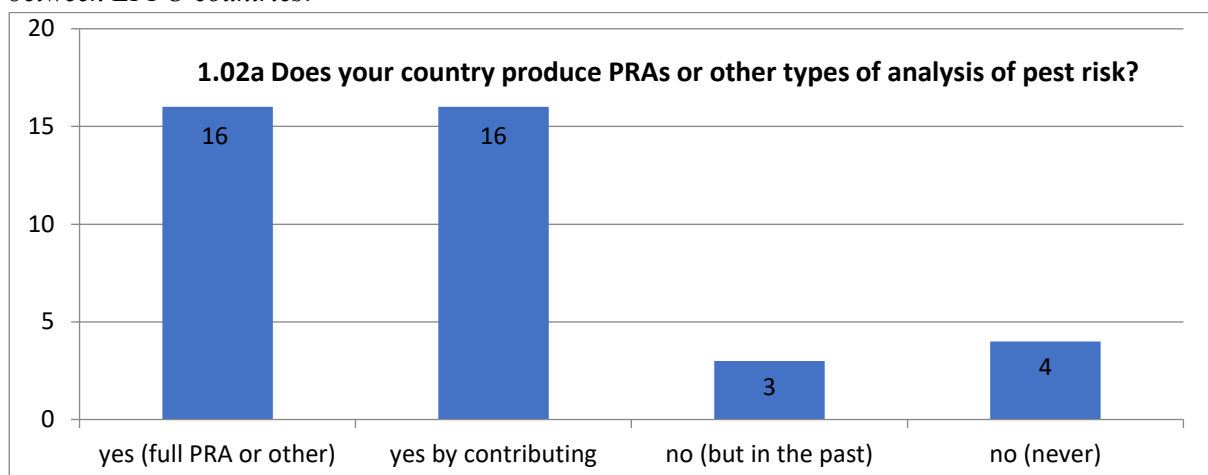
Among the 24 countries that answered to the questionnaire, 16 Countries (AT, BE, CZ, DE, DK, ES, FI, FR, GB, LV, MT, NL, NO, RU, SI, TR) declared preparing PRAs or other analysis of pest risk, and 16 declared contributing to EPPO or EFSA PRAs (AT, BE, CZ, DE, DK, ES, FI, FR, GB, IT, LT, LV, MT, NL, NO, PL). Most countries preparing PRAs nationally also contribute to other PRAs (EFSA or EPPO).

Out of the 7 countries that do not perform PRAs, 3 used to do it in the past (CH, LT, PL) and 4 declared having never performed PRAs or other types of a pest risk analysis (BA, CY, IE, LU).

Note: Some countries are known to perform PRA and have not answered (e.g. Israel in particular commodity PRAs. Italy has declared only contributing to EPPO and EFSA PRAs but national PRAs are also performed in Italy. Two countries (TR, RU) did not declare contributing to EPPO PRAs even if some Turkish or Russian experts recently took part in such PRAs (and are ‘core members’ of EPPO PRA Expert Working Groups).

A majority of respondents (16 out of 23 – 70%) prepare PRAs. It could be explained by the fact that the countries producing PRAs are more prone to answer to a PRA survey than others.

The EPPO Secretariat was not aware that so many countries were performing PRAs. Some countries share their PRAs (e.g. on Internet or in EPPO Panels) but not all PRAs are easily accessible. Sharing outcomes of these PRAs (including when the conclusion is that there is no risk) may be a mean of promoting cooperation between EPPO countries.



The countries that do not perform PRAs have provided the following reasons:

- 71% No trained staff and
- 71% Insufficient budget.

The fact that it is not a national priority is indicated for 2 countries. Absence of risk linked to imports from overseas is also given as an explanation for not performing PRAs.

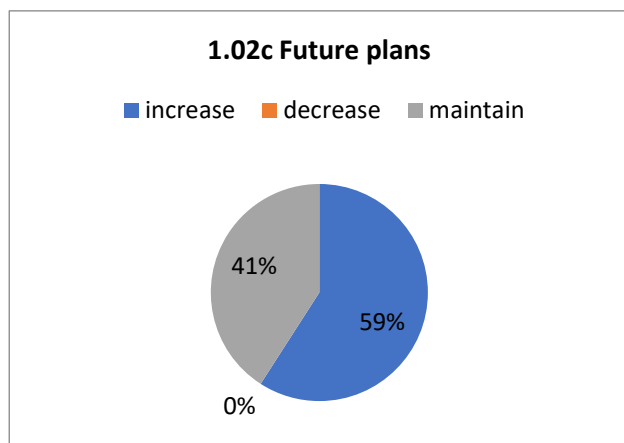
Countries that do not perform PRAs usually rely on PRAs performed by EFSA, EPPO and other countries.

Future plans regarding PRA activities:

13 countries plan to increase risk analysis activity (BA, CH, CY, CZ, DE, DK, FR, IE, IT, LT, LU, SI, TR), 9 plan to maintain risk analysis activity (AT, BE, ES, FI, GB, LV, NL, NO, RU) and no country plan to decrease this activity.

All countries not performing PRAs at the moment plan to increase this activity. Among countries with an existing PRA activity, 65% plans to maintain this activity.

According to the survey, within a few years all respondents will perform PRAs.



Reasons for performing PRAs

The three most common situations where countries are carrying out PRAs are “after detection of a new pest on their territory” (AT, BE, CZ, DE, FI, FR, LV, MT, NL, SI), “after interceptions at import” (AT, DE, TR), and “to revise regulations or justify pest lists” (FR, GB, LV, NL, RU, SI). Other reasons are also listed: “detection of a new host for a pest already regulated” (BE), “literature reviews” (DE), “new trade” (DE), “pest detected in the neighboring country” (LV), “new emerging pest risk identified” (GB, SI), “intentional imports of pests or plants” (SI)...

Even if a few prospective PRAs are conducted (new trade, pest detected in a neighboring country, literature review); most of the PRAs are conducted in reaction to the detection or interception of pests at national level (more details are provided in section 2 of this survey).

Geographical coverage of the PRA

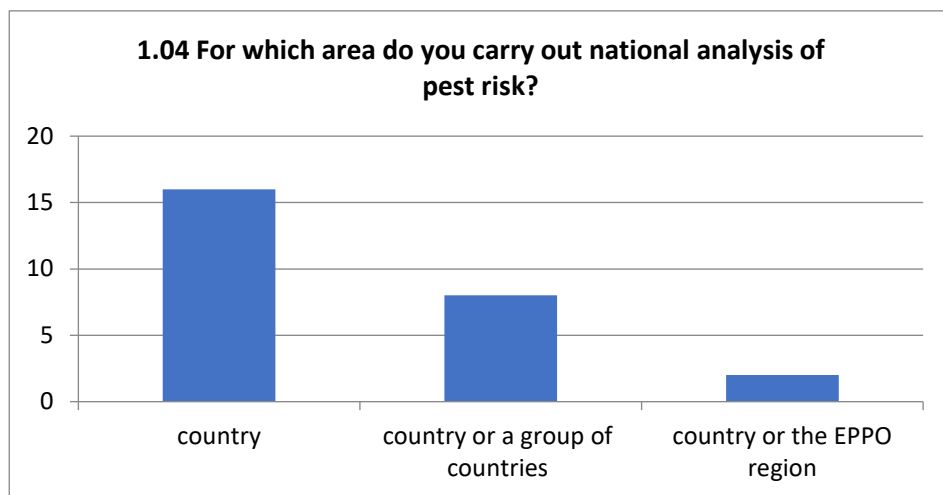
A majority of countries (16) perform PRAs only for their country (AT, BE, CH, DK, FI, FR, GB, LT, LV, MT, NL, NO, PL, RU, SI, TR), 8 countries for their country or a group of countries such as the EU or the Custom Union (CZ, DE, ES, FR, GB, LT, NL, RU), and only 2 for their country or the EPPO region (ES, GB). Some PRAs are conducted with other member countries (GB). FI is interested in larger cooperation, especially with Nordic and Baltic countries.

There is some cooperation between EPPO countries which have common phytosanitary regulations. However it is possible to better use PRA work done at national level for the benefit of a group of countries (e.g. with same eco-climatic conditions).

Only 2 countries produce PRAs for the EPPO region (much less than PRAs for a group of countries): A reason is that PRAs conducted by individual countries for the entire EU are used to support a revision of the regulation (for example deregulation).

Some countries include in their PRAs a brief analysis of the risk for other countries, which can be useful for others. It would be beneficial to all member countries to have more PRAs covering the EPPO region. To be discussed.

