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Guidance of the EFSA PLH Panel on quantitative pest risk assessment

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Abstract

This Guidance describes a two-phase approach for a fit-for-purpose method for the assessment of plant pest risk in the territory of the European Union (EU). Phase one consists of pest categorisation to determine whether the pest fulfils the criteria of a quarantine pest or those of a regulated non-quarantine pest for the area of the EU. Phase two consists of pest risk assessment, which may be requested by the risk managers following the pest categorisation results. This Guidance provides a template for pest categorisation and describes in detail the use of modelling and expert knowledge elicitation to conduct a pest risk assessment. The Guidance provides support and a framework for assessors to provide quantitative estimates, together with associated uncertainties, regarding the entry, establishment, spread and impact of plant pests in the EU. The Guidance allows the effectiveness of risk reducing options (RROs) to be quantitatively assessed as an integral part of the assessment framework. A list of RROs is provided. A two-tiered approach is proposed for the use of expert knowledge elicitation and modelling. Depending on data and other resources available and the needs of risk managers mandating the assessment, pest entry, establishment, spread and impact steps may be assessed directly, using weight of evidence and expert knowledge (first tier), or they may be elaborated in sub-steps using quantitative models (second tier). Guidance is provided on how to derive a model of minimum complexity to conduct an assessment. Each assessment is operationalised using Monte Carlo simulations which can compare scenarios for relevant factors, e.g. with and without RROs. Comparisons between scenarios are made to draw conclusions on the magnitude of pest risks and the effectiveness of RROs. This document provides guidance on the application of the two-phase assessment method and on how to communicate its results.

Keywords: guidance, quantitative pest risk assessment, risk reduction option, model, uncertainty, risk communication, expert knowledge elicitation (max. seven keywords)

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Summary

The European Commission requested EFSA to evaluate the status of a number of plant pests listed in Annexes of Directive 2000/29/EC to inform future plant health regulatory requirements. A two-phase approach was developed to streamline the process and make conceptual improvements over previous approaches. The first phase entails pest categorisation to determine whether the pest fulfils the criteria of a quarantine pest or those of a regulated non-quarantine pest for the area of the European Union. For selected pests, a second phase requires a pest risk assessment, and upon request the identification of risk reduction options (RROs) and an assessment of the effectiveness of current EU phytosanitary requirements. The EFSA Panel on Plant Health took the opportunity to review previous Guidance (EFSA PLH Panel 2010), and developed a methodological framework for pest risk assessment recognising that risk assessors should aim to express pest risk and uncertainty in quantitative terms to the extent that this is scientifically achievable (EFSA Scientific Committee, 2018a) so as to minimise the use of ambiguous expressions of risk and to better inform risk management decisions which are often based on comparisons of scenarios e.g. with and without selected risk management measures in place.

This document provides guidance on how to apply this two-phase pest risk assessment method. The Guidance focuses on the second phase (assessment); a template for the first phase (categorisation) is given as Appendix A.

The Guidance aligns with international IPPC phytosanitary standards ISPM 2 (FAO, 2016) and ISPM 11 (FAO, 2017) and is consistent with EFSA Guidance documents (e.g. EFSA PLH Panel 2011; 2012; EFSA Scientific Committee, 2018a).

The Guidance provides advice to assessors on how to design the risk assessment and manage the assessment process to deliver a fit for purpose assessment of pest risk. It emphasises the need for interaction with risk managers / decision makers at key points, e.g. during problem formulation in which the scope of the assessment is defined, to ensure that the risk assessment addresses the mandate given by the requestor. A two-tiered approach is proposed for the use of expert knowledge elicitation and modelling. Depending on data and other resources available and the needs of risk managers mandating the assessment, pest entry, establishment, spread and impact steps may be assessed directly, using weight of evidence and expert knowledge (first tier), or they may be elaborated in sub-steps using quantitative models (second tier). Guidance is given for the development of a quantitative model for assessing entry, establishment, spread and impact of the target organism. The model should contain sufficient detail to enable quantification of key processes and address questions of the requestor on the effectiveness of risk reduction options, but should be simple enough to remain transparent and suitable for parameterization with the data and resources available.

The Guidance provides a framework within which a quantitative assessment can be performed. The framework is adaptable so as to make the assessment appropriate given the resources available. The framework for pest risk assessment is built upon adopting a scenario based approach beginning with a conceptual model that describes the general system to be assessed e.g. an entry pathway leading to pest establishment then pest spread within the EU area, ultimately leading to an assessment of the consequences of the pest's entry and spread at a future time horizon. The conceptual model should identify the necessary characteristics on which to build a formal quantitative model at an appropriate level of complexity. Advice on how to achieve this is provided.

This Guidance supports the production of quantitative assessments of pest risk. Developing definitions to describe components of risk requires some interpretation of the evidence in quantitative terms and can be an iterative process in which the needs of the assessment are considered against available data. Advice is provided regarding data gathering and information collection. Recognising that precise and relevant data from empirical studies, surveys and monitoring are seldom available at the level of resolution required for all steps of a plant pest risk assessment model, expert knowledge elicitation (EKE) will often be required to estimate the values of model parameters. Procedures are outlined in accordance with the EFSA uncertainty Guidance (EFSA Scientific Committee, 2018a) to conduct the expert knowledge elicitation in a way that is transparent, rigorous and time-efficient. Uncertainties are expressed quantitatively where possible, and in terms of verbal descriptions if quantitative expression

is not possible. Recognising that transparency is a fundamental principle of EFSA's work, the framework requires assessors to reveal what uncertainties are identified during the assessment and what impact uncertainty has on the assessment of pest risk.

Appendices provide the phase one pest categorisation template and a phase two pest risk assessment template, together with examples of pest entry pathways and tools to identify potential RROs. Examples of a conceptual and formal entry pathway model are also provided to illustrate how the framework can operate.

The purpose of risk assessment is to inform risk managers of the nature and potential magnitude of entry, establishment, spread and impact, and the effectiveness of risk management options and thus inform their risk management decisions. It is essential to communicate the results of the risk assessment in an unambiguous and transparent way and this Guidance recommends approaches to adopt to facilitate the communication of results for each step in the assessment which has been assessed, e.g. entry, establishment, spread and impact. Examples of how quantitative results from assessments can be presented in a consistent manner are suggested.

Specifically, when reporting the results of the likelihood of pest entry, this should be reported as the uncertainty distribution of the estimated number of founder pest populations potentially establishing in the risk assessment area as a result of entry along each individual entry pathway assessed. This assessment is made separately for each pathway and also in aggregate as the sum of potential establishment along all pathways. All estimates are made using supporting Monte Carlo simulations to express the range of uncertainty, unless this uncertainty is estimated in one step using EKE.

Establishment should be described as the uncertainty distribution of the likely number of founder populations establishing due to entry, and taking into account climatic and other factors affecting the establishment to hosts and surviving for the foreseeable future at the selected spatial and temporal resolution.

Spread should be reported as an uncertainty distribution for the increase in the geographic range of the pest within the risk assessment area, expressed as the increased number of spatial units occupied, or area occupied at the appropriate spatial and temporal scale.

The consequences of pest introduction and spread should be reported in terms of estimated uncertainty distributions of changes to crop output, yield or quality under different risk management scenarios. Environmental impacts should be reported in terms of changes in estimated uncertainty distribution of ecosystem services provisioning and biodiversity levels.

Conclusions should clearly respond to the questions that the assessment sought to address. The key interpretations based on the results sections should appear in the conclusion. Median estimates should be reported together with a probability interval representing the uncertainty. We recommend that the standard range reported should be the 95% probability interval, between the 2.5th and 97.5th quantile of the distribution.

A risk assessment opinion consists of an abstract, summary, the main body of the text and possibly annexes and, or appendices. The Guidance advises on what form of expressing the results is best suited for each section of a published risk assessment opinion. As a reader progresses from abstract to summary to main body, the level of detail increases, while maintaining a consistent message.

In conclusion, this draft Guidance provides a framework built upon agreed principles of pest risk assessment and includes flexibility allowing assessors to design conceptual and formal models at appropriate levels of sophistication and resolution to suit the needs of each assessment. As with all EFSA Guidance, this Guidance should be regularly reviewed (EFSA Scientific Committee, 2015) to take into account the experiences of the EFSA Plant Health Panel and the needs of those requesting pest risk assessments.

Table of contents

1. Introduction

1.1. Background

The current European Union plant health regime is established by Council Directive 2000/29/EC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community (OJ L 169, 10.7.2000, p. 1). The Directive lays down the phytosanitary provisions and the control checks to be carried out at the place of origin on plants and plant products destined for the Union or to be moved within the Union. In the Directive's 2000/29/EC annexes, the list of harmful organisms (pests), whose introduction into or spread within the Union is prohibited, is detailed together with specific requirements for import or internal movement.

Following the evaluation of the plant health regime, the new basic plant health law, Regulation (EU) 2016/2031 on protective measures against pests of plants, was adopted on 26 October 2016 and will apply from 14 December 2019 onwards, repealing Directive 2000/29/EC.

With mandates from European Commission DG SANTE (ref.: ARES 2014 970361 – 28/03/2014; ARES 2015 1418918 – 31/03/2015; ARES 2017 1111340 – 02/03/2017) EFSA was requested to prepare pest categorisations and pest risk assessments for regulated harmful organisms or groups of harmful organisms included in the annexes of Directive 2000/29/EC. In line with the experience gained with the first batches of pest risk assessments of organisms, requested to EFSA, and in order to further streamline the preparation of risk assessments for regulated pests, the work should be split in two phases, each with a specific output. As a first phase EFSA is requested to prepare and deliver first a pest categorisation for the requested pest (phase 1). Upon receipt and analysis of this output, the Commission would inform EFSA for which organisms it is necessary to complete the pest risk assessment, to identify risk reduction options (RROs) and to provide an assessment of the effectiveness of current EU phytosanitary requirements (phase 2).

With the aim to deliver a scientific advice that replies to the needs of the risk managers a dedicated Working Group of the EFSA PLH Panel has been created to develop a fit for purpose methodology, with the introduction of the two-phase approach to perform the risk assessments in close liaison with risk manager needs. In accordance with EFSA requirement to use quantitative risk assessment as far as possible (EFSA Scientific Committee 2009; EFSA Scientific Committee, 2018a), a new quantitative pest risk assessment methodology has been developed and tested in eight pest risk assessments by the EFSA PLH Panel (EFSA PLH Panel, 2016a,b,c,d; 2017a,b,c,d). Based on the experience gained by the application of this methodology in these pest risk assessments and following the feedback received from the risk managers, a new quantitative pest risk assessment methodology has been developed to conduct the pest risk assessments as well as to assess the effectiveness of risk reduction options. This methodology also includes the step-based risk assessment approach.

1.2. Terms of reference

Based on the experience gained by the application of the quantitative pest risk assessment methodology in eight pilot pest risk assessments in the period 2015-2017, the EFSA PLH Panel is requested to deliver a Guidance on the methodology to conduct quantitatively pest risk assessment as well as the evaluation of effectiveness of risk reduction options. Such Guidance, which should include a description of the step-based risk assessment approach, should be delivered by June 2018.

1.3. Scope and objectives of quantitative risk assessment

1.3.1. Context of risk assessment in plant health

In general risk assessments seek to provide science-based evidence to inform decision making. A risk assessment therefore forms a link between scientific data and decision makers or risk managers.

Pest risk assessment provides the scientific basis for the evaluation of risks posed to cultivated and wild plants by plant pests. It involves the synthesis of knowledge and characterization of risks by estimating the potential for introduction (entry, transfer and establishment) and spread of plant pests and the subsequent impacts to crops and plants in the wider environment (FAO, 2013). An assessment of the effectiveness of RROs informs risk management decision making and helps risk managers identify appropriate strategies against those pests (Favrin and Cree, 2016).

The purpose of this document for quantitative risk assessment of plant pests is to guide risk assessors to express the constituent parts of risk, i.e. likelihood and magnitude of entry, establishment, spread and impact and associated uncertainty, in quantitative terms to the extent that it is scientifically achievable (EFSA Scientific Committee, 2009; FAO/WHO 2015, EFSA 2017). One important reason for this is that qualitative expressions of risk, or components of risk, are often ambiguous (e.g., Theil, 2002; MacLeod and Pietravalle, 2017).

Quantitative methods also allow risk assessments to be updated more transparently as new information becomes available. Furthermore, they can provide systematic and dynamic representations of the processes liable to generate risks and can also evaluate the effectiveness of risk reduction options (RROs).). A Risk Reduction Option (RRO) is defined as "a measure acting on pest introduction and/or pest spread and/or the magnitude of the biological impact of the pest should the pest be present" (Jeger et al., 2012). A RRO may become (or not) a phytosanitary measure, action or procedure according to the decision of the risk manager. Many risk management decisions involve selecting from a limited range of alternative RROs. Such decisions could be better informed and made more transparent if risk assessments were underpinned by quantitative descriptions of the effects that RROs have on risk and uncertainty (Morgan et al., 2010). Until recently, risk assessment of plant pests for the European Union by the EFSA Plant Health Panel has been based on qualitative assessment as outlined in earlier Guidance (EFSA PLH Panel, 2010).

The present Guidance, replacing the EFSA Guidance from 2010 (EFSA, PLH Panel, 2010), still progresses through the steps of entry (including transfer), establishment, spread and impact, but now each step of the assessment can be mechanistically linked to the following step. Thus, the risk can be assessed as a sequence of these steps, representing, and following the flow of, potential real world events, such as pest movement with commodities, as well as the processes that have an effect on pest population abundance such as RROs that aim to lower pest levels on commodities. The consideration of population abundance ("population-based approach") is applied in all steps throughout the assessment. Usually, steps are examined in more detail considering sub-steps, adding complexity but providing greater insight into a step. In specific cases, the assessment can be done on the level of steps. For these reasons this Guidance advocates the use of a process-based mechanistic approach.

The estimation of the assessed variable in each step or sub-step is made quantitatively. The assessed variables are uniquely and unambiguously defined in terms of measurable quantity based on a clear question using empirical and physical data or evidence in the physical world (e.g. the number of infected plants arriving in EU ports in one year, the variation in the rate of spatial expansion of the pest founder population in km/year).

The Guidance provides for a flexible approach and allows a variety of quantitative methods to be used at different levels of complexity, from relatively rapid semi-formal expert knowledge elicitation (EKE) to more sophisticated quantitative modeling, describing the process of change in the abundance and distribution of the invading pest populations that can also take into account the effect of RRO.

In practice, some elements of the assessment process may not be fully process-based, but simply descriptive, e.g. in the case of correlative models describing the area of potential establishment. Whilst this fact is acknowledged, the ambition remains to develop an assessment approach based as much as possible on fundamental biological mechanisms using quantifications expressed in real world terms. The framework directly incorporates the assessment of uncertainty and the effect of RROs, using a scenario-based approach. In developing guidance for the framework and testing and applying the approach, eight case study pests were assessed (EFSA 2016a, b, c, d; 2017a, b, c, d) and stakeholder feedback was sought via public consultation.

1.3.2. Key users and audience

This Guidance is principally designed for assessors conducting pest risk assessments for EFSA. The primary users of the outputs produced using the Guidance are the authorities for plant health risk management of the European Union (EU), the relevant authorities in EU Member States, the EU

Standing Committee of Plants, Animals, Food and Feed (PAFF), the associated Working Groups. Secondary audiences are other stakeholders (e.g. food and farming and related industry bodies), researchers (e.g. entomologists, plant pathologists, nematologists, virologists), and interested members of the public.