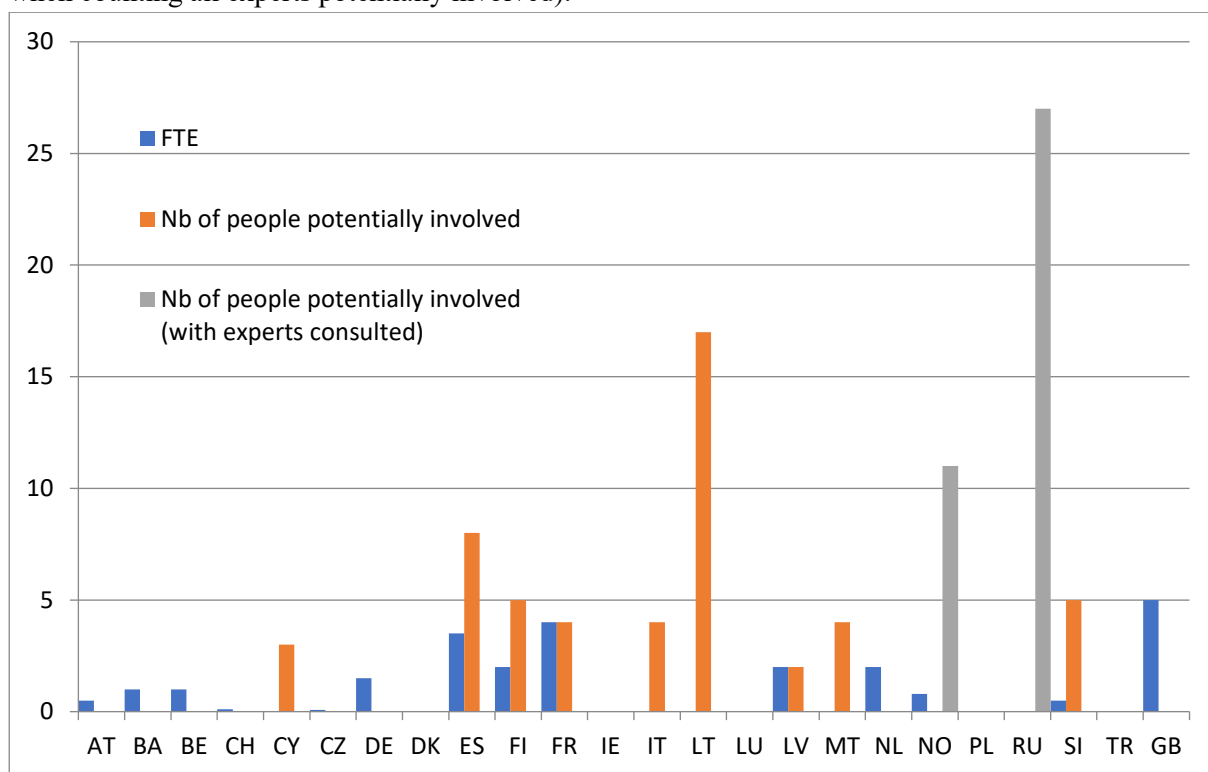
Cooperation could also be achieved by a systematic publication of PRAs performed at the national level.



Experts performing PRAs.

14 countries have a dedicated team or person performing PRA (within the NPPO or within an agency working for the NPPO) (BA, DE, ES, FI, FR, IT, LV, MT, NL, NO, RU, SI, TR, GB) whereas 10 countries (AT, BE, CH, CY, CZ, DK, IE, LT, LU, PL) do not have any dedicated team. Sometimes the work is performed by PRA-teams established on an ad hoc basis (other experts ...). Several countries mentioned that their experts have been trained in BTSF courses or by EPPO.

When no dedicated team has been established, PRA work is performed by 0.1 to 1 FTE (Full Time Equivalent). When a dedicated team has been established, work is done by 0.5 to 5 FTE (2 to 8 persons involved, up to 27 when counting all experts potentially involved).



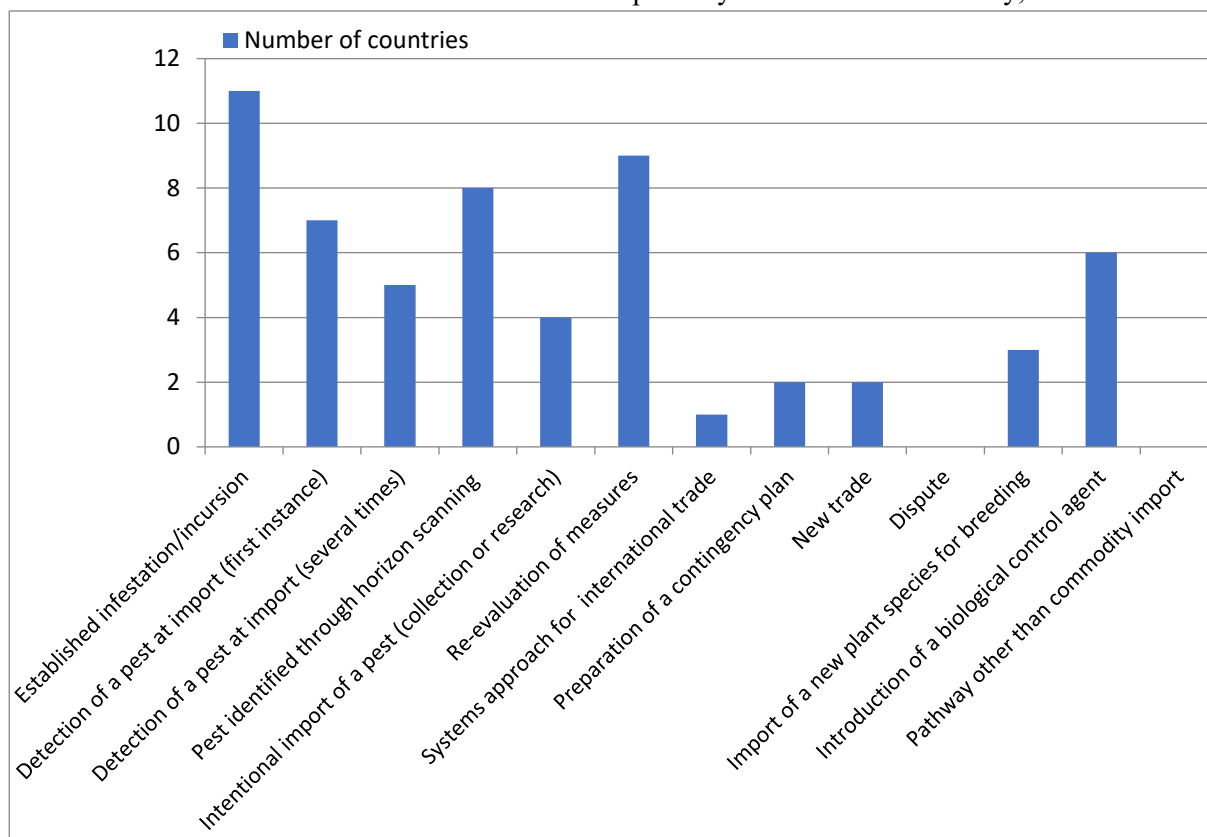
1.05 If a quantitative analysis is considered possible (based on available data) and helpful to support the conclusions of the PRA, is there capacity to conduct this within the team?

Only 18 countries answered this question. 10 countries declared to have the capacity to conduct quantitative risk analysis (AT, DE, ES, FR, NL, NO, RU, SI, TR, GB), whereas 8 countries answered they don't (BA, BE, CH, CY, CZ, DK, FI, IT). It was noted that specific skills (e.g. modeling) are needed and that that enough data has to be available. For AT, such quantitative analyses were only performed when projects were funded.

PART II - Circumstances for use of different risk assessment schemes

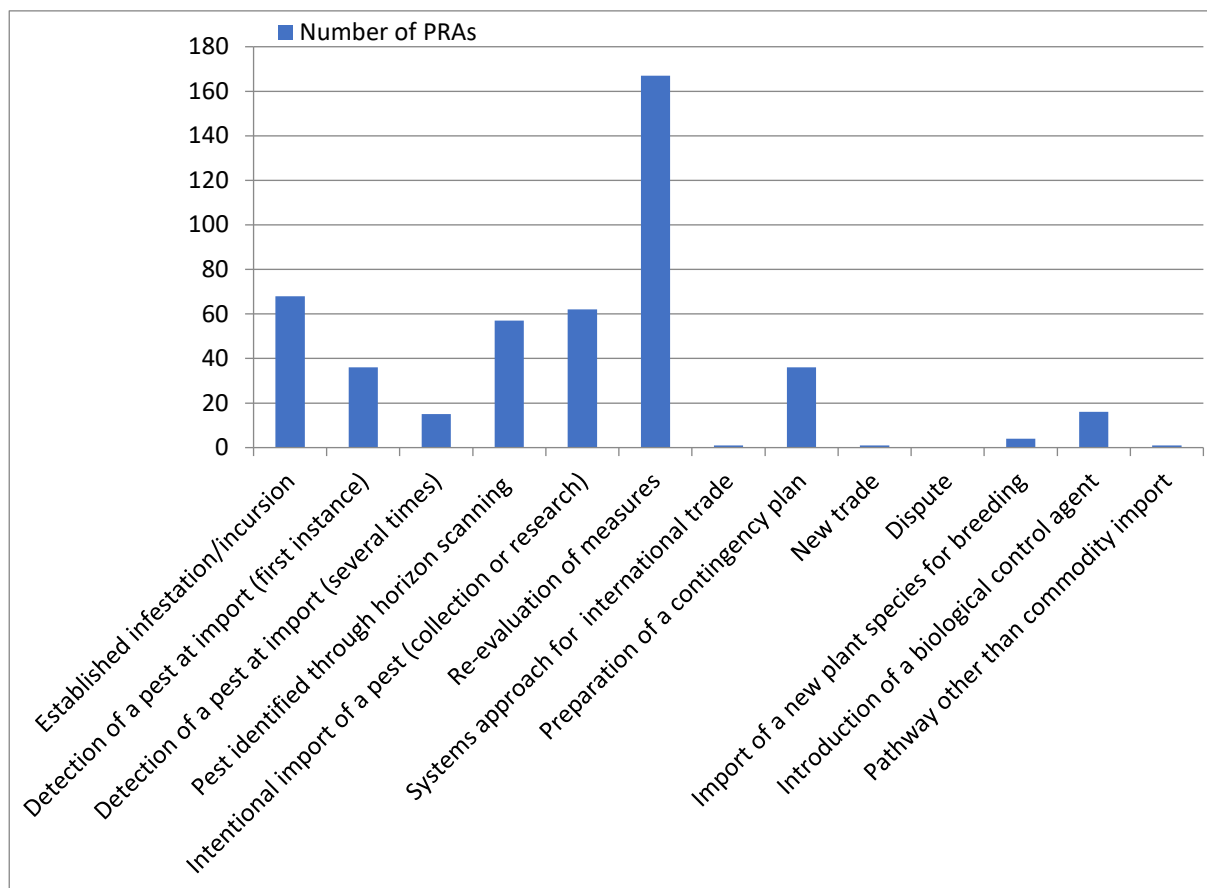
Overview:

Over the last 2 years, the most common circumstances for use of risk assessment schemes are the finding of an infestation/incursion, the detection of a pest at import, the re-evaluation of measures and horizon scanning. No countries use PRA schemes to evaluate risks of a pathway other than a commodity, or in case of a dispute.



Number of countries performing PRAs for each type of circumstances (24 countries answered, several answers possible)

Many pest risk assessments are produced in the EPPO region: among the 24 countries which answered, 464 assessments were produced over the last 2 years. A vast majority of them do not follow EPPO Standards PM 5/5 or PM 5/3. Details for each circumstance are described below but the circumstances for which most pest risk assessments were produced were the finding of an infestation/incursion and horizon scanning. The re-evaluation of measures and the intentional import of a pest reach high numbers mainly because of one country in each case.

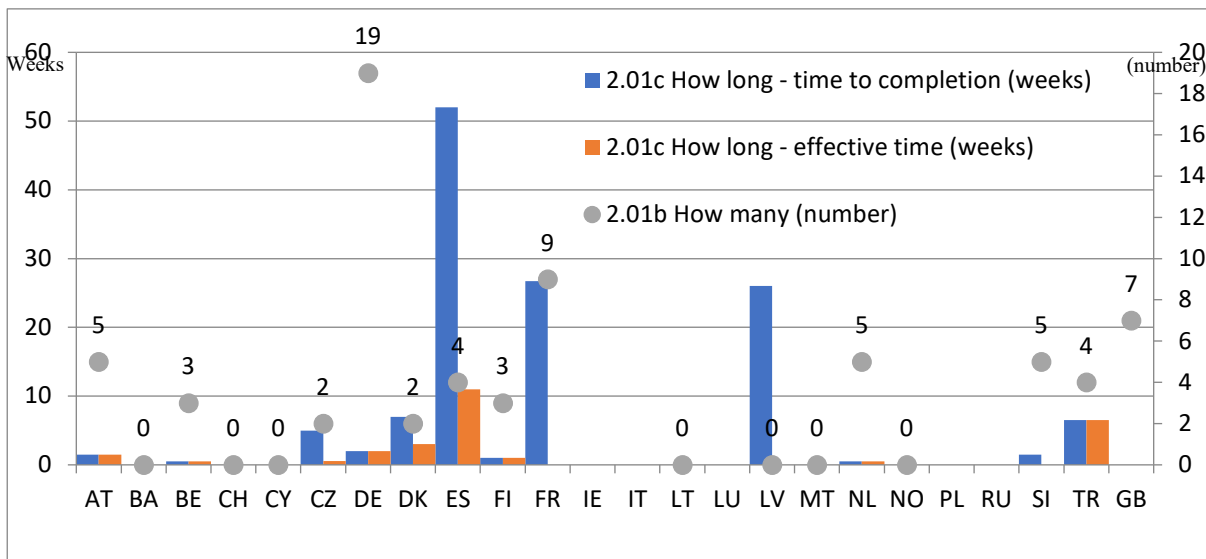


Number of PRAs for each type of circumstances for the 24 countries which answered the survey

2.01 An established infestation or an incursion of a pest has been discovered in the PRA area

11 countries produced risk analyses in the situation of “an established infestation or an incursion of a pest in the PRA area”: It is the situation where the highest number of countries performs PRAs. Countries produced between 2 and 18 PRAs (NL indicated that they perform 25 assessments for circumstances 2.01 to 2.05). 7 of these countries have used national schemes (AT, BE, CZ, DE, FI, NL, GB), 4 have used EPPO Standard PM 5/3 (ES, FR, TR, GB), 4 have used EPPO Standard PM 5/5 (AT, ES, FR, SI), 2 have used the “EFSA guidance documents for the Risk Assessment” (DK, FR) and one has used ISPM 11 (TR). National PRA schemes are sometimes used as guidance by other countries (“Adopted German Express PRA Scheme” for AT and CZ, “GB PRA” for IE and CZ, “NL” scheme for CZ). Time to completion has a lot of variability, ranging from 1 day to 1 year.

Among the 5 countries which performs the more risk assessments (more than 5 a year), 4 used a national scheme (19 for DE and 7 for GB, 5? for NL, 5 for AT).

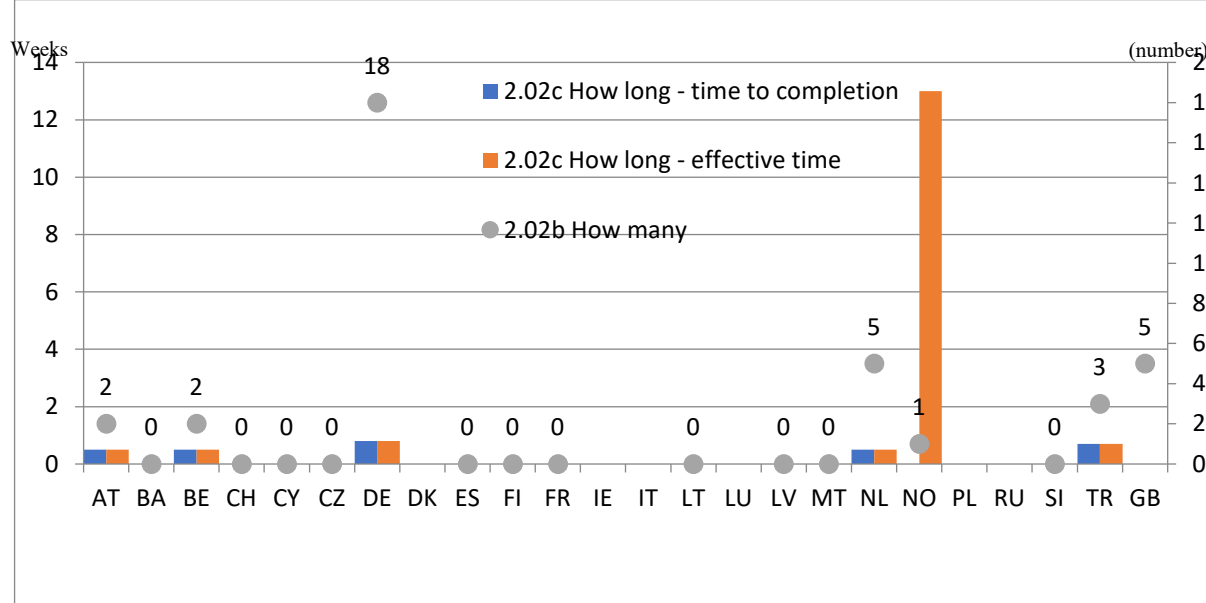


2.02 A pest has been detected in an imported consignment (first instance)

7 countries (AT, BE, DE, NL, NO, TR, GB) performed a risk analysis when a pest is first detected in an imported consignment: 5 of these countries have used national schemes (AT, BE, DE, NL, GB) and 3 have used PM 5/5 (AT, NO, TR). Time to completion is usually less than one week (AT, BE, DE, TR) except in one case (NO with 39 weeks). Countries produced between 1 and 5 risk assessments for this circumstance.