1.3.3. Fit for purpose risk assessment

The general objective of this methodology for pest risk assessment is to deliver fit for purpose scientific advice responding to the needs of risk managers. The specific objective is to take stock of more than 10 years PLH Panel experience and its use of Guidance documents (EFSA Plant Health Panel Guidance - EFSA PLH Panel, 2009; 2010; 2011, 2012, other relevant EFSA Guidance documents (EFSA, 2014a; EFSA Scientific Committee, 2009; 2014b; 2014c; 2016; 2017) , international standards (FAO, 2013, 2016a), regional pest risk analysis methods (e.g. EPPO, 2007, 2011), and risk assessment projects (e.g. PRATIQUE (Baker, 2011), Prima phacie (MacLeod et al., 2012), PPM Pirates (Holt et al., 2016), QPA Food (Holt et al., 2016) QPA non-food (Douma et al., 2016), to develop and test:

- A two-phase approach including interaction with risk managers, in order to clarify the needs of the risk managers. The first phase consists of pest categorisation (Appendix A), the second phase consists of risk assessment and evaluation of RROs,
- Communication with risk managers regarding the interpretation of the Terms of Reference (ToR) set by risk managers, and the translation of ToR into risk scenarios by the risk assessors who seek to address the information needs of risk managers,
- A quantitative approach to pest risk assessment including the evaluation of RROs to improve transparency, facilitate knowledge accumulation, and avoid ambiguity,
- A standardised approach and templates for both phases (pest categorisation and risk assessment/evaluation of RROs), including clear definitions and procedures for estimating the values of the assessment variables for the different steps (entry, establishment, spread and impact) and sub-steps (i.e., any subdivision of the steps) in the risk assessment, as well as standardized descriptions for RROs.
- A method for quantifying and evaluating the effectiveness of RROs, which is integrated within the risk assessment methodology.

1.3.4. Two-phase approach

Phase 1: Pest categorisation (see Appendix A)

Plant protection organizations and authorities need to prioritise which pests require detailed risk assessment (Devorshak, 2012; Baker et al., 2014). So as to avoid wasting resources, an early section within the risk assessment process is the pest categorization (FAO, 2013). Pest categorization allows organisms that do not have the characteristics of a quarantine pest, or those of a regulated non-quarantine pest, to be screened out from further consideration. Pest categorisation can be considered a preliminary assessment and can be conducted with a limited amount of information (ISPM -FAO, 2013).

A dedicated pest categorisation template (Appendix A) was developed built on the pest categorisation criteria of Regulation (EU) 2016/2031. The pest categorisation template provides guidance to the assessor in the form of explanatory text under each section. Conclusions of the key sections on entry, establishment, spread, impacts and mitigation measures are presented in boxes at the beginning of each section, to enable the reader to focus on the key information. Identification of knowledge gaps contributing significantly to uncertainty helps risk managers to specifically target these in case of a request for a future full risk assessment, for which specific scenarios to examine or specific research may be requested.

In case the pest categorisation reveals that the assessed organism is a potential quarantine pest (see Article 3 of Regulation (EU) 2016/2031), the European Commission may request a full pest risk assessment and the EFSA PLH proceeds to phase 2.

Phase 2: Pest risk assessment

In line with EFSA's values of innovation and openness (https://www.efsa.europa.eu/en/about/values), and to seek consistency and harmonisation between assessments, this Guidance provides the methods for quantifying risk components and associated uncertainties, providing a template for performing pest risk assessments (Appendix B), indicating for each assessment the relevant questions and data requirements. Guidance for the identification and evaluation of RROs at sub-step's level is also given.

To identify RROs and evaluate their effectiveness, the PLH Panel developed:

- an inventory of RROs (RRO datasheets – see Appendix C).
- a procedure for systematic identification of the RROs relevant to a particular pest problem,
- a linkage between the sub-steps in the risk assessment methodology and the different RROs, including the assessment of the effectiveness of combinations of RROs.

Advantages of the quantitative approach

The feasibility and benefits of the quantitative approach are still under scrutiny. The EFSA PLH Panel has so far carried out eight case studies using the principles of this quantitative approach. Overall, the case studies showed that the anticipated advantages are real, and that fit for purpose assessment based on quantitative thinking can be made with the available data.

The main advantages of the quantitative approach can be summarised as follows,

1. The assessment outcome (risk) is expressed in quantitative units measurable in the physical world allowing risk managers a more concrete understanding of the assessment result and hence a better basis for decision making.
2. The effect of RROs can be assessed quantitatively and fully integrated in the risk estimations.
3. Risk estimates and associated uncertainty can be updated transparently when new data become available.
4. Risk is expressed in quantitative terms facilitating comparison between pests allowing possible ranking and prioritization.
5. Choosing a target quantity for assessment that is measurable in the physical world allows mechanistically-based explicit linkages between subsequent steps in the assessment process, and comparison or validation with measured data when available.
6. An assessment scheme with numbers of founder/source populations in the EU territory, deriving either from new entry or from spread existing populations, allows a quantitative evaluation of the contribution of RROs to reducing impacts
7. The assessment takes into account both quantified and unquantified uncertainties.

~~1.3.5.~~ Challenges of the quantitative approach

1. The use of quantitative approaches may result in increases in assessment effort, assessment time and skills on quantitative estimation required (Soliman et al., 2015). However, the additional time and effort is expected to diminish when becoming familiar with the quantitative methodology, which will also allow to explore more efficient possibilities and to select the appropriate level of detail in the assessment.
2. Quantitative risk assessment is data intense (see 3.4). In many cases the proposed procedure would benefit from empirical data which are not available. In those cases the expert knowledge elicitation procedure (EFSA, 2014a) may be used to collect information required for the assessment, which represents an advantage of this methodology, since it can also be conducted with scarce information available.
3. The proposed approach requires the assessor to make their interpretation and evaluation about the events and processes involved in the assessment explicit. This greatly enhances

transparency, making explicit the uncertainties that a risk assessor may have around their estimates.

4. There is a chance that risk assessors lose sight of the goal of developing a fit for purpose assessment. It can be a challenge to avoid developing very complex conceptual models with each step of the assessment consisting of many sub-steps. Assessors should aim to develop a parsimonious model (see 3.1).
5. The capacity to access data sources and the availability of suitable databases and an inventory of models to be used for standard approach to step or sub-step specific processes need to be (further) developed and to be used consistently.
6. Communication between EFSA and risk managers should be intensified to
    a. enhance mutual understanding of the risk expressions, and
    b. raise awareness of the potential for interpretational bias.

1.4. Guiding principles

This Guidance aligns with the IPPC International Standards ISPM 2 (FAO, 2016) and 11 (FAO, 2017), providing an approach to support technical justification for phytosanitary measures

In developing this Guidance, four earlier Guidance documents by the PLH Panel were reviewed according to EFSA Scientific Committee (2015). The four documents were:

- PLH Panel Guidance on a harmonised framework for risk assessment (EFSA PLH Panel, 2010)

The procedure for pest risk assessment and the identification and evaluation of risk management options were reviewed taking into account the experiences of the EFSA PLH Panel and the request for quantitative assessment and the development of a two-phase approach. The main principles of the PLH Panel Guidance on a harmonised framework were taken on board and further developed in this Guidance, in particular proposing a quantitative approach and incorporating the risk reduction options directly into the assessment. The Guidance replaces entirely the PLH Panel Guidance on a harmonised framework for risk assessment (EFSA PLH Panel, 2010).

- PLH Panel Guidance on methodology for evaluation of the effectiveness of options for reducing the risk of introduction and spread of organisms harmful to plant health in the EU territory (EFSA PLH Panel, 2012)

The current methodology for quantitative risk assessment replaces the following sections of the above Guidance:
    - 1.8. Qualitative assessment of risk reduction options
    - 1.9. Quantitative pathway analysis and other quantitative tools for assessing risk reduction options

The other parts of the above Guidance remain valid and should be used together with this methodology as a source of additional information with regard to the underlying principles of pest risk assessment and the identification of RROs.

- PLH Panel Guidance on the environmental risk assessment of plant pests (EFSA PLH Panel, 2011)

The methodology for quantitative risk assessment is developed in line with the principles reported in the PLH Panel Guidance on the environmental risk assessment (ERA) of plant pests. In particular, population abundance is regarded as the variable determining the impact, and the evaluation of the environmental impact, which is based on estimating the reduction of provision of ecosystem services and of biodiversity components. The quantitative methodology does not replace the Guidance, which can be still used for detailed ERA of plant pests. However, it introduces the important novelty of assessing the impact on ecosystem services and biodiversity in terms of continuous uncertainty distributions, as done for the impact on crop yield and quality, and includes the assessment of RROs.

- PLH Panel Guidance on the evaluation of pest risk assessments and risk management options prepared to justify requests for phytosanitary measures under Council Directive 2000/29/EC. (EFSA PLH Panel, 2009)

The purpose of the above Guidance is to outline the process and scientific principles when evaluating documents prepared by EU Member States or third parties to justify requests for phytosanitary measures under Council Directive 2000/29/EC, this Guidance remains valid and should be used together with the quantitative methodology, if appropriate.

In developing this Guidance, the following EFSA Guidance documents have been taken into account, as can be seen by the citations in the text.

- Scientific Committee Guidance on Transparency in the Scientific Aspects of risk assessments carried out by EFSA. Part 2: General Principles (EFSA Scientific Committee, 2009);
- EFSA Guidance on Expert Knowledge Elicitation in Food and Feed Safety Risk Assessment (EFSA, 2014a).
- Scientific Committee Guidance on the structure and content of EFSA's scientific opinions and statements (EFSA Scientific Committee, 2014b);
- Scientific Committee Guidance on Statistical Reporting (EFSA, 2014b);
- Scientific Committee Guidance on Weight of Evidence assessment (EFSA Scientific Committee, 2017);
- Scientific Committee Guidance on uncertainty (EFSA Scientific Committee, 2018a).

Furthermore, the method is based on the principles outlined in the subsequent sections.

1.4.1. Adaptability

The Guidance recognises the need to produce fit for purpose assessments and so provides a flexible method to enable assessors to develop an assessment appropriate to the data and resources available Adaptability is needed to account for conditions and resources for the assessment, data availability or other aspects relating to the pest, the objective and the resources of the assessment. With reference to the ToR, and in consultation with risk managers, risk assessors select the aspects to be included and the complexity of the assessment to ensure that the assessment is fit for purpose. This includes the objectives of the assessment, the definitions that are specific for the assessment, the pathways that are considered, the different scenarios to evaluate different conditions, e.g. different RROs or no RROs at all (see section 2.2), the conceptual model and the tools (models in particular) to be used when quantifying the risk of the pest. The interpretation of the ToR should take into account the needs of the risk managers, the resources (time, money) available, the urgency of the assessment, the importance of the pest, the importance of the host(s) etc. For example, it may be necessary to consult with risk managers regarding which scenarios (in particular pathways, RROs) and which steps of the risk assessment are most important.

1.4.2. Assessment based on scenarios

Pest risk assessment refers to the evaluation of the effects of introduced pests on plants in a defined spatial and temporal frame. The assessment is based on plausible and often simplified description of how the future might develop, starting from a coherent and internally consistent set of assumptions about key driving forces and relationships. Therefore, pest risk assessment is performed on a scenario basis. To conduct the assessment, several scenarios can be envisaged according to the mandate and its ToR. For example, a mandate may request a risk assessment for a pest that is being considered for deregulation. In this case, assessors would compare one scenario that describes the current regulation/situation against another scenario where the pest is deregulated and RROs are removed. By assigning different scenarios to a pest, including pests not yet present, the probability distribution of the expected impacts can be estimated and compared, thus informing risk management decision-making regarding appropriate RROs. Scenarios should state whether they include conditions other than RROs, e.g. specific environmental conditions such as climate change.

Since the approach is based on the assessment and comparison of different scenarios, all scenarios and scenario components should comply with the mandate to ensure that the risk that is being assessed is actually the risk that risk managers need information about. Scenarios can be considered a translation of the contents of the ToR aimed at defining conditions and elements for the application of the quantitative risk assessment methodology and at deriving the information requested by the risk managers.

Hence it is useful for assessors to interact with risk managers to confirm the scenarios to be assessed. Once scenarios are confirmed, the risk assessment is carried out for the selected scenarios, always considering a baseline scenario, A_0, which reflects the current situation: all relevant pathways, applied regulations, RROs. To account for the time horizon for the assessment, the current situation is projected to a certain time point into the future. Changes in the pathways or RROs etc. (scenarios A_1 to A_n) can then be evaluated against this baseline scenario. Clear units and values assigned to the assessed variables and parameters increase the transparency of the assessment, like that, the assessment, including the assumptions being made and the procedures being applied, can be checked.

1.4.3. Mechanistic-population based approach

The scenario definition corresponds to problem definition in the terminology of the EFSA Scientific Opinion on good modelling practice (EFSA PPR Panel 2014). Once scenarios are defined and their capacity to operationalize the questions of interest for the risk managers has been ascertained, the mechanistic population-based approach is implemented through the definition of the conceptual model, and then appropriate formal models to compute the change in population abundance and distribution across assessment steps are selected.

The conceptual model provides a general and qualitative description of the system to be assessed. It characterises the environmental, biological and trade events and processes involved in the assessment, their interactions and interdependencies, either relying on data and existing models or on expert judgment. The conceptual model also clarifies the points where RROs are integrated. The design of the conceptual model translates the scenario into a sequence of (pre-defined) steps and sub-steps, which are all characterized by variables (e.g., number of product units in the trade (also called "pathway units"), number of potential founder populations, number of spatial units, percentage of reduction in crop yield) to be estimated and by sets of processes changing these variables.

Once the conceptual model has been designed, variables and parameters are defined and linked together into mathematical equations or algorithms (i.e., the formal model) describing the consequences of events and processes involved in the assessment (EFSA PPR Panel, 2014). The mechanistic approach implies that events and processes are based on an understanding of the behaviour of a system's components (e.g., the rate of survival of the pest in relation to control measures, the rate and pattern of population dispersal). The approach directly integrates the RROs among the factors changing the pest abundance. The RROs are assessed by considering specific scenarios in which they are applied at the appropriate step of the invasion process, e.g. during the entry or the establishment steps. The effectiveness of RROs can be quantified by comparing scenarios, e.g. comparing the number of potential founder pest populations that enter the pest risk assessment area with and without RROs in place.

1.4.4. Quantitative reporting of risk

Probability distributions are used to describe both knowledge and uncertainty about the quantities in the assessment. To make the results of the assessment more transparent and to increase consistency between assessments, the outcome of the assessment is expressed in quantities with an explicit and univocal meaning that can be measured in the physical world. This contrasts with alternative methods expressing pest entry in terms of probability of entry without revealing the magnitude of entry, i.e. without revealing propagule pressure. The approach expresses pest entry in terms of the distribution of the number of potential founder populations potentially establishing in the pest risk assessment area in the selected time unit (typically a year) and for a certain temporal horizon and spatial domain (e.g. 10 years and the continental EU) as a result of entry. Establishment is expressed as the probability distribution of the actual number of established pest populations in the risk assessment area; spread as the probability distribution of the number of spatial units (e.g., NUTS-2 regions) or area occupied by the pest, and impact as the probability distribution of impact on yield, crop quality, ecosystem services or biodiversity components in the spatial units or area as well as the number of spatial units or area requiring additional risk mitigation measures and the number of spatial units or area representing the endangered area - each under the different scenarios.