The number of risk analysis declared in such a situation seems surprisingly low. The strategy based on quick risk analysis with national schemes is probably linked to the high level of reactivity needed after such detection (importance of costs for immobilization of the infected consignment, reactivity if the consignment has already been moved, etc.).

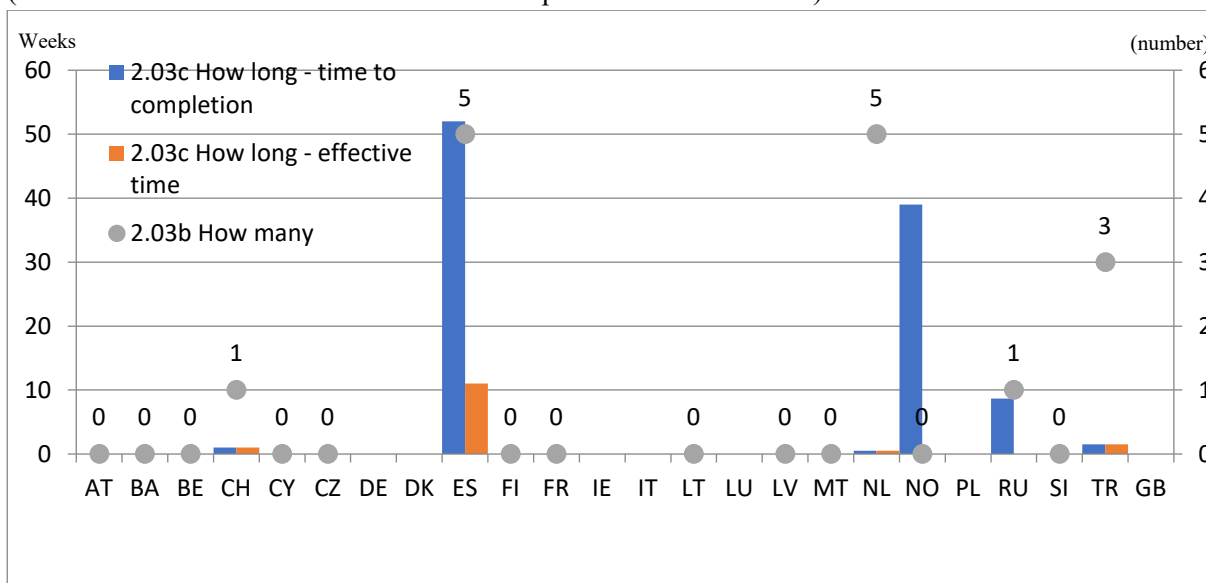
No country used EPPO PM 5/2 Pest risk analysis on detection of a pest in an imported consignment. The Secretariat wonders if this Standard should not be withdrawn.



2.03 A pest has been detected several time on imported consignments (several detections, possibly on different types of consignments)

This question was posed to analyze the situation of repeated detections at import (not associated with the issue of releasing a specific consignment). 5 countries have produced a PRA (CH, ES, NL, RU and TR) for “a pest

detected several times on imported consignments”: NL used its national scheme, 3 countries used PM 5/3 (ES, RU, TR) and 2 used PM 5/5 (RU, TR). Sometimes EFSA guidance document (ES), ISPM 11 (TR) or simplified express PRA (CH) have also been used. DE does not make a distinction depending on the number of detection (a PRA is initiated at the first detection if the pest is new for the area).

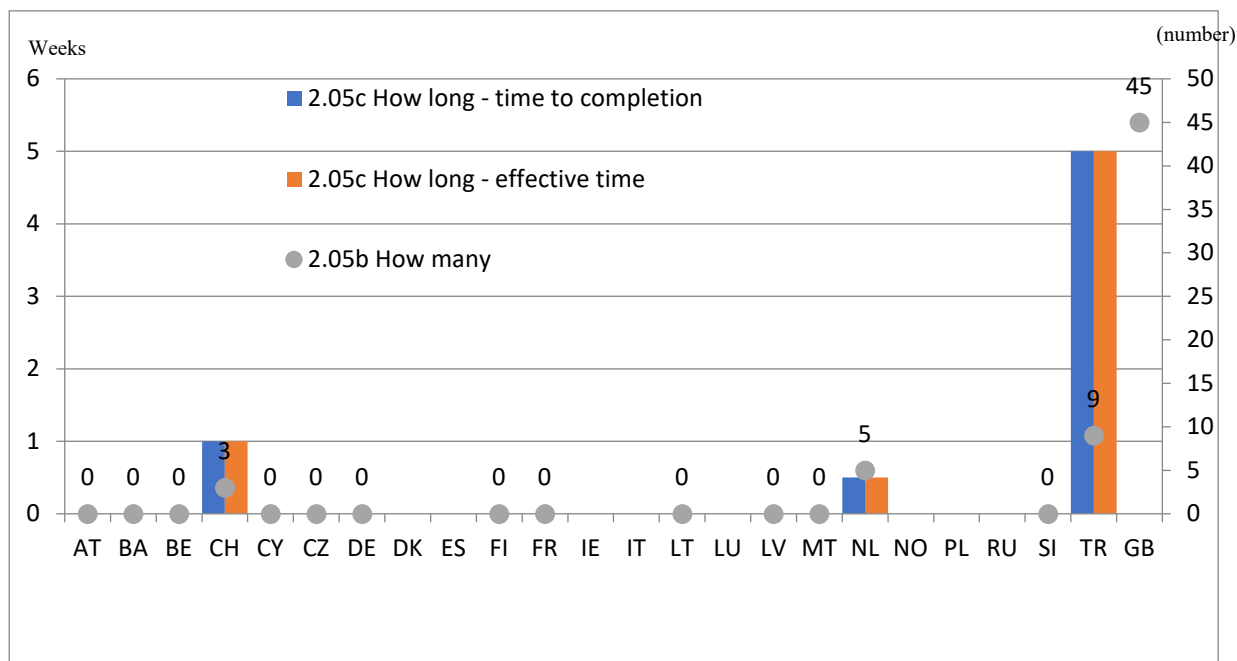


2.04 A pest or a vector of pests has been identified through horizon scanning (a pest identified through scanning of literature, websites, contacts with stakeholders, between researchers...)

As a result of a horizon scanning, risk analyses were conducted in 9 countries on a pest or a vector of pest (CH, ES, FI, FR, GB, NL, RU, TR): 3 of these countries have used PM 5/3 (FR, RU, TR), 4 countries have used national schemes (GB, NL, RU, TR). Sometimes EFSA guidance document (ES), ISPM 11 (TR), PM 5/5 (ES) or simplified express PRA (CH) have also been used. Such risk analyses are usually longer than the ones done in relation with interceptions at import: time of completion ranges from one week (NL, CH) to one year or more.

2.05 A request is made for the intentional import of a pest i.e. for collection or research. (Pest not regulated in the importing country)

Only 4 countries declared producing PRAs for a request made for the intentional import of a pest (CH, GB, NL, TR). It is limited to a few PRAs, except for the UK where 45 PRAs have been produced.

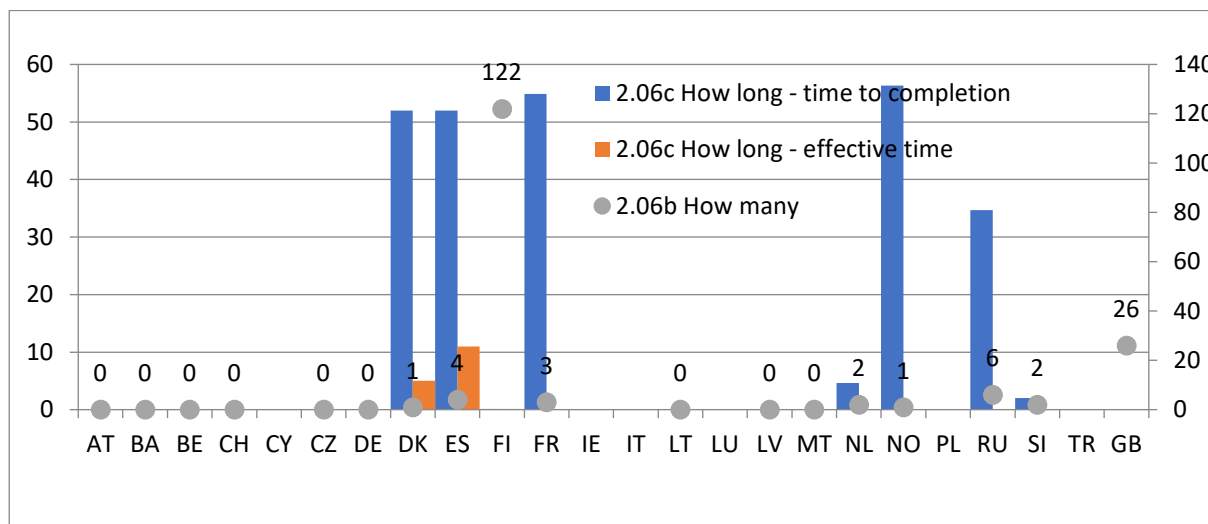


2.06 Re-evaluation of measures (import measures, including possible deregulation or strengthening of measures, or domestic measures being re-evaluated) or revision of phytosanitary regulations

Many countries (9 countries: DK, ES, FI, FR, GB, NL, NO, RU, SI) use risk assessments schemes to re-evaluate measures or revise phytosanitary regulations: It is the second most frequent situation where risk analysis are performed. It covers different cases: in-depth review of measures for regulated pests (with only a few PRAs produced and 6 to 18 months for completion), and prioritization processes when preliminary risk analysis are produced in a few days. Out of the 165 risk assessments produced under this circumstance, 120 were in Finland and 26 in the UK. It should be noted that other countries have elaborated prioritization processes to re-evaluate regulated pests but have not reported this in the survey.

Schemes used were as follows: 4 countries used PM 5/3 (ES, FR, NO, RU), 4 used a national scheme or an *ad hoc* methodology (DK, FI, FR, NO, RU): it includes prioritization study of pests and other quick processes. Some countries also used ISPM 11 (NO), PM 5/5 (NO, SI, TR), EFSA guidance document (ES). Several countries noted that they rely on EFSA or EPPO PRAs to revise legislation/measures.

EPPO Standard PM 9/18 *Decision-Support Scheme for prioritizing action during outbreaks* is only used by SI in this framework.



2.07 Systems approach or other management change is proposed for an international trade

Only the Netherlands produced 1 risk assessment for a “systems approach or other management change proposed for an international trade”. It required about 5 weeks.

2.08 A contingency plan is being prepared

According to the answers provided, it seems that this question was not understood and countries indicated the number of contingency plans prepared instead of the number of PRAs produced in order to prepare a contingency plan. This is explained by the fact that contingency plans are mostly prepared for pests that are already regulated (including by emergency measures). Some countries indicated that they rely on EPPO/EFSA PRAs to prepare contingency plans

EPPO Standard PM 9/10 Generic elements for contingency plans was used in this framework by 6 countries to produce 1 to 3 PRAs (CH, LT, LV, MT, RU, TR, SI), and national schemes were used by the countries that produced the more contingency plans (GB, NL and RU for 8 to 10 plans). NL indicated that they prepare eradication protocols rather than full contingency plans.

2.09 International trade is initiated in a commodity not previously imported into the country or in a commodity from a new area or new country of origin

Only 2 countries produced risk assessment because “*International trade is initiated in a commodity not previously imported into the country or in a commodity from a new area or new country of origin*”: FR (based on Australian Impact Risk Analysis) and TR (based on ISPM 11 and PM 5/3). The process for such a risk analysis ranges from 2 to 9 months.

Two countries (TR and RU) declared using Standard PM 5/7 *Screening process to identify the need for a commodity PRA to import plants for planting* (no information on the number of assessments done in this framework).

As indicated by ES, the current open legislation in the EU does not promote such risk analysis. However this situation will evolve in the future (linked to the new EU Plant Health Law).

2.10 A dispute arises on phytosanitary measures

No country declared to producing risk analyses for dispute arising on phytosanitary measures.

2.11 Import of a new plant species for breeding or research purposes is being planned

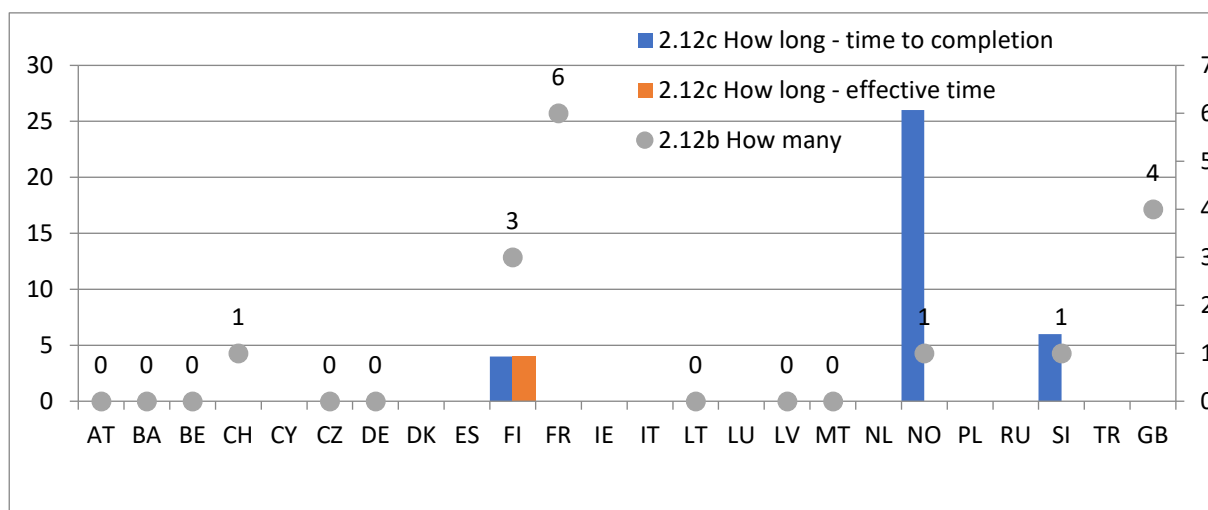
Only 3 countries have conducted a risk analysis for the “*Import of a new plant species for breeding or research purposes*”. This was done once or twice for each country. It followed a national scheme for CH and SI (similar to PM5/5 and Commission directive 2008/61/EC for SI), PM 5/3 for DE.

Such import may concern a new plant that has not been imported in the past because of the lack of interest, as well as a plant prohibited in the past at import. Such analysis may be more systematic in the future for EU countries because of the new Plant Health Law.

2.12 Introduction of a biological control agent is being planned

A total of 6 countries (CH, FI, FR, GB, NO, SI) have conducted risk analyses before the introduction of a biological control agent (between 1 and 6). This is always linked to national regulations that may describe the evaluation process through a national scheme, sometimes based on PM 6/1 and PM 6/2 (GB, FI).

It should be noted that the EPPO Panel on Biological Control Agents is trying to harmonize the evaluation process in the EPPO region.



2.13 A pathway other than a commodity import is identified (natural spread, packaging and packing material, mail, garbage, passenger baggage, etc.)

No country declared to do risk analysis when “A pathway other than a commodity import is identified”. However such risk analysis are not distinguished (DE noted that within the PRAs prepared because of interceptions, several were for pests found in packing material), or may be part of a PRA made for a specific pest (NL).

NO is currently working on a risk assessment of slaughterhouse waste as a pathway for spread of pests and weeds within Norway (not as a pathway for entry from other countries): relevant parts of ISPM 11 are used.