1.4.5. Transparent expression of variability

Probability distributions can be used to quantify variability as well as uncertainty. However, this generally involves adding extra dimensions to the model, with some distributions representing variability and others representing uncertainty about the parameters of the variability distributions. This in turn requires more complex methods for expert elicitation and computation. These complications can be avoided, as in the approach currently proposed, by framing the risk assessment in terms of total quantities for a single region, time period and scenario, thus removing the need to quantify variability in space or time, or variability due to conditions that are defined for the scenario (this might include, for example, trade volumes, RROs or environmental conditions). Consequently, every quantity in the assessment is a parameter with a single value, the uncertainty of which is quantified by a probability distribution, and hence no distributions are needed to quantify variability. Where differences between specified alternative scenarios, regions etc. are of interest, these can be quantified by conducting separate assessments for each alternative and comparing the results (section 3.9). In principle, the approach could be extended to quantify variability within a single assessment, but is more complex and better left until the simpler approach is well established.

1.4.6. Consistent communication

Consistent communication of results within and between assessments facilitates understanding. Therefore, a strategy to support harmonized communication has been developed, designed to aid the interpretation of quantitative results and ease communication with users. The guidance on communication (see section 3.9) emphasises:

- the need to focus on issues within the ToR;
- that the results are presented in a clear and understandable way;
- that the estimated risk should be reported in a manner that appropriately reflects the degree of approximation or precision of the data, knowledge and information used;
- that the degree of uncertainty shall be primarily expressed by reporting an appropriate probability distribution or uncertainty interval associated with the risk estimates;
- that assessments should be reported without verbal qualifiers to avoid implying any value judgements, and
- that sources of quantified and unquantified uncertainties should be noted.

Comparisons between risk estimates for different scenarios is an important feature of communicating results as is the consideration of the sources of uncertainties and their relative contribution to results.

2. Risk assessment design

2.1. Work flow

2.1.1. Introduction and focus

Recognising that conducting a pest risk assessment and/or the evaluation of RROs has all the features of a delivery-focused project, e.g. initiation, planning, implementing, and controlling a team to deliver a product within a specified time frame, it is necessary to adopt good project-management practice to ensure that a fit for purpose opinion is provided using the data, expertise and resources (e.g., time) available.

Following initiation (i.e., the mandate sent to the EFSA PLH Panel), the key issues in ToR should be identified, which effectively outline the scope of the assessment. Advice needs to be provided that will inform pest risk management decision making, therefore it is important to remain pragmatic and avoid adding unnecessary complexity to an issue.

This is a first point when communication with the requestor will probably need to be explicitly planned, for a preliminary exchange about any element arising at this early stage (e.g. clarification of the ToR, adaptability, selection of the scenarios) Having identified and confirmed with the requestor the key issues in the ToR to be addressed, the work flow should be planned and organised, including agreed milestones, objectives and target dates for deliverables. This should then inform the appropriate number of meetings (physical or web meetings) needed and when they are to be scheduled e.g. to review deliverables. Using tools such as a Gantt chart can help visualise the anticipated workflow and could reveal dependencies between activities within an assessment.

2.1.2. Dealing with data and evidence

Different principles for using data and evidence in the assessments described in the EFSA PROMETHEUS Project (EFSA, 2015) could be taken in consideration and implemented during the risk assessment process and address EFSA's core values for the use of evidence that are: impartiality, excellence in scientific assessments (specifically related to the concept of methodological quality), transparency and openness, and responsiveness.
As described in EFSA (2015) the process for dealing with data and evidence in a scientific assessment consists of:

1. Planning upfront a strategy for the assessment;
2. Conducting the assessment in line with the planned strategy and documenting the modifications to it;
3. Verifying the process;
4. Documenting and reporting the process, results and conclusions, and ensuring accessibility of methods and data.

Monitoring and new data acquisition may occur in support of any of the phases of the risk assessment process, wherever needed.
The PROMETHEUS (see EFSA, 2015) approach also recognises that modifications of the strategy may arise in the course of the development of the risk assessment following the analyses of the available evidence and the discussion with the requestor, and that these should be documented or justified.

2.1.3. Implementing the plan

The overall framework for implementation is illustrated in Figure 1.

2.1.3.1. Problem formulation

The problem formulation phase is essential to provide a fit for purpose deliverable focusing the assessment on the issues that could be posed by the quarantine pest to plant health in the EU.
The aim of this preparatory phase is to analyse the ToR and identify the data and evidence needs to address the request.

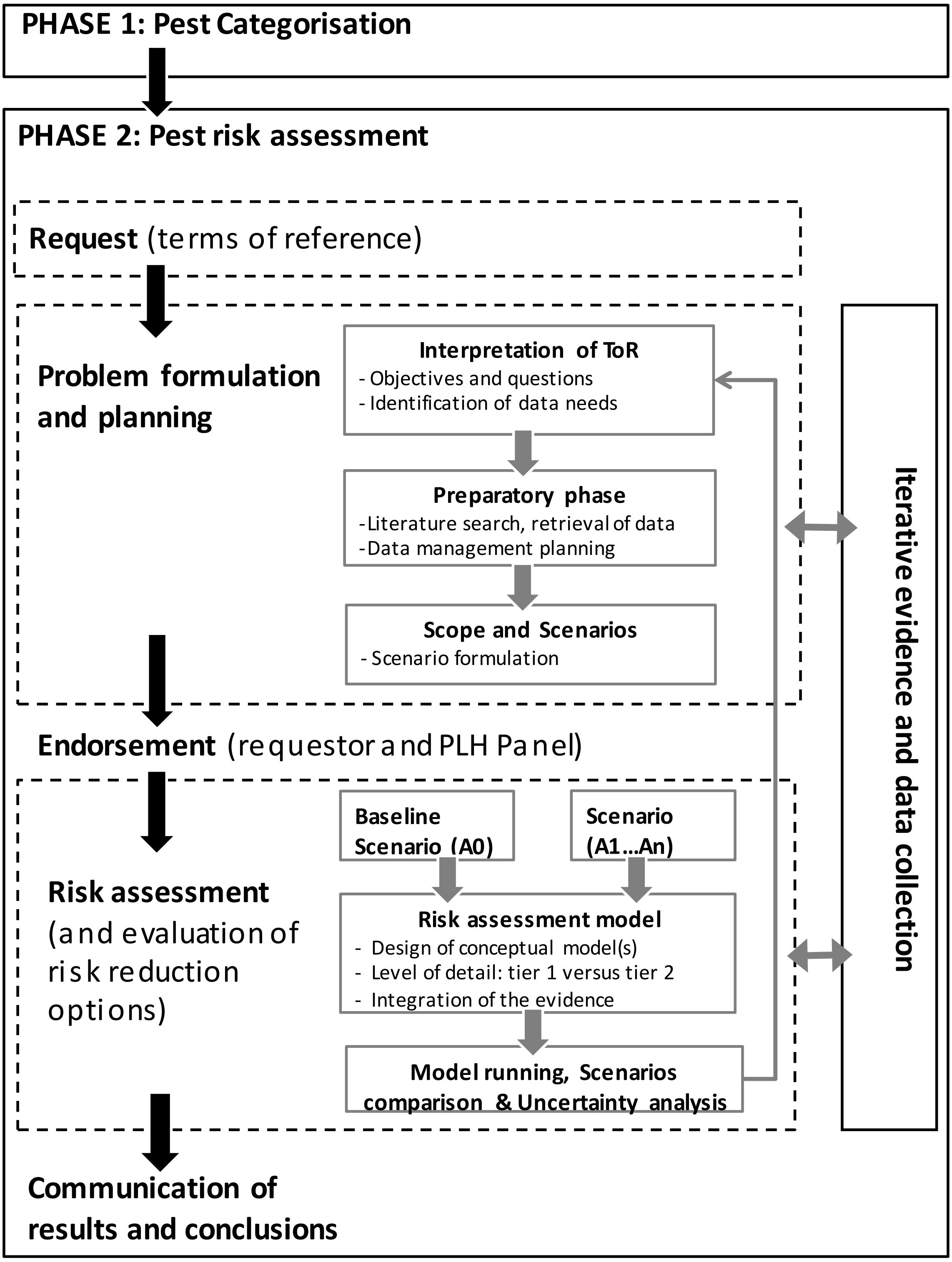


Figure 1: Conceptual framework for the pest risk assessment process and its relationship to pest categorisation

During planning, risk assessors and requestors of the mandate discuss the focus, scope and complexity of the assessment. As suggested in the EFSA PROMETHEUS Project (EFSA, 2015) this phase can be decomposed in:

- the clarification of the scope of the assessment;
- the definition of the conceptual framework;
- the identification of the evidence needs; and,
- the approach for dealing with data and evidence.

Before starting any activity of data collection and/or risk assessment, in the interpretation of the terms of reference, it is crucial to ensure that the risk managers and the risk assessors have a common understanding of the request.
The following two types of information should be considered when interpreting the terms of reference:

Reasons for the initiation of the risk assessment

It is recommended to scrutinize the received ToR and to list the reasons leading the risk manager to ask EFSA to perform the risk assessment. This process of initiation of the risk assessment is described in ISPM11 (Pest risk Analysis for quarantine pests, 1. Stage 1: Initiation) (FAO, 2017) and suggests that the PRA process may begin as a result of:

i. the identification of a pathway that presents a potential pest hazard (for example a new commodity or a new origin of the commodity or natural spread, packing material, mail, garbage, passenger baggage etc.);
ii. the identification of a pest that may require phytosanitary measures or;
iii. the review or revision of phytosanitary policies and priorities.

Formulation of the objectives and break-down in elementary questions for the assessment:

Then, the main objectives of the assessment need to be formulated and broken down into elementary questions. This activity is a means to check that all the relevant aspects of each objective will be addressed in the assessment.

For example, in the case study of the mite *Eotetranychus lewisi* (EFSA PLH Panel, 2017d), four objectives were formulated with the corresponding elementary questions. Some examples are presented below:

Objective 1: Assess the distribution of *E. lewisi*
- Is *E. lewisi* currently present in Madeira?
- What is the distribution of *E. lewisi* in the EU excluding Madeira?
- What is the world distribution of *E. lewisi*?

Objective 2: Assess the potential impact of *E. lewisi* in the EU
- What is the host range for the pest?
- What is the host-pest association in the world?
- etc.

Objective 3: Conduct a full pest risk assessment under different scenarios.
- What area is the pest likely to establish in during the time horizon of the risk assessment? etc.

Objective 4: Explore reasons for a possible absence of *E. lewisi* in the EU (excluding Madeira)
- Which are the pathways that remain open for internal movement?

Preparatory phase

During the preparatory phase the goal is to develop a structured work plan for gathering the evidence and data required to address the sub-questions. The evidence could be found in the scientific literature and in the grey literature, including previous EFSA opinions. At the end of this phase it is also necessary to match the required and available expertise. For each objective after reviewing the literature, the preliminary results would give an idea of the available information and respective quality on the specific topic. At this point, it is already possible to estimate the efforts and resources required to gather the evidence in a systematic manner and to appraise the evidence. At the end of this preparatory phase, the expertise required for adressing the different sub-questions can already be identified.

Scope

Depending on the specific questions of the ToR and the scope of the assessment and available knowledge and data, sub-steps may be distinguished for one or more steps in the conceptual model. RROs may then be identified and their effect evaluated at the level of each sub-step.

The quantities (variables and parameters) to be assessed increase proportionally with the number of risk assessment steps and sub-steps, and with the number of scenarios. It is therefore important to clearly define the scope of the assessment and limit the number of scenarios and sub-steps to be included according to the demands of the requestor as specified in the ToR. The effects of RROs are assessed in line with the level of detail selected in the design of the conceptual model. Only those RROs that are explicitly considered in the steps and sub-steps included in the conceptual model, will then be evaluated.

Two types of assessment can be considered: full risk assessment, addressing all steps of the risk assessment: entry, establishment, spread, impact, and partial risk assessment, addressing only a selection of steps as specified in the ToR. An important issue in designing the conceptual model is whether a full risk assessment is necessary or a partial risk assessment is sufficient to answer the questions posed in the ToR. In the latter case the assessment is only conducted for the selected risk assessment steps. For example, after interpretation of the ToR it may become clear that the requestor of the risk assessment may only be interested in the risk of entry through a specific pathway. In that case, it is sufficient to only assess the risk of entry for that pathway. It may be sufficient to only assess the risk of spread and/or impact if the requestor has asked questions only on the assessment of the effectiveness of eradication measures for reducing spread and impact.

During the testing phase of the quantitative risk assessment methodology two case studies of partial risk assessment were conducted by the EFSA PLH Panel: Flavescence Dorée opinion (EFSA PLH Panel, 2016a) and *Atropellis* spp. opinion (EFSA PLH Panel, 2017c). In the first case the choice was justified by the fact that entry from 3rd countries may be insignificant (Council Directive 2000/29/EC Annex IIAII), in the second quantitative assessment focused on entry because there was no uncertainty regarding the ability of the pest to establish in the EU.

Scenarios formulation in general terms

On the basis of the preliminary analyses and explorations described above, a formulation of the scenarios can be proposed to the requestor of the mandate and adjusted if needed. The risk mitigation strategy and its implementation should be clearly captured in the scenario formulation.

Since the approach is based on the assessment and comparison of different scenarios, all scenarios and scenario components should comply with the mandate to ensure that the risk that is being assessed is actually the risk about which risk managers need information. Fit for purpose scenarios and scenario components should be proposed to ensure that the ToR are properly addressed. It is therefore useful for assessors to have consulted with risk managers to confirm the scenarios to be assessed. In cases where there is a change to the risk managers' concerns during the conduct of the risk assessment, it is possible to add additional scenarios. Once scenarios are confirmed, the risk assessment is carried out for the selected scenarios. Based on the interpretation of the ToR in general a baseline scenario is compared with one or more alternative scenarios. The baseline scenario reflects the current situation: all open pathways, applied phytosanitary regulations, current state of ecological factors and conditions and RROs within the temporal and spatial scale for the assessment. The alternative scenarios reflect the scenario components that can be changed and combined to address the requests in the ToR.

2.1.3.2. Pest risk assessment

During this phase, the conceptual model for the risk assessment is designed and steps and sub-steps in the assessment are identified according to the relevant biological, ecological, trade and management processes to be considered (including RROs implemented in legislation). Then, the formal models are defined to describe the transition between steps/sub-steps (e.g., an ecological niche model is used to aid the assessment of area of potential establishment). Data and expert judgement are used to estimate quantities (model variables and parameters). The evidence is gathered specifically for each quantity following the principles described in EFSA (2015). During the pest risk assessment, for each scenario, the risks are described and each variable or parameter is estimated quantitatively.