Pathway analysis is very rare at national level, even for import (see question 2.11). Such analysis would be of value to support regulations (e.g. for passenger baggage, internet sales...) or/and to help stakeholders to identify good practices for their internal phytosanitary procedures.

PART III - Needs of risk managers / PRA users

3.01 What do you consider to be the appropriate length for a PRA document? If you think different lengths are appropriate for different purposes, please explain.

All answering countries consider that the appropriate length for a PRA depends on the context (interception and quick decision needed, to decide permanent measures, deregulation) and on what the PRA is about (single organism or not, complexity of the subject, amount of information available, weight of proofs and uncertainties associated to the risk, if this is a pest- or a pathway-analysis).

Several countries propose a stepwise approach (BE, DE, IE, PL) with a first PRA limited in size (only the most important questions regarding potential establishment, impact and control) which may be extended later if needed.

The size for a short PRA, usually to allow prompt decision is estimated between 5 and 30 pages.

The size for a full PRA, usually to decide on permanent phytosanitary measures, should be 20-70 pages, but some recommended that it should be “as long as necessary”.

Some countries insist on the size of the executive summary that should consist in maximum 5 pages (BE, CH, TR).

For deregulation, DE proposes that only a pest categorization might be necessary (except for specific cases). This approach was also chosen by the EU in the context of the revision of the status for pests listed in annex IIA2 of Council directive 2000/29/CE. DK proposes to reduce PRA reports to 2-10 p. when regulation is no longer needed.

3.02 Do you consider that current PRA documents should have a maximum length? If yes, what it is?

A total of 17 countries consider that current PRA document should not have a maximum length (BA, CZ, DE, ES, FI, FR, IE, IT, LT, LV, MT, NL, NO, PL, RU, SI, TR), whereas only 5 countries (AT, CH, CY, DK, GB)

consider that such a maximum is needed. When a maximum is given, it ranges from 10 to 50 pages. GB proposes 50 pages maximum without being absolutely prescriptive.

Most countries agree that guidelines may indicate a maximum length depending on the purpose and context of the PRA as PRAs need to keep a reasonable size, but specific size should not be imposed.

It should be noted that all proposed maximum sizes are all significantly smaller than the one currently produced by the EPPO and EFSA.

3.03 What are the main criteria for you to determine the level of detail needed in a PRA (rank them)? Others: specify

3.03 “Potential for the PRA to be challenged due to the important impact of the recommended measures on trade” and “Relevance of the additional detail to the resulting recommendations and risk management options” are the two main criteria for determining the level of detail needed in a PRA (13 countries ranked them first for each option). The “potential challenge due to the scientific content of the PRA (e.g. uncertainty of the potential for establishment of a pest)” was only ranked first once. Other criteria mentioned included if PRAs should allow prompt decisions, and the intended use of the PRA (prospect for it supporting Regulation)

3.04 If only one section of the PRA is likely to be challenged would you be ready to accept that details are only provided for this section and a shorter description for other sections. If no, please explain: [free text]

21 countries accept that, if only one section of the PRA is likely to be challenged, details are only provided for this section and a shorter description for other sections. It was also suggested that questions that do not add to the overall risk should be skipped.

However DK suggested doing it with caution if aiming at permanent regulation and FR underlined that relevant details needed for any legislative recommendations should be included. IE and MT considered that details are required for all sections to have a better understanding of the pest.

It should be noted that EFSA has agreed with the EU commission that some PRAs could focus on critical elements of risk. These are called ‘conditional PRAs’.

3.05 Are there any particular questions or sections of PM 5/3 that can be reduced, simplified or deleted?

12 countries consider that no particular questions or sections of PM 5/3 can be reduced, simplified or deleted (AT, BA, FR, GB, IT, LT, LV, MT, PL, RU, SI, TR), whereas 8 countries (BE, CH, CZ, DE, DK, ES, NL, NO) would recommend it: Some countries proposed to simplify parts of the PRA for which the probability of being challenged is low and that questions that do not add to the overall risk can be skipped (AT, CH). Most of the simplification proposed concern entry (DE, DK, FI, NL, NO) and establishments (NL, FI) sections. ES and CZ said that they agreed with the proposals made by the core members (doc 14-19657 and 14-19632 see documents in extranet).

It could be proposed to better adapt the analysis to the pest.

3.06 Would you be ready to support the addition of a pest to the EPPO A1 or A2 List based on a short PRA (e.g. 5 to 10 pages)?

21 countries (all answering countries except AT) would be ready to support the addition of a pest to the EPPO A1 or A2 List based on a short PRA (e.g. 5 to 10 pages). It is noted that it may this approach may be useful to have a precautionary approach for emerging pests. Also short PRAs are sufficient for clear-cut cases.

AT considered that it is unlikely to address adequately the assessment and management stage within 5-10 pages. Among countries that agreed with short PRAs, some noted that there may be cases where more details are required (longer documents) (IE, NL), or such longer documents may be needed in a second stage for establishing or revising permanent regulation (DK, FR).

3.07 Would you be ready to recommend the inclusion of phytosanitary measures in your national legislation based on a short PRA (e.g. 5 to 10 pages)?

17 countries (all answering countries except AT, BA, ES and IE) would be ready to recommend the inclusion of phytosanitary measures in their national legislation based on a short PRA (e.g. 5 to 10 pages). For several of these countries (CZ, DK, FI, LT, NL, SI), it is a way to react quickly to a newly identified risk with emergency measures but it should be completed later on by a more comprehensive document (e.g. for permanent regulation). However the use of such a short document may depend on the impact of the measures (BE, CZ), the pest (FI), data available (FR), until further research indicates otherwise (MT).

Some EU countries noted that phytosanitary measures are mainly decided at EU level.

3.08 To aid transparency, some PRAs ask for a level of uncertainty / confidence to be provided by assessors when they use judgments to provide responses to PRA questions (e.g. PM 5/5). Please describe how this helps.

First of all, several countries underlined added value of indicating a level of uncertainty to help understanding the robustness of the evaluation (AT, CZ, DE, LT). The uncertainty will impact the definition of risk mitigation measures (BE, CH, CY, ES, FI, IT, MT, NO). It is also a way to identify gaps and research needs (AT, CZ, DE, DK, FR, IE, NO, SI). SI considers that it helps identifying sections for which a detailed assessment is needed. NL considers that the qualitative risk ratings both for the risk level as for the level of uncertainty are not very consistent among PRAs. Therefore, risk managers cannot fully rely on these ratings.

Overall, such ratings are useful, but still need harmonization.

GENERAL CONCLUSIONS:

- EPPO Standards from the series PM5 Pest Risk Analysis are not widely used, in particular by countries producing many PRAs but PM 5/5 (Express scheme) is used more than PM 5/3 and some national schemes are quite similar to PM5/5 (e.g. in Germany and in the UK). The Panel on Phytosanitary Measures wished that PM 5/5 is made available through the CAPRA system.
- PM 5/2 is not used at all. *The Working Party should consider whether PM5/2 should be withdrawn.*
- There is no need to include more details in the current EPPO Standards for PRAs (there is a general acceptance of short PRAs, and a requested need for more flexibility to focus on the key questions only).
- Many PRAs produced in the region are performed at national level. The Panel on Phytosanitary Measures considered that it would be beneficial for EPPO members to be aware to PRAs being undertaken by other members, and to share these national PRAs on a common platform [*to be further elaborated if the Working Party agrees with this idea*].
- The Panel underlined that EPPO should carry on conducting PRAs with Expert Working Groups for important pests. EPPO PRAs are recognized as high quality.

Annex 8 Proposed revision of EPPO Standard PM 5/5 *Decision-Support Scheme for an Express Pest Risk Analysis* by the Secretariat, not yet presented to Panels

PM 5/5(2)

Guidelines on Pest Risk Analysis

Lignes directrices pour l'analyse du risque phytosanitaire

Decision-Support Scheme for an Express Pest Risk Analysis

Specific scope: This standard provides a simplified scheme for the rapid production of pest risk analyses.

Specific approval and amendment: 2012-09

Additional guidance included in 2018

Introduction

The EPPO Standards on Pest Risk Analysis (PRA) are intended to be used by National Plant Protection Organizations (NPPOs), in their capacity as bodies responsible for the establishment of phytosanitary regulations and the application of phytosanitary measures while respecting the requirements of the International Plant Protection Convention, ISPM 1 *Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade* and ISPM 11 *Pest Risk Analyses for Quarantine Pests*. They are also used by the technical bodies of EPPO to formulate recommendations on phytosanitary measures to the NPPOs. In this framework EPPO has developed different Standards to be used in different circumstances. PM 5/2 was developed to provide a simplified PRA scheme to be used when an unfamiliar pest is detected in an imported consignment, in order to decide whether phytosanitary action is needed. PM 5/3 is based on ISPM11 and provides detailed instructions for the following steps of PRA for quarantine pests: initiation, pest categorization, probability of introduction and spread, assessment of potential economic consequences and pest risk management.

This standard provides a simplified scheme for undertaking a rapid PRA to determine whether an organism has the characteristics of a quarantine pest, and if appropriate, to identify potential management options. Its use is particularly suitable to support recommendation of phytosanitary measures for an emerging pest. This scheme may also be used in the framework of a pathway-initiated PRA to evaluate individual pests likely to be carried by this pathway. In the case of an express PRA initiated by an outbreak, risk managers should also use the information provided to consider actions to be taken internally (such as establishing surveillance to confirm the status of the pest in the country).

An EPPO Standard on “*Generic elements for contingency plans*” (PM 9/10) describing essential elements for an emergency response for a pest outbreak or a suspected pest outbreak was adopted in 2009. In addition, a decision-support scheme for prioritizing action during outbreaks is under development to decide on measures to be applied in an outbreak area.

It is important that all steps of the Express PRA should be documented, indicating how each decision was reached and on what information it was based. The first 7 questions should be answered first. Then the assessor may decide to focus first on critical points for the assessment (e.g. the probability of establishment). The assessor may stop the assessment at any point if the evidence provided is sufficient to reach a conclusion on the pest risk. Note that text written in green is provided for guidance to risk assessors and should be deleted from the final PRA.

A computerized version of this Express PRA Scheme with the CAPRA software is available at capra.eppo.int.

Summary²⁹ of the Express Pest Risk Analysis for “<i>pest name</i>”			
PRA area: <i>specify the PRA area being assessed</i>			
Describe the endangered area: <i>(see question 14)</i>			
<p>Main conclusions</p> <p><i>Overall assessment of risk: (Copy your answer from Q 15).</i></p> <p><i>Phytosanitary Measures: indicate whether the pest should be recommended for immediate action in the PRA area. Summarize your answer from Q 16.</i></p> <p><i>Note: If the assessment shows that phytosanitary measures are not required for your country but there are indications that other EPPO countries are at higher risk, mention it.</i></p>			
Phytosanitary risk for the <u>endangered area</u> <i>(Individual ratings for likelihood of entry and establishment, and for magnitude of spread and impact are provided in the document)</i>	High <input type="checkbox"/>	Moderate <input type="checkbox"/>	Low <input type="checkbox"/>
Level of uncertainty of assessment <i>(see Q 17 for the justification of the rating. Individual ratings of uncertainty of entry, establishment, spread and impact are provided in the document)</i>	High <input type="checkbox"/>	Moderate <input type="checkbox"/>	Low <input type="checkbox"/>
<p><i>Other recommendations: include any recommendations other than phytosanitary measures resulting from the PRA, such as</i></p> <ul style="list-style-type: none"> <i>• Inform EPPO or IPPC or EU</i> <i>• Inform industry, other stakeholders</i> <i>• State whether a detailed PRA is needed to reduce level of uncertainty (if so, state which parts of the PRA should be focused on)</i> <i>• Specify if surveys are recommended to confirm the pest status</i> <i>• State what additional work/research could help making a decision.</i> 			

²⁹ The summary should be elaborated once the analysis is completed

Express Pest Risk Analysis:

.....
(Pest name)

Prepared by: *Name and affiliation of the assessor(s). Contact details.*

Date:

Stage 1. Initiation

Reason for performing the PRA: *(e.g. interceptions, outbreak)*

PRA area: *specify the PRA area being assessed*

Stage 2. Pest risk assessment

1. Taxonomy: *e.g. Genus, species/ subspecies, Authority, Family, Order, Kingdom.*

Include information on strains and populations, etc. if relevant, and synonyms if appropriate.

Suggested subheadings:

Taxonomic classification

Previous names

Common names:

2. Pest overview

- *Summarize the life cycle (e.g. length of life cycle, location of different life stages, temperature thresholds, humidity requirements; capacity for dispersal) and other relevant information (damage should be described in Q 12). If a datasheet is available, this section should only include the basic information. If available place illustrations of the pest and the symptoms caused in Appendix 1.*
- *Host plants (for pests)/habitats (for invasive plants) (more detail should be provided in Q 7)*
- *Symptoms*
- *Detection and identification (note if a diagnostic protocol is available). State if and how the pest can be trapped.*

3. Is the pest a vector?

Yes No

If the pest is a vector, which organism(s) is (are) transmitted and does it (do they) occur in the PRA area?

4. Is a vector needed for pest entry or spread?

Yes No

If a vector is needed, which organism(s) serves as a vector and does it (do they) occur in the PRA area? Consider both the pest and the vector in the assessment.

5. Regulatory status of the pest

Is the pest already regulated by any NPPO, or recommended for regulation by any RPPO? (Assessors can check this by reference to EPPO PQR, RPPO and IPPC websites in addition to normal search mechanisms).

6. Distribution

Continent	Distribution (list countries, or provide a general indication , e.g. present in West Africa)	Comments <i>Provide comments on the pest status in the different countries where it occurs (e.g. widespread, native, introduced....)</i>	Reference
Africa			
America			
Asia			
Europe			
Oceania			

Information on distribution may be retrieved from PQR (<http://www.eppo.int/DATABASES/pqr/pqr.htm>), CAPRA datasets (<http://capra.eppo.org/>), CABI maps, etc.

Comments on distribution: (e.g. if known, please comment on the area of origin, how the pest has spread and on any evidence of increasing range / frequency of introductions)

Uncertainties/doubtful/invalid records: *it may be useful to state any doubtful or unreliable records*

7. Host plants /habitats* and their distribution in the PRA area

If the host range is large, you may group plants (e.g. deciduous trees, or at the family level, e.g. Brassicaceae, Rosaceae), and/or focus on those occurring in the PRA area. When appropriate, the difference of susceptibility between hosts should be noted. If there are many habitats, focus on those occurring in the PRA area. Reference to FAOSTAT and EUROSTAT may help assess distribution of host plants.

Host name (common name) / habitats*	Scientific (common name)	Presence in PRA area (Yes/No)	Comments (e.g. total area, major/minor crop in the PRA area, major/minor habitats*)	Reference

*Specify habitat for invasive plants, host plants for other pests.

8. Pathways for entry

Which pathways are possible and how important are they for the probability of entry?

Examples of pathways are:

- *Plants for planting*
 - plants for planting (except seeds, bulbs and tubers) with or without soil attached
 - bulbs or tubers
 - seeds
- *Plant parts and plant products*
 - cut flowers or branches
 - cut trees
 - fruits or vegetables
 - grain
- *Wood and wood products*
 - non-squared wood
 - squared wood
 - bark
 - wood packaging material
 - chips, firewood, waste wood...
- *Natural spread*
- *Other possible pathways*
 - other packaging material
 - soil/growing medium as such

- pollen
- stored plant products
- conveyance and machinery
- passengers
- hitchhiking
- plant waste
- manufactured plant products
- intentional introduction (e.g. scientific purposes)

Depending on the availability of information, and the time to perform the PRA, there may be more or less information available

Possible pathways <i>(in order of importance)</i>	Short description explaining why it is considered as a pathway	Pathway prohibited in the PRA area? Yes/No	Pest already intercepted on the pathway? Yes/No

Possible pathways	Pathway 1
Short description explaining why it is considered as a pathway	
Is the pathway prohibited in the PRA area?	
Has the pest already intercepted on the pathway?	
What is the most likely stage associated with the pathway?	
What are the important factors for association with the pathway?	
Is the pest likely to survive transport and storage along this pathway?	
Can the pest transfer from this pathway to a suitable habitat?	
Will the volume of movement along the pathway support entry?	
Will the frequency of movement along the pathway support entry?	
Rating of the likelihood of entry	Low <input type="checkbox"/> Moderate <input type="checkbox"/> High <input type="checkbox"/>

Rating of uncertainty	Low <input type="checkbox"/>	Moderate <input type="checkbox"/>	High <input type="checkbox"/>
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Do other pathways need to be considered?

if yes
if no

Repeat table above
Go to 9

Pathway	Pathway 1
Coverage	
Pathway prohibited in the PRA area?	
Pathway subject to a plant health inspection at import?	
Pest already intercepted?	
Most likely stages that may be associated	
Plants concerned	
Important factors for association with the pathway	
Survival during transport and storage	
Trade	
Transfer to a host	
Likelihood of entry and uncertainty (ratings: low, moderate, high)	

Rating of the overall likelihood of entry	Very low <input type="checkbox"/>	Low <input type="checkbox"/>	Moderate <input type="checkbox"/>	High <input type="checkbox"/>	Very high <input type="checkbox"/>
Rating of uncertainty		Low <input type="checkbox"/>	Moderate <input type="checkbox"/>	High <input type="checkbox"/>	

Unlikely pathways may also be noted

9. Likelihood of establishment outdoors in the PRA area

Consider in particular the presence of host plants/habitats and climatic suitability and describe the area where establishment is most likely (area of potential establishment). Reference to maps such as Köppen-Geiger climate zones, day degrees and hardiness zones may help assess the likelihood of establishment (see e.g. http://capra.eppo.org/files/links/Rating_Guidance_for_climatic_suitability.pdf).