It is important to consider in the planning phase the resources available in terms of data collection, time for analyses, experts involved in the process in relation to the resources needed for the assessment that are directly proportionate to the level of complexity of the conceptual models. The definition of the scenarios, the conceptual model and the formal models should be inspired by the criterion of minimizing the complexity (e.g., number of sub-steps to be considered in a step and the complexity and the number parameters in the functions used in the model). Having established a work plan, significant changes should be avoided. Any change should be carefully evaluated considering cost and benefit. The cost refers to the additional work load for data collection and model parameter estimation and the benefit refers to the additional information provided to risk managers evaluating and comparing the assessed scenarios (i.e., reduction in the level of uncertainty).Therefore, the WG needs to consider whether a change to the plan is likely to make a significant difference to the outcome and the related action or decision of the risk managers.
Finally, the estimated models run will generate the data and knowledge that are the basis for the assessment's conclusions and the scenario comparison. Nevertheless the final results will be reviewed regarding unquantified uncertainties, which may include the uncertainty of the model itself.
This phase should be developed in line with the planned strategy and ideally document the modifications to it.

It is recommended at the end of this phase that the PLH Panel verify that all the different issues of the request and the derived assessment objectives are addressed by the risk assessment and agree with the distributions used within the assessment, or provide new evidence not considered by the WG, which is then used to produce an agreed assessment. Panel members should also have in mind consistencies with former quantitative assessments.

In line with the principles of transparency and openness it must be ensured that at the end of the assessment phase all information needed to reproduce the process, results and conclusions are accessible in term of methods and data. The Zenodo platform (https://zenodo.org/) may be used for archiving data and models.

2.1.3.3. Communication of the risk assessment results

After completion, the risk assessment's findings are communicated to the requestor of the mandate, who determine a course of action. The strategy for communication is clearly described in section 3.9.

2.2. Outline of scenario development and assessment

The request for a pest risk assessment by the European Commission usually includes a question related to the evaluation of the effectiveness of the current phytosanitary measures (baseline scenario, see section 2.2.1) and the identification and evaluation of one or more alternative scenarios in which other combinations of RROs (as specified in ToR) are considered. The definition of the scenario components includes:

- the identification of pathways (if assessing entry, and then the selection of specific pathways (assessments should be focussed on the pathways anticipated to lead to the highest likelihood of pest introduction) (see section 2.2.1.1. for more detail);
- the selection of the appropriate RROs (see section 2.2.2.2. for more detail);

- the units used in the assessment (e.g., the pathway units) including the units for expressing the abundance of the pest at the step and sub-step levels;
- the ecological factors and condition considered in the assessment;
- the temporal and the spatial scale for the assessment.

2.2.1. Definition of the baseline scenario

The baseline scenario is generally assessed and is the reference point for the comparison of the effect of alternative scenarios. Basic information should already be available from the pest categorisation phase that has to be completed before the full risk assessment is done. Usually, the pest categorisation contains the necessary information on significant pathways, spread mechanisms, impact and current phytosanitary measures in place as defined in current plant health legislation, which can then be used to define the baseline scenario.

2.2.1.1. Define the pathways

In accordance with the interpretation of the ToR only the relevant pathways of introduction should be considered. The pathways can be identified based on the host range and geographical distribution of the pest, trade flows, plant parts traded, conveyances etc. Pathways can be defined broadly, for example plants for planting from countries where the pest is present. A pathway can also be defined narrowly, for example for a specified commodity or for a specific origin.

The main relevance of human-assisted pathways is the existence of international trade of plants and plant products (e.g., plants intended for planting, fruit and vegetables and wood). Other pathways such as conveyances (hitchhikers); internet trade (Giltrap et al., 2009; Kaminski et al., 2012) and the exchange of scientific material should be considered where appropriate. For a list of examples of pathways see Appendix D.

Entry by natural spread should be considered in particular if the pest is present in countries from which it can spread naturally into the EU.

There can be numerous potential pathways of introduction. The assessment should be restricted to the most relevant pathways and list and document the pathways that are identified but not assessed. Reasons for not assessing a particular pathway are, e.g.:

- There is no significant trade in the identified pathway (though it might need to be considered in a precautionary way, if there is the chance that trade will be established in the future)
- It may be worthwhile to first assess the risk of transfer before including the pathway in a risk assessment. In case the risk of transfer is estimated to be near zero it may be decided to exclude this pathway from the further assessment. (e.g. *E. lewisi* on the strawberry pathway EFSA PLH Panel (2017d), where the assessment on the pathway ended after probability of transfer was assessed to be near zero).

Usually the pathways of entry in the assessment are also included as a mechanism of spread of the pest within the risk assessment area. Mechanisms of spread different from the pathway of entry should be considered, as for example:

- EU internal trade for closed import pathways. For example the plants for planting of *Prunus*, (an important pathway for *E. lewisi*), are prohibited for import into the EU whereas there are no restrictions for internal movement within the EU.
- Natural spread (active or passive (movement of the pest itself) (e.g. by wind, water, animals).
- Waste of packing and handling companies.

2.2.1.2. Define the units used in the assessment

Quantification and expert knowledge elicitation are only possible if the subject of the quantification and assessment are clearly defined. Clear definitions are therefore essential. Risk assessors are required to list their definitions in section 2 of the opinion. In practice, developing definitions and interpreting the evidence in quantitative terms is an iterative process in which the needs of the assessment are weighed against the available data.

The following units need to be considered in the assessment:

Pathway unit: A unit of material or other means potentially affected by the pest that can be used to measure the flux along the pathway (number of pathway units per time unit). Examples are: a specific/certain number of crates of nectarines, metric ton of seed potatoes, cubic metre for wood/timber. The flux can be expressed in terms of a certain number of pathway units e.g. per year. A pathway unit may or may not be affected.

Pathway sub-unit: In some cases it is necessary to consider that the pathway unit is composed by several elements. A pathway sub-unit is an element within a pathway unit, for which the abundance of a pest can be measured. For example one rose in a box of roses, one tuber in a ton of seed potatoes. A pathway sub-unit may or may not be affected.

Transfer unit: A unit composed by one or more pathway units or sub-units which moves as a cluster within the risk assessment area, and carries a pest population that goes to the final destination where establishment occurs (e.g. a field) and which can come into contact with the host and potentially be a founder population. Example: 100 tubers of seed potatoes to be planted in the same field.

Spatial unit: Any partition of the risk assessment area defined for the purpose of the assessment. The definition of the spatial units is relevant for establishment, spread and impact of the pest. Examples are the NUTS-3 regions of the EU or of a certain EU MS, the the LAU2 and the FAO GAUL.

Time unit: For the pest risk assessment it is first necessary to define the time horizon, which is a fixed point of time in the future at which the outcome of certain processes will be evaluated. A time unit is any partition of the time horizon to be considered for describing the processes related to entry, establishment, spread or impact. The time unit varies according to the process considered and the objective of the analysis. Examples: if the time horizon chosen for spread is 10 years and the time unit for evaluation is 1 year, then the risk assessment can be done for the end of the time horizon or each year.

Product unit: A unit used to quantify the production (e.g. kg of olives per tree, tons of barley per hectare etc.). This definition is needed for the assessment of the estimated loss of quantity/quality caused by the pest and to define the endangered area (see glossary).

Note that in the context of this Guidance the term "affected" means carrying the pest under assessment.

The units for the abundance of the pest are relevant in different sections of this assessment scheme (e.g., the abundance of the pest on the host in the area of origin in the Entry section and in the Impact section, for the risk assessment area).

The abundance of the pest can be expressed in different ways in the production/growing area (e.g. percentage of affected pine trees in a hectare of forest, number of affected leaves on a grapevine plant). Also the abundance of the pest along the pathway can be expressed in different ways. For example:

- For the pathway unit it can be of interest knowing if the material or other means constituting the unit are affected or not by the pest (i.e. yes/no)
- An informative definition of abundance for the pathway unit is the average percentage of affected sub-units in a pathway unit, e.g. 30 % of affected nectarines in one crate, 20% of affected cut roses in a box, 10% of affected tubers in 1 ton of seed potatoes, the number of nematodes in 1 ton of soil
- For the sub-unit a possible definition of the abundance is the number of individuals present on it, e.g. 4 thrips per rose, 2 nematodes per potato tuber.

The units for the abundance of the pest could be defined in different ways in different sections of the assessment. It might be necessary for the abundance in the production/growing area to be transformed to the abundance along the pathway and vice versa (e.g. percentage of infested plants by a mite in the field, number of adult mites per leaf).

2.2.1.3. Define ecological and other factors

For the baseline scenario the current state of the ecological factors and conditions in the assessment area is considered the same for the future time period of the assessment. Other scenarios can be defined relating to change for example in the climate (e.g., a systematic increase of 2°C of temperature), the resistance and resilience of the receiving environment (e.g., natural enemies that adapt to the pest), and in host range (e.g., a new *Fraxinus* species susceptible to *Agrilus planipennis*).

2.2.1.4. Define time and spatial scale

The temporal scale refers to the time horizon in which the assessment is performed (e.g., consideration of a time horizon of 1 year, 5 years, 30 years...), it should also be decided whether the analysis should describe conditions during and up to the time horizon (e.g., describing pest spread and impacts over time), or only report on the anticipated situation at the end of the time horizon (e.g., only describing the area occupied by the pest at the time horizon, without reporting the pattern of spread leading up to the time horizon). Having selected the time horizon a brief explanation about why this horizon was selected is required.

If necessary, also take into account the temporal resolution (i.e., the time unit that is considered for the estimation, e.g., what is measured in 1 year). The temporal scales should be defined for:

- Entry (e.g., number of affected pathway units entering the risk assessment area in a time horizon of 5 years; temporal resolution: number of affected pathway units entering in one year).
- Establishment (e.g., the estimated number of pest populations establishing in the risk assessment area within a time horizon of 5 years; temporal resolution: number of pest populations establishing in one year).
- Spread (e.g., the extent of the area newly occupied by the pest within the area of potential establishment in a time horizon of 20 years; temporal resolution: average area newly occupied in one year for the selected time horizon).
- Impact (e.g., the changes to crop output due to the pest after a time horizon of 5 years; temporal resolution: amount of annual production losses on average in the selected time horizon).

The spatial scale refers to the spatial extent of the assessment (e.g., the whole risk assessment area), and the spatial resolution (e.g., points of entry or NUTS-3).The spatial scales should be defined for:

- Entry (e.g., spatial extent: the whole risk assessment area; spatial resolution: Member State);
- Establishment (e.g., spatial extent: the whole risk assessment area; spatial resolution: NUTS-3);
- Spread (e.g., spatial extent: the whole risk assessment area; spatial resolution: 25×25 km grid);
- Impact (e.g., spatial extent: the whole risk assessment area; spatial resolution: Member States).

2.2.2. Definition and evaluation of the risk reduction options in the baseline scenario

2.2.2.1. Description of the production and trade processes of the commodities

A pathway can be characterized by different processes of the production and trade of the commodities. Understanding of these processes can help the assessor identify where phytosanitary measures can be implemented.

For each process of the pathway a 'critical point' can be identified where the commodities could undergo plant health controls for pest freedom. The measurement of the effectiveness of the RROs in terms of estimated impact on the pest abundance could take place at these critical points.

Such critical points of the process of a commodity along the pathways need to be described. These could include for Entry items as shown in Table 1:

Table 1: The critical points of the process of a commodity along the pathways, example for Entry.

Production and trade process	Critical points
Ensuring a pest free environment	Start of the production cycle
Production of the commodity	Harvest of the commodity
Preparation of the consignments (packing, grading, culling)	Prepared consignment
Export certification	Immediately prior to export
Transport	Multiple points where relevant
Storage	
Import inspection	Immediately prior to customs clearance
Movement to final destination (end use of the commodity)	Destination (glass house, open field, retailer, final consumer)

The Panel recommends schematize this information in relation to the scope of the assessment. This should facilitate the development of the conceptual models for all the steps involved in the assessment and the identification of the sub-steps within a step in the conceptual model.

The Panel recommends keep the description of the processes as simple as possible, though at a level that is necessary to understand the system to be assessed. The level of resolution of the models is related to the complexity of the processes and to the corresponding critical points.

2.2.2.2. Define currently implemented risk reduction options

A Risk Reduction Option (RRO) is defined as "a measure acting on pest introduction and/or pest spread and/or the magnitude of the biological impact of the pest should the pest be present" (Jeger et al., 2012). A RRO may become (or not) a phytosanitary measure, action or procedure according to the decision of the risk manager. RROs contribute to reduction of the pest population abundance assessed at each step (see section 3.2.1.). Tools were developed to guide the assessors in the systematic identification of the relevant RROs for the baseline scenario (and alternative scenarios, see Annex A). The result of this exercise is the identification of the model components corresponding to the risk assessment sub-steps where RROs act alone or in combination (e.g., cultural practices and waste disposal; rogueing and pesticide treatment).

For detailing the RRO components of the baseline scenario (A_0) it is necessary to interpret the current EU-legislative requirements in RRO, to 'translate' all phytosanitary measures into corresponding RROs, and to distinguish between pest-specific and non pest-specific RROs for the pest being assessed. Non pest-specific RROs are implemented in the legislation for at least one more regulated pest. When formulating alternative scenarios the non pest-specific RROs cannot be removed or altered.

<u>Pest-specific requirements laid down in the EU legislation</u>

In the EU legislation (Council Directive 2000/29/EC) <u>pest-specific requirements</u> for import and EU-internal trade are specified in Annex IV of this Directive. In accordance to international standards of the IPPC these pest-specific requirements are expressed for a specific unit of pest freedom (see below). Additional pest-specific requirements may be specified in emergency measures.

<u>Non pest specific requirements laid down in the EU legislation</u>

(a) import prohibitions for commodities, as for example for forest tree genera or fruit tree genera;
(b) requirements for other pests which share regulated host plant genera with the pest that is assessed;
(c) For EU-internal trade, commodities that need to be accompanied by a plant passport are specified in Annex V-A
(d) For import into the EU (import from third countries), commodities for which a phytosanitary certificate and general plant health inspection is required are specified in Annex V-B.

Standardized checklist of RROs

To harmonise the use of RROs in EFSA PLH opinions a list of specified RROs was compiled that should be used to select the relevant RROs for the scenarios in the assessment (Appendix C). For the specified RROs information sheets are being developed that contain the definition, description, examples, and limitations of the RRO. The latest versions of these information sheets are available at http://doi.org/10.5281/zenodo.1164805.

RROs as specified in pest freedom requirements

The phytosanitary import requirements as specified in EU legislation 2000/29/EC are based on the concept of "pest freedom". This concept allows exporting countries to provide assurance to importing countries that plants and plant products are free from a specific pest and meet the phytosanitary import requirements.

The concept of pest freedom can be applied for areas (Pest Free Area, PFA, ISPM 4; FAO, 1995), production places (Pest Free Production Place, PFPP, ISPM 10: FAO 1999) and consignments (Pest free Consignment, PFC, EPPO standard PM 3/72(2); ISPM 12 & 23, FAO 2016b,c). Pest management procedures (i.e. a set of specified RROs) have to be put in place to assure pest freedom of the pest free unit. If the specified pest is found in a PFA or PFPP, that unit loses its pest free status.

For a plant health strategy aiming at prevention of introduction and spread of pests, the preferred order of RROs are Pest Free Area, Pest Free Place of Production and Pest Free Consignment, reflecting a progression towards smaller units of pest freedom. The level of protection of the EU territory can go from prevention to correction as summarised in Figure 2.

Pest Free Area

The largest unit of pest freedom is a Pest Free Area. A PFA may include many places of production and may extend to a whole country. Within the EU the PFAs correspond largely to protected zones. By definition all places of production and commodities produced in an officially recognized PFA are pest free. A pest free area is managed as a whole by the NPPO of the exporting country. The NPPO may use official surveys to ensure the area is still pest free, or eradication measures and if necessary the implementation of a pest free buffer zone.

Pest free place of production

As specified in ISPM 10 (FAO, 1999), a "pest free place of production" is a: "place of production in which a specific pest does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained for a defined period".

A place of production situated in a PFA may satisfy, by that fact (i.e. it lies in a PFA), the requirements for a PFPP.

A place of production situated in an area where the pest is present may be declared pest free if specific pest management procedures are applied to assure pest freedom of the place of production.

Specific measures are required to prevent the entry of the pest into the place of production or production site, or to destroy previously undetected occurrences.

These measures may include:

- preventive measures (e.g. pest free propagating material, elimination of other hosts);

- exclusion measures (e.g. physical barriers, screens, controls on equipment, machinery, plants, soil and growing media);
- pest control measures (e.g. cultural methods, treatments, and resistant cultivars).

Pest free consignment

Production places that cannot guarantee pest freedom can still produce pest free consignments if specified pest management procedures are in place. These measures may include treatment of the commodity with an officially accepted treatment, for example heat treatment of wood commodities. Another type of measure to guarantee a pest free consignment is a restriction of plant material that is allowed to be traded. There is a range of pest risk associated with the type of plant material moved. The import of commodities could be restricted to certain specified commodities. For example, for plants for planting different types of plant material are specified in Annex 1 of ISPM 36 (FAO, 2017d) (Integrated measures for plants for planting). See for example the *Diaporthe* opinion (EFSA, 2017b).

Export and import inspection is a control procedure performed by exporting and importing countries to verify the compliance of the consignment with the appropriate phytosanitary requirements

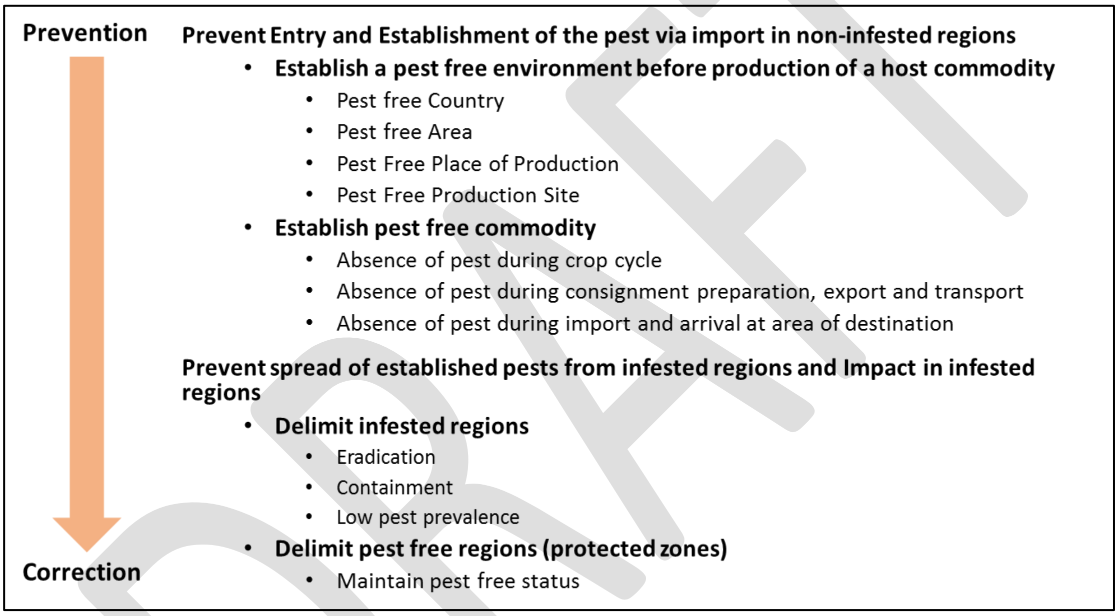


Figure 2: Overview of risk reduction options to prevent or reduce entry, establishment, spread and impact on exotic plant pests. From top to bottom, the emphasis shifts from prevention to correction or containment. Terminology is aligned with that of ISPM 11, and is further defined in the text and in the glossary.

2.2.2.3. Evaluation of risk reduction options

Under the baseline scenario, the assessed pest abundance at each step or sub-step is affected by the RROs that are currently implemented as phytosanitary measures, hence the baseline scenario may not represent unrestricted development of pest abundance. If according to the ToR an assessment of the effectiveness of current phytosanitary regulations is requested, an alternative scenario must be formulated in which RROs are removed. However, it is often not possible to remove all RROs because some of the current phytosanitary measures may be targeted at one or more other pests, which are out of the scope of the ToR. This alternative scenario still needs to include RROs that follow from phytosanitary measures targeted at multiple pests. By comparing the development of pest abundance in the baseline scenario and this alternative scenario, only the effectiveness of current phytosanitary measures that are specific to the pest under assessment can be demonstrated.

For any other scenarios, it should be clearly stipulated if the effectiveness of RROs in a scenario is assessed relative to the RROs in the baseline scenario or relative to the RROs in the scenario excluding pest specific RROs.

The level of detail in the assessment of effectiveness of RROs follows from the level of detail for steps and sub-steps chosen for the risk assessment (Section 3.1). For each step (or sub-step), the RRO or RROs implemented at that sub-step must be specified. The set of RROs implemented at a sub-step is referred to as the 'RRO combination' for that sub-step. The effect on pest population abundance at that sub-step must be assessed for the RRO combination rather than for each individual RRO. The effect of a RRO combination is quantified based on the available scientific and technical data and/or expert knowledge and is expressed in terms of the quantiles of a probability distribution (see section 3.5.). This distribution represents both the effect and related uncertainties of the RRO combination. The estimates for each quantile should be supported by a short text describing the justification of the probability distribution.

Under the baseline scenario, the quantiles of the probability distribution for pest abundance at each sub-step reflect the effect of the RRO combination as implemented in current phytosanitary legislation.

The model output under the baseline scenario should be scrutinized before defining RRO combinations of the alternative scenarios. For example, in EFSA PLH Panel (2017d) for the pest risk assessment of *E. lewisi* it became clear that one pathway under the baseline scenario did not result in established founder populations. Therefore, more stringent RRO combinations were not assessed for this pathway.

Under each alternative scenario the effect of the new RRO combination on the pest abundance at each sub-step can be expressed as the quantiles of a new probability distribution for the pest abundance. The new probability distribution represents the Panel's expectation of the pest abundance at the particular sub-step under the alternative scenario.

If no other factors are considered, the difference in pest abundance between scenarios reflects the difference in effectiveness of the RRO combinations implemented in each scenario.

When estimating the probability distribution for the population abundance at a sub-step of the assessment under the specified RRO combination, due consideration should be given to the level of pest reduction that is achieved by the RRO combination and to limiting factors that may reduce the attainable level, increase uncertainty or cause variability. It is acknowledged by the IPPC that absolute absence of a pest is not always attainable: pest freedom is defined by the IPPC as the absence of a specific pest in an area, production place or consignment in quantities that can be detected by the application of phytosanitary procedures (e.g., inspections, tests, surveillance). For example, an RRO combination may be implemented in a scenario to establish PFPPs in an area where the pest is present. Limiting factors for pest freedom may be that the RRO combination cannot fully prevent the entry of the pest on a production place (e.g. physical protection is lacking or not effective) resulting in a smaller number of PFPPs than aimed for. It may also be that the level of surveillance is insufficient for early detection of the pest in production places, resulting in increased uncertainty, or that chemical pest control in buffer zones is affected by weather conditions, resulting in increased variability of pest presence.

In Annex A more guidance on potential limiting factors to consider in the assessment is provided for each RRO, and an example of an intuitive and self-explanatory tool for articulating the discussions around the limiting factors is presented. The analysis of the limiting factors should focus on biological effects and practical implementation of the RROs and not on economic and social factors.

In preparation of the experts' assessment of the limiting factors, the evidence and related uncertainties should be systematically listed. The related uncertainties need to be clearly formulated in this process.

2.2.3. Definition and evaluation of alternative scenario(s)

Based on the ToR alternative scenarios may be defined and evaluated. The baseline scenario is the reference point for the comparison of the effect of alternative scenarios. For each alternative scenario the differences with the baseline scenario should be documented. Examples are:

- Differences in phytosanitary measures;
- Differences in environmental conditions;
- Comparison of importance of the pathways.

In a risk assessment for a new (non-regulated) pest, pest specific requirements are not specified in the phytosanitary legislation. In this case an alternative scenario with new pest specific measures could be proposed, for example RROs that can be translated in specified requirements that have to be implemented to guarantee a PFA or a PFPP.

For a listed pest alternative scenarios could be defined to assess the effect of deregulation (i.e., lifting of pest-specific measures) or the effect of adapted (strengthened) phytosanitary measures.

The effectiveness of the proposed RROs in the alternative scenario is evaluated in the same manner as described for the evaluation of the measures in the baseline scenario (section 2.2.2.3).

3. Developing the quantification framework for the risk assessment

3.1. Introduction: choosing an appropriate level of detail

The end of quantitative PRA is *not* to have a characterization in full detail of all processes relevant to entry, establishment (including transfer), spread and impacts. Having a full characterization is a never ending process and is not a fit-for-purpose aim of assessment. Risk assessors need to prioritize what they will do in the time available. The model should be detailed enough to be useful in risk assessment and in the evaluation of risk reduction options. Adding a greater degree of detail adds more work and may result in a decrease in transparency. Data availability can also be an obstacle to building a detailed model. Because of these difficulties, a tiered approach is proposed.

A tiered approach is one whereby a base level quantification (first tier) is done directly assessing the uncertainty distribution of the result for all the steps (Entry, Establishment, Spread and Impact) and scenarios without detailed modelling (without quantifying sub-steps). A second (more detailed) level quantification using modelling, however is done only if it is both necessary and possible.

The following criteria may be used to decide whether the first tier approach is sufficient or a second tier assessment is both necessary and possible:

1. A more detailed assessment may be **necessary** to achieve a higher level of accuracy of the assessment result. This is particularly the case when the first tier assessment reveals the need to consider multiple influencing factors that are difficult to combine without making a more elaborate model. Detailing is then needed to allow the risk assessors make a meaningful quantification in line with their knowledge and expertise.
2. A more detailed assessment may be **necessary** to provide the risk manager with information to improve the capacity to decide if consequences of entry, establishment, spread or impact are unacceptable. If a first tier approach provides sufficient information to the risk manager there is no need for a second tier approach.
3. A more detailed assessment may be **necessary** if it is difficult to assess the effectiveness of RROs without elaborating the analytical framework in more detail.
4. A more detailed assessment is **possible** if pertinent data or expert knowledge for a more detailed assessment are available.
5. A more detailed assessment is **possible** if sufficient time, competences and resources are available to the working group.

3.2. Logical design of the analysis: conceptual model

3.2.1. Endpoints of the four steps of the conceptual model

The conceptual model provides a general and qualitative description of the system to be modelled. It provides insight into the environmental, biological, trade and management processes and their interactions and interdependencies (EFSA, 2014b). Conceptual models are often summarised in diagrams (figures and words) of the quantification framework that risk assessors will elaborate to assess quantitatively entry, establishment, spread and impact. To build a conceptual framework, risk assessors must identify the appropriate units and scales, and the temporal and spatial extent and resolution of the system they aim to quantify.

Experts have flexibility in their use of expert elicitation and modelling, and the choice of the level of detail in each step of the assessment, but they should respect the endpoints (i.e., the assessed quantities) that are estimated as an output in each step of the assessment. The quantitative risk assessment framework is designed to estimate the following endpoints for the four steps:

Entry: number of potential founder populations in The EU, considering the scenario-specific size of trade flows, proportion of infested plant product in the trade flows, the probability of transfer to hosts, given the use of the product within the EU territory and the prevalence of host plants, and the applied RROs. Potential founder populations are the number of encounters between infested "transfer units" and hosts, where a transfer unit is the number of pathway units of plant product that reach their final destination together (e.g. a shipment of plants for planting going as a batch to a nursery).

Establishment: actual number of founder populations in The EU, considering the number of potential founder populations (output of entry step) and the probability of establishment of each founder population, based on the possibility that it will persist over a long enough period to enable spread of the organism to new hosts.

Spread: number of spatial units (e.g. NUTS regions) or plants or area that are affected by the pest across the EU territory as a result of dispersal of the organism from the spatial units or plants or area originally affected due to transfer and establishment, or due to dispersal of the organism from existing foci of infestation within the EU territory. The process of spread requires both movement of the organism and its establishment.

Impact: total yield loss and effects on crop quality across The EU, and a quantification of the effect of the pest on the ecosystem services and biodiversity.

3.2.2. Entry

In the case of entry, the first tier consists of estimating, for a given scenario, a distribution for the number of potential founder populations on the basis of the size of the trade flow, the proportion of infected material in the trade, and the probability of transfer. This estimate should be made by expert judgement, based on the available evidence, and should be expressed in the form of a probability distribution representing the uncertainty of the estimate. The distribution should be elicited following the approach described in section 3.5.2.

The second tier consists of a more elaborate model for the entry process. In essence, a basic model for entry in the second tier for a single pathway contains three variables:

- The size of the trade flow in terms of units of plant product "pathway units" entering the EU territory per year (e.g. number of citrus fruits per year, m^3 of oak wood per year);
- The proportion of the units that carries the pest (probability of infestation), or the abundance of the pest in the traded material (proportion of citrus fruit infected with *Phyllosticta citricarpa* in the case of countable pathway units and number of beetle larvae per m^3 of oak wood imported per year)
- The probability of transfer, i.e. the probability that an infested product unit or a beetle emerging from the infested wood comes into contact with hosts in the EU territory.

The three quantities may be elicited directly by expert judgement (taking into account available evidence) and then multiplied to calculate the number of potential founder populations, on the assumption that each contact between the infested product or that the organism can start a new population of the pest that can give rise to daughter populations.

As a second tier, a more elaborate model may be developed. In the second tier approach, entry is considered as a chain of processes and events, including the application of RROs, modifying the pest abundance along the pathway from the place of production to the transfer to the host in the assessment area. This chain is characterized by specific sub-steps in which the abundance of the population is assessed, and transitions in which a series of processes modify the abundance in the pathway units/sub-units. The effects of these processes are represented by a multiplication factor changing the abundance of the population from one sub-step to the next. To account for uncertainties in the estimation of the multiplication factors, quantiles of their expected values are requested.

Five sub-steps can be considered in the entry assessment procedure:

- Abundance of the pest when leaving the place of production (e.g., field, glasshouse) in the export country/countries (sub-step E_1)
- Abundance when crossing the border of the exporting country (sub-step E_2)
- Abundance when arriving at the EU point of entry (sub-step E_3)
- Abundance when leaving the EU point of entry (sub-step E_4)
- Number of potential founder populations within the risk assessment area for the specified temporal and spatial scales as a result of entry of the pest from third countries (sub-step E_5)

For the first sub-step, the initial conditions for the assessment are defined as the estimated pest abundance in the countries of origin/export, if available information about the pest abundance is used. To account for uncertainty in the estimation of the initial conditions, the distribution of the expected values of the pest abundance when leaving the place of production is considered. The values for the 5 quantiles of this distribution (median, lower and upper limit, and the 25% and 75% quantiles) are estimated by the assessor. The estimated distributions have to be supported by justifications and explanatory text.