The following subheading may be used to structure the assessment of the likelihood of establishment:

9.1 Climatic suitability

9.2 Host plants: presence in the area of suitable climate

9.3 Other factors (pest management practice, other abiotic factors, presence of natural enemies, etc.)

Rating of the likelihood of establishment outdoors	Very low <input type="checkbox"/>	Low <input type="checkbox"/>	Moderate <input type="checkbox"/>	High <input type="checkbox"/>	Very high <input type="checkbox"/>
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Rating of uncertainty	Low <input type="checkbox"/>	Moderate <input type="checkbox"/>	High <input type="checkbox"/>
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10. Likelihood of establishment in protected conditions in the PRA area

Consider the presence of host plants within protected cultivation (e.g. glasshouses, shade houses) and the management practices and consider whether the pest may establish in protected cultivation, and where. For invasive plants consider if protected conditions are a suitable habitat.

Rating of the likelihood of establishment in protected conditions	Very low <input type="checkbox"/>	Low <input type="checkbox"/>	Moderate <input type="checkbox"/>	High <input type="checkbox"/>	Very high <input type="checkbox"/>
Rating of uncertainty	Low <input type="checkbox"/>	Moderate <input type="checkbox"/>	High <input type="checkbox"/>		

11. Spread in the PRA area

- Natural spread
- Human assisted spread

Briefly describe each mode of spread (e.g. natural flight of invertebrate pests, wind dispersal, carried within plants or plant products, carried with traded commodities), and indicate the rate or distance of spread.

If possible consider how long it would take for the pest to spread widely within the area of potential establishment if no phytosanitary measures are taken. If no specific data are available, compare with similar organisms.

Rating of the magnitude of spread	Very low <input type="checkbox"/>	Low <input type="checkbox"/>	Moderate <input type="checkbox"/>	High <input type="checkbox"/>	Very high <input type="checkbox"/>
Rating of uncertainty	Low <input type="checkbox"/>	Moderate <input type="checkbox"/>	High <input type="checkbox"/>		

12. Impact in the current area of distribution

Briefly describe the economic, ecological/environmental and social impacts in the current area of distribution. Impact on biodiversity, ecosystem services and socio-economic impact may need to be detailed separately, in particular for invasive alien plants.

Briefly describe the existing control measures applied against the pest.

Rating of the magnitude of impact in the current area of distribution	Very low <input type="checkbox"/>	Low <input type="checkbox"/>	Moderate <input type="checkbox"/>	High <input type="checkbox"/>	Very high <input type="checkbox"/>
Rating of uncertainty	Low <input type="checkbox"/>	Moderate <input type="checkbox"/>	High <input type="checkbox"/>		

The rating chosen should be based on the highest type of impact.

13. Potential impact in the PRA area

Consider whether impacts in the area of potential establishment will be similar to that in areas already infested, taking into account availability of plant protection products, natural enemies, cultural practices, etc. in the area of potential establishment. Consider other consequences (e.g. export loss) if applicable. If impacts are considered largely similar, there is no need to provide details, but only the reasoning explaining why it would be similar.

Will impacts be largely the same as in the current area of distribution? Yes /No

If No

<i>Rating of the magnitude of impact in the area of potential establishment</i>	<i>Very low</i> <input type="checkbox"/>	<i>Low</i> <input type="checkbox"/>	<i>Moderate</i> <input type="checkbox"/>	<i>High</i> <input type="checkbox"/>	<i>Very high</i> <input type="checkbox"/>
<i>Rating of uncertainty</i>	<i>Low</i> <input type="checkbox"/>		<i>Moderate</i> <input type="checkbox"/>	<i>High</i> <input type="checkbox"/>	

14. Identification of the endangered area

Define the endangered area (as defined in ISPM 5 “An area where ecological factors favour the establishment of a pest whose presence in the area will result in economically important loss.”): describe in which part of the area of potential establishment significant impact is expected.

If relevant, it may be described how climate change will affect the endangered area in future according to a given scenario.

15. Overall assessment of risk

Summarize the likelihood of entry, establishment, spread and possible impact without phytosanitary measure. An overall rating should be given in the summary part which is placed at the beginning of the Express PRA. Then consider whether phytosanitary measures are necessary.

If the assessment shows that phytosanitary measures are not required for your country but there are indications that other EPPO countries are at higher risk, mention it.

If relevant, it may be described how climate change will affect the different ratings of the pest risk assessment (entry, establishment, spread, impact) according to a given scenario.

Stage 3. Pest risk management

16. Phytosanitary measures

Suggested headings

16.1 Measures on individual pathways

Describe potential measures for relevant pathways and their expected effectiveness on preventing introduction (entry & establishment) and / or spread. See reference document on growing period, on PFA, and on buffer zones, and PM 5/9.

16.2 Eradication and containment

If possible, specify prospects of eradication or containment in case of an outbreak. Indicate effectiveness and feasibility of the measures. Useful guidance may be found in EPPO Standard PM9/018(1) Decision-Support Scheme for prioritizing action during outbreaks

Measures to prevent entry may be presented in a table

Possible pathway	Measures identified
<i>Pathways as named in section 8</i> Example: Host plants for planting with roots	<i>Suggested measures</i> Pest free area Or Pest-free production site or pest-free place of production (with all production sites pest-free), with detailed requirements as listed in Annex 1 Or Growing under complete physical isolation (EPPO Standard PM5/8) (with requirements appropriate for <i>M. mali</i>)

A table summarizing the main possible measures may be included in an Annex, see table below for an example

Annex 1. Consideration of pest risk management options

The table below summarizes the consideration of possible measures for host plants for planting (based on EPPO Standard PM 5/3). When a measure is considered appropriate, it is noted “yes”, or “yes, in combination” if it should be combined with other measures in a systems approach. “No” indicates that a measure is not considered appropriate. A short justification is included.

Option	Pathway 1
Existing measures the PRA area	
Options at the place of production	
Visual inspection at place of production	
Testing at place of production	
Treatment of crop	
Resistant cultivars	
Growing under complete physical isolation	
Specified age of plant, growth stage or time of year of harvest	
Produced in a certification scheme	
Possibility for pest-free production site/place of production/area?	
Pest free production site and pest free place of production	
Pest-free area	
Options after harvest, at pre-clearance or during transport	
Visual inspection of consignment	
Testing of commodity	
Treatment of the consignment	
Pest only on certain parts of plant/plant product, which can be removed	
Prevention of infestation by packing/handling method	
Options that can be implemented after entry of consignments	
Post-entry quarantine	
Limited distribution of consignments in time and/or space or limited use	
Surveillance and eradication in the importing country	

See also <https://zenodo.org/record/1170121#.Wn2ya2eGOUk>

17. Uncertainty

List and describe the main sources of uncertainty within the risk assessment and risk management.

State whether a detailed PRA is needed to reduce key aspects of uncertainty (if so state which parts of the PRA should be focused on). Comment on what work would be needed to address uncertainties (e.g. for distribution the need for surveys, produce epidemiological data...)

18. Remarks

Add any other relevant information or recommendations. For example when phytosanitary measures are not considered appropriate, recommendations for the development of other control strategies can be made (e.g. Integrated Pest Management, certification schemes).

Once the analysis has been completed, a summary should be prepared
(see the summary box at the beginning of the Express PRA)

19. REFERENCES

Provide references cited above (see [Instructions for authors to the EPPO Bulletin](#))

When referring to websites, include the web address and date accessed.

List also personal communications with the date.

Appendix 1. Relevant illustrative pictures (for information)

<i>Photo 1 (pest)</i>	<i>Photo 2 (e.g. symptoms)</i>
<i>Source/ copyright owner</i>	<i>Source/ copyright owner</i>