Based on this initial estimation the values of the abundance for the following sub-steps are calculated, considering the estimated distributions for the multiplication factors. These distributions have to be estimated by the assessors. The values for the 5 quantiles (median, lower and upper limit, and the 25% and 75% quantiles) are asked to consider the uncertainty affecting the estimation of the multiplication factors. The estimated distributions of the multiplication factors have to be supported by justifications and explanatory text. If certain factors are not relevant the multiplication factor is set equal to 1 so the values of the abundance are not changed.

In case there is a need to transform the units expressing the pest abundance along the pathway (e.g., from field product to trade product) or to take into consideration the aggregation or disaggregation of the affected units (e.g., for the calculation of the number of transfer units originating from a pathway unit/sub-unit), a units conversion coefficient or an aggregation/disaggregation coefficient) are taken into account, respectively.

To perform the (computational part of the) assessment, a calculation tool will be applied, based on the values given in the tables.

The estimated number of potential founder populations is calculated for the different pathways and based on this the overall conclusions on entry should be drawn.

3.2.3. Establishment

In the case of establishment, the first tier consists of estimating a distribution for a single factor accounting for the number of actual founder populations across The EU, given the number of potential founder populations. This estimate should be made by expert judgement, based on the available evidence, and should be expressed in the form of a probability distribution representing the uncertainty of the estimate. The distribution should be elicited following the approach described in section 3.5.2.

The second tier entails a more elaborate model. This model can take many forms. For example, the model could use a fundamental niche map of The EU (based on presence of hosts and suitable climate) to distinguish areas where the probability of establishment is high (red zone), medium (yellow) and low (blue), and it could then proceed to estimate establishment factors for each of these three zones. Alternatively, the second tier model could consider geographic zones within The EU and allocate the number of potential founder populations of the pest to regions on the basis of the trade flows to each region. Then information from a fundamental niche map could be used to elicit establishment factors for each region. This approach was followed in the opinion on the risk to plant health of *D. vaccinii* (EFSA PLH Panel, 2017b).

The output from the entry step is an estimation of the number of potential founder pest populations that enter the risk assessment area along the assessed pathways. The establishment step estimates the number of potential founder pest populations that can establish for the selected temporal and spatial scales (as selected in 2.2.1.4).

For assessing the probability of establishment the change in the abundance is not considered, and the probability of transition from a potential founder population into an established population is assessed only. In order to provide an estimate, consider the factors influencing the possibility that a potential founder population transform into an established population:

- Presence of host plants;
- Biology of pest;
- Presence and biology of the vector (if any);
- Environment;
- Human activities;
- RROs.

The multiplication factor transforming a potential founder population into an established population is estimated taking into account the above mentioned factors. This multiplication factor represents the probability of establishment of the pest. To account for uncertainty in the estimation the 5 quantiles are considered. More complex option can be considered if the probability of establishment is greater than 0 (i.e., there are no factors preventing establishment) and if there is a need to make the effect of the RROs explicit on the different factors for establishment.

3.2.4. Spread

In the case of spread, the first tier consists of a direct assessment (weight of evidence) of a distribution for the expected spread of the organism within the risk assessment area at the end of the time horizon. This assessment should be made by expert judgement, based on the available evidence, and should be expressed in the form of a probability distribution representing the uncertainty of the estimate. The distribution should be elicited following the approach described in section 3.5.2.

For the second tier, several options are available. A simple option uses the same units of plant product (pathway unit or subunit) that was used in the entry model. Spread would consist of these units spreading over space (whole of The EU as a spatial extent) and (in some cases) infecting other units. Previous opinions on *D. destructor* (EFSA PLH Panel, 2016b), *R. similis* (EFSA PLH Panel, 2017a), *E. lewisi* (EFSA PLH Panel, 2017d), and *D. vaccinii* (EFSA PLH Panel, 2017b) considered the unit of plant product as the unit of spread. In all of these opinions, movement of plant material for planting was the main mechanism for long distance spread. In one opinion (*D. vaccinii*), plant to plant spread of the pathogen was also included in the spread model. Two opinions (*R. similis, E. lewisi*) considered that a larger unit (i.c. a glasshouse) would be infested if it contained one or more infested plants. These four opinions did not consider larger area units, such as NUTS-2 or NUTS-3 regions.

The EFSA Opinion on *C. platani* (EFSA PLH Panel, 2016d) used the NUTS-3 region, the one on *C. parasitica* (EFSA PLH Panel, 2016c) worked at the Member State level, and the risk assessment of Flavescence dorée phytoplasm (EFSA PLH Panel, 2016a) used the NUTS-2 region as the spatial unit of spread. A patch occupancy model was used to model the increase in the number of NUTS units over time. The opinion on Flavescence dorée phytoplasm modelled the increase in number NUTS regions with reported occurrence of the pathogen using a logistic growth model. The model was initialized using historic data on the number of affected NUTS regions. As this opinion was a partial assessment (without entry and establishment assessment) there was no linkage between spread and the previous two steps of entry and establishment. Theo pinions on *C. platani* and *C. parasitica* did link the spread step to the previous steps of entry and establishment although in a simplified way. In making this linkage, an assumption must be made on the degree to which established founder populations are clustered within a single NUTS region. Risk assessors need to determine whether it is necessary and possible to connect the spread step to the previous steps of entry and establishment. Linking steps can be considered a step-up in the level of complexity of the assessment, i.e. as a part of the second tier.

The result of the establishment step is an estimation of the number of founder populations capable of establishing in the pest risk assessment area. The aim of the spread step is to estimate the area (i.e., the number of spatial units) likely to be occupied by the pest in the risk assessment area for the selected temporal and spatial scales.

The following sub-steps are taken into account:

- Initial conditions for the spread (number of spatial units or area representing the initial condition for the spread in the different scenarios)
- Area of potential establishment (maximum number of spatial units or area for potential establishment in the risk assessment area for the relevant crops/habitats in the different scenarios)
- Increase of number of occupied spatial units or area due to the short and long distance dispersal spread. Two options are possible:
    - Option 1: A directly estimated, collective multiplication factor is used to derive the number of occupied spatial units due the spread of the pest from the initial condition for the spread in the different scenarios
    - Option 2: the increase of numbers of spatial units occupied by the pest due to the spread is decomposed by considering the contribution of different spread factors to better calculate the effect of RROs on each of this.
- Increase in the spread due to the new entries (a multiplication factor taking into account the increase of number of occupied spatial units due to the new entries in the different scenarios is considered)
- The number of occupied spatial units for the selected spatial and temporal scales is calculated based on the initial conditions, the area of potential establishment and the estimated multiplication factors.

To account for uncertainty, for each of these estimates (variables and multiplication factors) a distribution over 5 quantiles is given. The spread process can be modelled by cell occupancy model (a simple spatial implicit metapopulation model) represented by a discretized differential equation describing the temporal dynamics of the spatial units occupied by the pest.

3.2.5. Impact

Two impacts need to be assessed: on agriculture and on the environment. The first tier is a direct assessment (weight of evidence) of a distribution for the impact, without modelling. This assessment should be made by expert judgement, based on the available evidence, and should be expressed in the form of a probability distribution representing the uncertainty of the estimate. The distribution should be elicited following the approach described in section 3.5.2.

For the second tier, there are multiple options. If the spread is modelled at the level of individual plants, the impact calculation can be based on the yield loss per plant. This is straightforward. This was done in opinions on *D. destructor* and *R. similis* (EFSA PLH Panel, 2016b, 2017a). If the spread is modelled at the level of NUTS regions, elicitation or modelling is needed to assess the impact, taking into account that within a NUTS region, there will be spatial heterogeneity in the occurrence (presence) and density of the organism.

The result of the spread step is an estimation of the area occupied by the pest in the risk assessment area for the selected temporal and spatial scales. The area occupied is described in terms of the number of spatial units occupied. For pests already established within the risk assessment area, the total number of spatial units occupied by the pest includes those that have been already occupied.

Introduced pests are capable of causing a variety of impacts. The remit of EFSA limits assessors to consider the direct impacts of pest introduction on crop yield and quality and environmental impacts e.g. impacts on ecosystem services or biodiversity components. The impact on the crop, both on yield and quality, as well as on ecosystem services provision and biodiversity components is depending on the abundance in the occupied spatial unit and the distribution of the pest. It is important in the impact assessment to define the current quality criteria and thresholds to assess quality losses as these may change over time and may also be altered by the pest introduction.

The results of the assessment of spread are then used to calculate the impacts of the pest in the risk assessment area.

The impact of the pest on the crop output and quality and on the environment in the occupied spatial units is estimated. The assessment of the impact on the crop is done considering the change in the production unit (relative impact). The assessment of the impact on the environment is done considering the level of provision of ecosystem services and components of biodiversity. Since in most of the cases data on the value of ecosystem services and biodiversity are not available the estimation of the impact on the environment considers only the percentage of decrease in the ecosystem services provision level. The same is done for biodiversity components. The following estimations are considered:

- Abundance of the pest in the spatial units occupied by the pest under the different scenarios (estimated abundance of the pest in the relevant crops/habitats within the area of the spatial units occupied by the pest under the different scenarios);
- Change in crop production outputs in the spatial units occupied by the pest in the different scenarios (crop production outputs without the pest being present in the spatial units potentially occupied by the pest as assessed in the spread step in the different scenarios). The assessment should be repeated for every relevant crop/use of crop/habitat if appropriate;
- Change in crop quality outputs in the spatial units occupied by the pest in the different scenarios (crop quality outputs without the pest being present in the spatial units potentially occupied by the pest as assessed in the spread step in the different scenarios). The assessment should be repeated for every relevant crop/use of crop/habitat if appropriate;
- Change in ecosystem services provision levels (for selecting provisioning, regulating and supporting services) in the spatial units occupied by the pest in the different scenarios. For sake of simplicity ecosystem service provision levels without the pest being present in the spatial units potentially occupied by the pest in the different scenarios is set equal to 1;
- Change in biodiversity (e.g. percentage reduction in species richness) in the spatial units occupied by the pest in the different scenarios. For sake of simplicity biodiversity without the pest being present in the spatial units potentially occupied by the pest as assessed in the spread step in the different scenarios is set equal to 1;
- Area requiring additional risk mitigation measures (estimated as the number of spatial units occupied by the pest requiring additional risk mitigation measures in the different scenarios).

In a more complex model additional information is required to derive an absolute estimation of the impact at the EU level. It the following estimations are considered:

- Proportion of the area of the occupied spatial units where the relevant crops/habitats are present under the different scenarios
- Proportion of the area of the occupied spatial units where the relevant crops/habitats are present and where the pest is present under the different scenarios

- Proportion of the area of the occupied spatial units where the relevant crops/habitats are present and where the pest is present forming the endangered area under the different scenarios
- The estimation of the absolute impact at the EU level is done considering the occupied spatial units, the three proportions listed above and the estimated relative impact on yield, quality ecosystem services provision and biodiversity components, it is possible to derive the absolute impact at the EU level.

For each of the factors required a distribution over 5 quantiles is given. Impacts can be/are given separately for the different consequences assessed.

3.3. Formal model

3.3.1. Model scope

The quantitative framework described in this section aims to provide a flexible framework for assessing quantitatively the risk of entry, establishment, spread and impact. The risk assessment area may comprise the whole EU, or in the case of a protected zone organism, the protected zone from which the organism is absent or under official control. Specific choices are made to simplify the assessment process. These include the following.

1. The spatial extent of the assessment is the whole EU if the organism does not occur in the EU, but could be limited to a protected zone within the EU if the organism already occurs in the EU. The temporal extent depends on the organism and the ToR and can be decided accordingly by the risk assessor. It could span time periods varying from ~5 to ~50 years.
2. For the steps of entry and establishment, values pertain to the whole of the EU or the protected zone within the EU without further spatial differentiation. Thus, the entry step quantifies the number of potential founder populations, resulting from entry summed over the whole of the EU, while the establishment step quantifies the number of actual founder populations across the whole of the EU resulting from entry. There is no spatial differentiation. No attempt is made, for instance, to differentiate entry and establishment in Northern Europe from that in southern Europe. Risk assessors have the option to include spatial heterogeneity in the quantification of entry and establishment, but this will entail added complexity, and will increase the work load. The template does not propose to include results of fundamental niche maps into the quantitative assessment of entry. Such maps may be provided, but they may feed into the expert judgement following the modelling, rather than in the modelling activity itself.
3. In the spread step, the template provides an option to account for spatial heterogeneity within The EU by introducing the concept of "spatial units". Spatial units are - by definition - the areas, production units (e.g. fields or glasshouses) or plants that may be infested by the pest. In terms of an occupancy model, they are the units that are either black (infested) or white (not infested) (Levins model; Levins, 1969). Spatial units could be, for instance, administrative areas within the EU such as NUTS-2 or NUTS-3 regions (http://ec.europa.eu/eurostat/web/nuts). The grain size of the spatial unit (e.g. NUTS-2 versus more finely grained NUTS-3) is chosen by the assessors. The most important criteria for the choice of NUTS units are the availability of data and the needs of the assessment.

   A modelling framework is proposed that calculates the number of infested spatial units over time using a simple logistic growth model. Other choices may be made by the risk assessors if their organism and data justify a different choice. In several opinions (*D. vaccinii, D. destructor, E. lewisii, R. similis* – see EFSA PLH Panel, 2016b, 2017a,b,d), spatial units in terms of administrative areas were not used, but spread was assessed using the single plant as a unit that would be either "infested" or "not infested". This opinion makes the calculation of impact easier.
4. The impact step is again conceptualized at the level of the whole of The EU. In previous opinions in which the single plant was used as a spatial unit in the spread step (*D. vaccinii, D. destructor, E. lewisii, R. similis* – see EFSA PLH Panel, 2016b, 2017a,b,d), impacts in natural areas were not accounted for. Impact in agriculture can be assessed using expert knowledge on the relationship between the density of the pest or severity of disease and the yield loss. If the model for spread is conceptualized in terms of the number of colonized administrative regions the risk assessors

should assess the density of the pest within these areas (e.g. opinions on *C. platani* and *C. parasitica* - EFSA PLH Panel, 2016c,d). The issue of density is multi-scale and concerns which proportion of fields within a given NUTS area would be infested. It would also concern which proportion of the plants in infested fields would be infested. And finally, it would concern the density of the pest or the severity of disease on the affected plants. Modelling these multi-scale processes is extremely complicated and therefore out of scope for the risk assessment, but these multi-scale issues are amenable to expert judgement. Risk assessors are thus advised to use expert judgement to assess impact if they model the spread on the basis of administrative regions.

5. A final sensitivity analysis enables the risk assessor to identify the main sources of uncertainty in the risk assessment. In case of inconclusive results this may trigger additional effort to reduce the uncertainties in a tiered approach.

3.3.2. Notation

For the development of the formal model a specific notation should be selected. The following proposal can be adopted. The steps are defined as: E = entry, B = establishment, S = spread and I = Impact. The steps are linearly ordered in a sequence E → B → S → I.

The letter A defines an assessment, the relevant scenario is defined by a subscript j ($j = 0,1,2,\ldots$). A_0 represents the current scenario.

Different sub-steps are defined by an integer following the letter of the step, e.g., E1 is the first sub-step of the entry step, B2 is the second sub-step of the establishment step.

Variables

X = represents a population abundance, a letter (E, B, S, I) and a number (1, 2, …) in the subscript specify to which step and sub-step it refers to (e.g., X_{E1} represents the population abundance in the sub-step 1 of the Entry step)

N = represents a number, a letter (E, B, S, I) and a number (1, 2, …) in the subscript specify to which step and sub-step it refers to (e.g., N_{E0} represents the number of transfer units in the sub-step 1 of the Entry step)

Y = represents an area, a letter (E, B, S, I) and a number (1, 2, …) in the subscript specify to which step and sub-step it refers to

I = represents an impact, a number (1, 2, …) in the subscript specifies to which sub-step of impact it refers to

T = represents a time horizon

Parameters

e = a generic parameter appearing in the model for entry (with a subscript 1, 2, … in order of appearance in the set of formulas defining the entry process)

b = a generic parameter appearing in the model for establishment (with a subscript 1, 2, … in order of appearance in the set of formulas defining the establishment process)

s = a generic parameter appearing in the model for spread (with a subscript 1, 2, … in order of appearance in the set of formulas defining the spread process)

i = a generic parameter appearing in the model for impact (with a subscript 1, 2, … in order of appearance in the set of formulas defining the impact process).

3.3.3. Formal models for all the steps

In this section a brief introduction to formal models for all the steps and a short inventory of classes of models, or publications where they are reported, are given.

3.3.3.1. Entry

When the experts factor in many sub-processes in the quantification of entry, they engage in what is called "pathway modelling" (Douma et al., 2016). Pathway modelling is a formalization of the quantitative estimation of the quantity of a pest (in terms of individual organisms or spores or other propagules) entering a risk assessment area. In essence, pathway modelling is just performing a multiplication of the trade flow with factors that account for prevalence of the pest in the traded product and the effectiveness of processes during the entry process (from the source field in the country of origin to the target field in the EU) in removing propagules from the trade.

A pathway model with sub-steps can be visualized as in Figure 3.

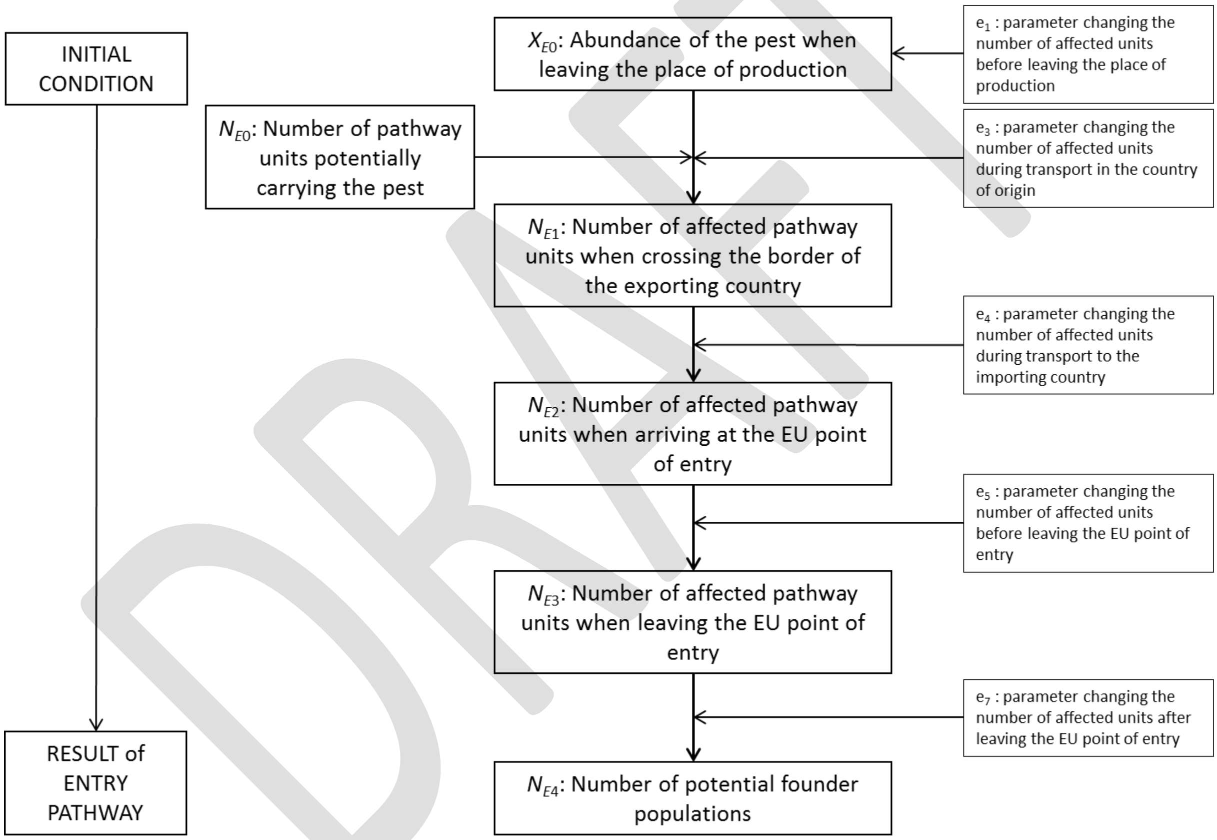


Figure 3: A pathway model with sub-steps

A full mathematical description of this model is given in Appendix F.

If there are multiple pathways of entry, these may be ranked in order of importance. This ranking should take account of:

- The volume of traded product;
- The proportion of the traded product that is infested with the pest.

In many full PRAs published by EFSA in the past, a list was provided of countries of origin and the size of the trade flow from those countries of origin. Temporal trends in the trade may also be considered, especially if a trade is changing rapidly.

Complications arise, for example, when pathways are difficult to identify because there are many host plants for the pest, when there is uncertainty on the abundance of the pest in different commodities, and when there are (important) differences between countries of origin in the abundance of the pest in the trade.

The problem of quantifying

trade volume x proportion of infested units

for different combinations of

commodity x country of origin

can quickly grow out of hand. Risk assessors need therefore to find a way to prioritize and aggregate countries of origin in clusters that show similarity in the factors affecting abundance of the pest in the trade. Prioritization can be done by focusing on a key commodity on which a pest can enter (leaving out one of the dimensions in the multiplication) or choosing those commodities for which the trade is large, the abundance of the pest is high, or transfer is likely. Countries of origin can be grouped in classes according to pest or grouping countries of origin in groups according to the occurrence of the pest, e.g., countries which are free of the pest, countries which have a low prevalence of the pest, and countries in which the pest is widespread. If one or more key pathways are prioritized for quantitative elaboration, the other pathways need to be clearly identified in the assessment report and taken into account as additional sources of uncertainty at the end of the assessment (section 3.9.7). Table 2 may be helpful in prioritizing pathways.

Table 2: Overview of pest risk associated with different pathways, by distinguishing three components: import volume, proportion of infested units in the trade, and the probability of transfer of the pest from the imported product to hosts in the EU territory.

Pathway	Yearly import	Proportion of units that is infested with the pest	Probability of transfer of the pest to a host (per each infested unit)
	Units of product per year	-	-
1			
2			
3			
4			
5			
6			

Table 2 already represents a simple pathway model, which can be specified formally as:

$$N_{transfer,i} = N_{import,i} * p_i * t_i$$

Where

$N_{transfer,i}$ is the yearly number of transfers of inoculum from an imported infested unit along pathway i to a host or hosts in the EU territory.

$N_{import,i}$ is the number of product units that are imported each year into the EU along pathway i

p_i is the proportion of imported units in pathway i that are infested with the pest

t_i is the probability that propagules of the pest transfer from an infested unit of product imported on pathway *i* to a host within the EU territory

A risk reduction option can be included in this simple model by considering that the proportion of infected units could be reduced by inspection and testing before export. Therefore,

$$N_{transfer,i} = N_{import,i} * (1 - r_i) * p_i * t_i$$

where

r_i is a proportional reduction in the proportion of infested product units due to improved inspection and testing before export.

The numbers on the right hand side of the equation are reported as unique numbers for a first calculation, but they should be represented by a distribution representing uncertainty as a second step after the model has been chosen (see paragraph ...).

In the estimation of trade volume the assessors are advised to estimate the anticipated trade volume in a future year (e.g., next year). An uncertainty distribution can be elicited for the future trade volume. If assessors feel unable to do this, they could instead make a convenient assumption, e.g. that trade will continue at its current volume, or use a range of assumptions (e.g. 1x, 2x, 3x) to explore their impact on the risk. However this does not remove the uncertainty, which must still be considered as an additional uncertainty at the end of the assessment (see section 3.7.).

The abundance of a pest is often not well known, not least because pests are supposed not to be present in the trade at all. Nevertheless, interception data usually show that pests do occur in consignments, and that a low level of abundance is unavoidable (Surkov et al., 2008; Eschen et al., 2017). Previous risk assessments used interception data and data on prevalence and control of pests and diseases in countries of origin to arrive at estimates of prevalence of pests in trade (CBS opinion – EFSA PLH Panel, 2014). Pre-export inspection and cleaning operations may be accounted for when assessing the abundance of the pest in an actual trade from a given country of origin or group of countries. Many subsequent processes may be factored in, e.g. multiplication or attrition of the pest during international transport, effectiveness of import inspection, multiplication or attrition of the pest during intra-EU transport, transfer.

3.3.3.2. Establishment

Establishment starts with the arrival of the pest in the territory and the transfer of inoculum or individuals to a host. The end point is a population of the pest that will persist indefinitely in the future (see Figure 4). For the PRA, establishment is quantified in terms of the number of founder populations that are established. Founder populations are local populations of the pest, e.g. one or a few infected or infested trees in an orchard, a patch of nematodes in a field, a cluster of infested trees in a forest. They are localized in the sense that outbreak control would still be feasible. A delay is possible (from a few to many cycles of multiplication) between the initial introduction and transfer of a pest and the establishment of a founder population that will persist indefinitely and produce offspring populations (spread).). This Guidance does not prescribe specific methods for assessing the establishment potential for a pest. There are many spatially explicit mapping approaches may be used to show and estimate the area in which establishment may occur ("the area of potential establishment"), and illustrate gradations in the suitability of areas according to their climate, presence of hosts, and other relevant factors. A basic approach, often used in pest categorisations and pest risk assessment is based on using hardiness zones or Köppen-Geiger maps of climate. Furthermore, species distribution maps are of value. Further refinement may be added by modelling parts of the life cycle (e.g. maturation and dispersal of spores of plant pathogenic fungi; EFSA PLH Panel, 2014) or calculating infection risks with plant pathogens using simple equations integrating the effects of temperature and humidity (Magarey, 2005). Ecological niche models (e.g. Maxent and Climex) are also useful to define the area of potential establishment, and within this area, the relative suitability for establishment. Process-based (i.e., mechanistic) demographic models can provide meaningful information for the purpose of assessing the establishment. They can produce a spatially explicit representation of an index that is a direct measure of the population abundance. This allows the description of the area of potential establishment as well as a point-based analysis of the habitat suitability. Demographic model are more suited not only for assessing the establishment but also for the impact since the population abundance represents the main driver determining the pest impact on the cultivated plants and on the environment.

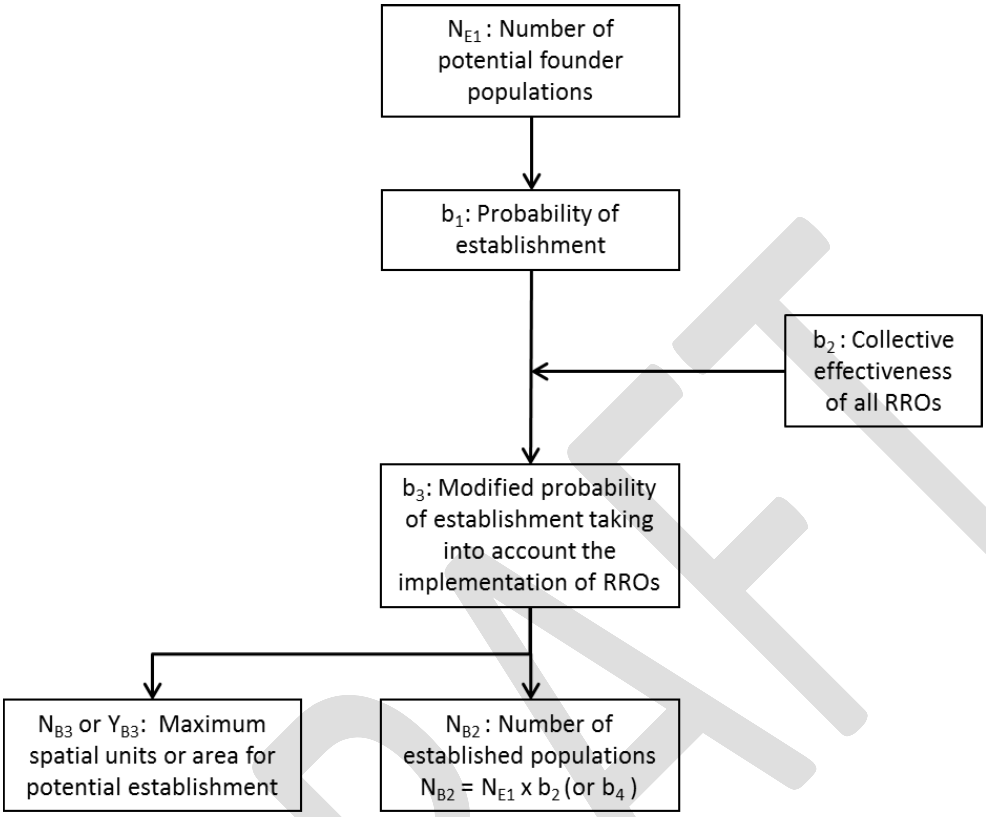


Figure 4: Flow chart depicting the information flow in a model of the establishment step.

In general we would expect the probability of a transfer resulting in establishment of a founder population to be small (Simberloff, 2009), maybe in the order of one in a hundred to one in a million. On the other hand, ecological niche models produce outputs that are usually scaled from 0 to 1, where 0 means that an area is completely unsuitable for establishment due to absence of hosts or unsuitability of the climate, whereas 1 means that the area is highly suitable. It would therefore be inappropriate to use the output of an ecological niche model directly as if it were a probability, which it is not. Instead, risk assessors need to interpret the risk values coming from an ecological niche model and use expert judgement to quantify establishment probabilities.

Risk assessors may use maps of establishment potential in quantification of the expected number of founder populations by doing expert knowledge elicitation on the relationship between the risk score from an establishment model and the probability of establishment (number of actual founder populations per potential founder population). However, it would be generally incorrect to use the risk score from a fundamental niche model directly in an equation for calculating establishment, as if the risk score was a true probability.

The probability of establishment is one or close to one if the organism can survive on the host or the plant material that is imported and this plant material or this host is long lived. For instance, in the opinions on the nematodes *D. destructor* and *R. similis*, (EFSA PLH Panel, 2016a, 2017a) it was considered that the pest was introduced with a living host as planting material, resulting in a probability of (near) one that introduction would result in establishment of a local population that would persist. The same is likely true for fungi in wood which are introduced with live trees, even if the establishment is facilitated by human activities (e.g., pruning, sanitary operations, construction work, road maintenance, boats travelling along rivers and canals, etc.) as for *C. platani* (EFSA PLH Panel, 2016d) and *C. parasitica* (EFSA PLH Panel, 2016c).

There are serious challenges involved in linking entry to establishment as expressed spatially on a map. First of all, the scores for establishment are not probabilities. Expert judgement will be needed to derive probabilities from the scores for establishment. Second, an assumption must be made on how potential founder populations are allocated to different positions on the map. A possible way forward is to group the grid cells on the establishment map in categories with high, moderate and low (no) potential for establishment, and use expert judgement to assess both the amount of incoming inoculum (potential founder populations) and the establishment probability for each category.

Risk assessors are advised to consider these challenges before deciding to make a linkage between entry and spatially explicit maps of establishment potential.

Modelling establishment and parts of establishment in a spatially explicit manner is very informative for risk managers because it clarifies in which areas establishment and impact may occur. Such maps may be interpreted in a conditional way, "*if* entry in this region happens, *then* the probability of establishment will be very high (accompanied by quantification). Coupling of entry and establishment in a spatially explicit manner is not required to allow decision making by risk managers that is spatially informed..

3.3.3.3. Spread

Spread is movement of a pest into a new area where it can persist. Essentially, the spread process is therefore the same process as entry + establishment, with the difference that the term entry is normally defined as movement crossing a border od risk assessment area, whereas spread occurs within this area, without crossing an external border (see Figure 5). An inventory of spread models was produced by Chapman et al. (2015). These authors provided an overview of 468 models for plant pest spread and dispersal from the literature and assessed strengths and weaknesses of these models for risk assessment. Chapman et al. (2015) also provided a DSS to help the assessors find the most suitable model. A set of simple models was proposed by Robinet et al. (2012). They note that epidemiological network modelling (Harwood et al., 2009) is potentially a powerful and mechanistically sound way to calculate spread processes. However, network modelling requires detailed information on trade pathways within the EU, and this information is not officially collected though it may be (partly) available in specific industries.

Approaches for spread modelling used in recent PRAs by the PLH panel during the pilot phase are:

- Pathway modelling (using few countries of origin in the EU as sources, and the rest of the EU as target areas for plants for planting) (*D. destructor* opinion – EFSA PLH Panel, 2016b).
- Logistic model for increase in the number of infested NUTS regions over time (Flavescence doree opinion – EFSA PLH Panel, 2016a, *C. platani* -EFSA PLH Panel, 2016d and *C. parasitica*-EFSA PLH Panel, 2016c) (Details on this model are reported in the Appendices of the above mentioned EFSA opinions).
- Matrix modelling (*D. vaccinii* opinion - EFSA PLH Panel, 2017b)

The diversity of approach in recent EFSA opinions underscores the findings from the literature (Robinet et al., 2012; Chapman et al., 2015) that no single approach fits all purposes. Risk assessors need to identify the aims of spread modelling and choose the most suitable approach given the nature of the problem.

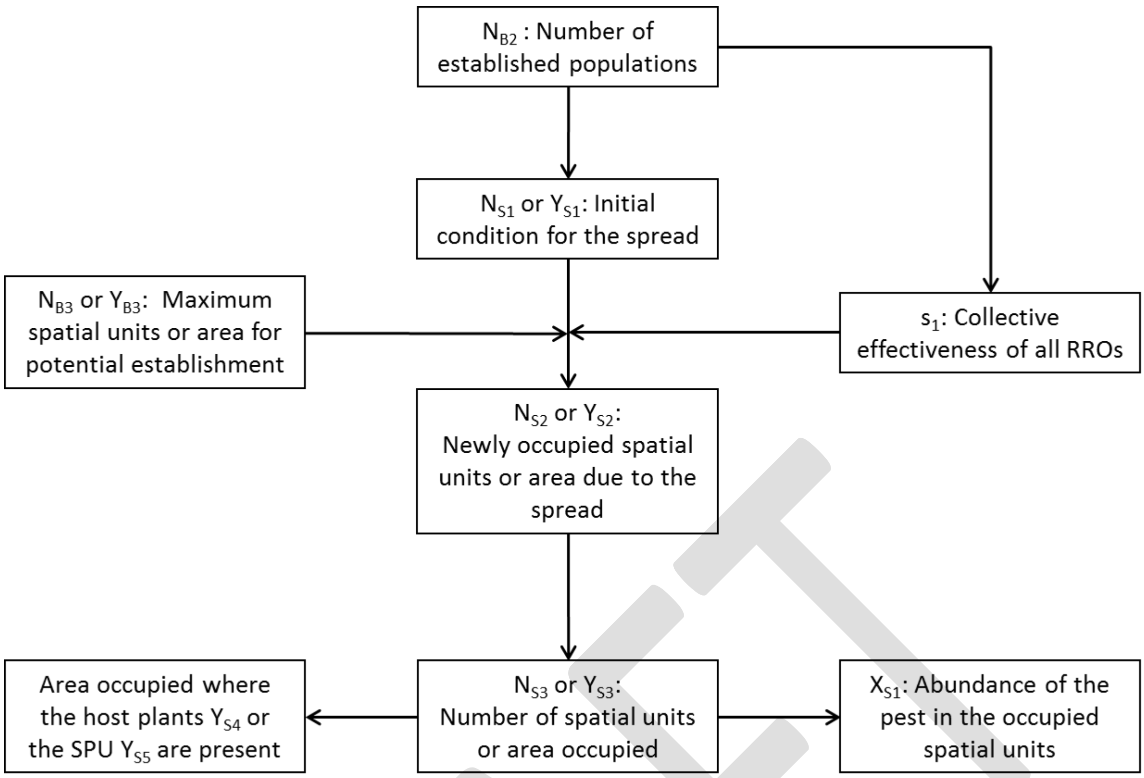


Figure 5: Flow chart depicting the information flow in a model of the spread step based on occupancy of spatial units, such as NUTS regions.

3.3.3.4. Impact

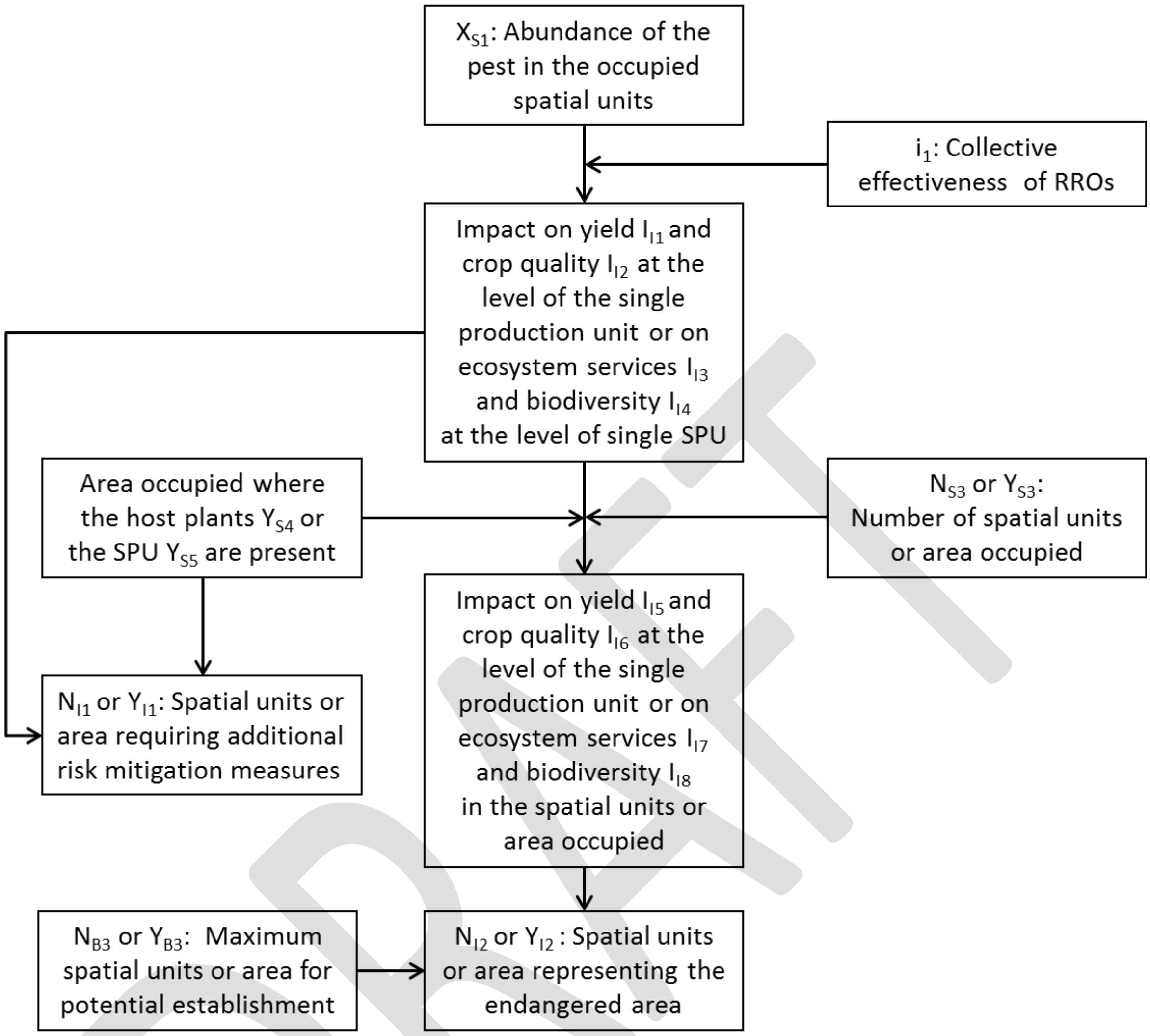


Figure 6: Flow chart depicting the information flow in a model of the impact step.

Models for impact are usually simple dose-effect relationships, where the "dose" is the abundance of the pest, and the "effect" is the plant response in terms of yield or quality (see Figure 6). For ecosystems the response can be in terms of ecosystem functioning and ecosystem services in the Service Providing Unit (SPU) (Gilioli et al., 2014; Gilioli et al., 2017). While the model for impact looks simple, it is not in all cases straightforward to link it to previous models for entry, establishment and spread, because the outcome of these previous models has a very large spatial extent (the whole EU) and the density of the pest within this very large spatial extent is heterogeneous at many levels. Therefore, the application of a model for impact requires an approach in which this heterogeneity or "granularity" is accounted for.

The simplest way to account for heterogeneity is to distinguish areas where the pest has established and where the host is present, such that impact can materialize. An assumption can be made on the density of the pest in these areas, and then the impact can be calculated.

A richer way to account for heterogeneity is to present it on a gridded map of the EU. Based on indicators for presence and abundance, impact may be calculated and presented.

3.4. Information needs

A fundamental activity that is required to support all stages of a risk assessment, or the evaluation of RROs, is the gathering of information to inform and support the necessary judgments required within the assessment process. The types of information required for pest risk assessment are outlined within the international standard ISPM 11 (FAO, 2013). The European and Mediterranean Plant Protection Organization (EPPO) also provides a check-list of information required for pest risk assessment in a regional phytosanitary standard (EPPO, 1998). Devorshak (2012) provides a table listing the types of information needed to assess pests and commodities.

The types of information required in a risk assessment will vary according to the specific issues identified. The level of detail required will depend on whether a first tier or a more detailed second tier assessment is being conducted. Nevertheless, in general pest risk assessments will require information on:

- pest taxonomy, detection and identification,
- biological characteristics of the pest, its life cycle, means of dispersal and adaptability,
- the host plants of the pest (or habitats if the assessment is of a pest plant); their occurrence in the risk assessment area,
- the geographical distribution of the pest, its area of origin and any spread from there together with its occurrence in the risk assessment area,
- the abiotic environmental requirements of the pest,
- pest management practices applied where the pest already occurs,
- pathways that could enable the pest to be introduced into the risk assessment area, including any industry processing and handling of hosts on which the pest could be transported,
- pest impacts on host plants and/ or ecosystem services and biodiversity,
- phytosanitary risk reduction options,
- inspection, detection and surveillance methods.

In a general guidance document, it is not possible to provide a comprehensive list of all the information needed to conduct a second tier assessment because the degree or resolution of information / data required will vary between assessments and be determined by the complexity of each assessment. Awareness of what information is available, and where EKE may be required to compensate should be taken into account in the design of the conceptual model (section 3.2) and formal model (section 3.3).

3.4.1. Gathering information

Generating a pest risk assessment can be data intensive (Baker and MacLeod, 2005; Kenis et al., 2009; Devorshak, 2012). Data and knowledge required are not only about the biology of the pest itself, but also on the situation in its current area of distribution (which for emerging pests may be dynamic), the pathways of entry, the factors affecting its establishment, spread and impacts in the area under threat and the measures available for its management. Gathering information can often be time consuming and an appropriate amount of time should be provided, also taking into account the urgency of the assessment (see section 2.1.3). The information required for each risk assessment will depend on the complexity of the issues and the specific terms of reference.

When searching the literature for relevant information, a suitable combination of key word searches and combined key word searches, using Boolean operators, should be used. The search strategy should be recorded and documented (see section 2.1.3. and Prometheus project, see EFSA, 2015). An efficient way to manage the literature is to download the journal citations identified by the search, and their abstracts, into a reference manager (e.g., Procite, Reference Manager, EndNote).

Older literature, not available on abstracting databases, should not be overlooked and additional search techniques may be required (e.g. checking the reference lists of information sources as they are retrieved). If appropriate, a relevance screening procedure should be introduced (Prometheus project, see EFSA, 2015).

Technical information such as data from national pest surveys and interception records of pests is relevant for pest risk assessment (FAO, 2007; MacLeod, 2015). This information may not be publically available although it could potentially be provided on request. Sharing information regarding pest status within a contracting party to the IPPC is an obligation under the IPPC (Article VIII.1(c)) and should be facilitated by official contact points (Article VIII.2) (FAO, 1997a). The IPPC publishes pest reports from contracting parties within the country pages on the IPPC website (https://www.ippc.int/en/countries/).

An inventory of international and national data sources containing information relevant to pest risk assessment or the evaluation of RROs has been compiled by Rossi et al. (2009) and the EU 7th Framework Programme project PRATIQUE (PRATIQUE online: https://secure.fera.defra.gov.uk/pratique/publications.cfm#fldr_D2). The IPPC manages a website of phytosanitary resources that can also support pest risk assessment (http://www.phytosanitary.info/).

The quality and completeness of the information gathered can influence the confidence of (i) risk assessors in constructing the risk assessment and (ii) risk managers when taking risk management decisions.

3.4.2. Uncertainty within information

ISPM 11 recognises that assessing the probability of pest introduction (entry and establishment) and the potential consequences that result, involves many uncertainties. The following are common sources of uncertainty in pest risk assessments:

- limitations in the information: e.g. conflicting data, old and potentially outdated data,
- limitations in terminology, e.g. ambiguous or imprecise wording in literature,
- experimental and observational limitations, e.g. sampling uncertainty, measurement uncertainty,
- the selection of the line of reasoning, simulation model, or mathematical distribution for data fitting (model uncertainty), when alternative approaches are available and the selected approach might influence the conclusion of the assessment,
- for many types of information estimations are extrapolations based on information from where the pest occurs to the hypothetical situation being assessed for the risk assessment area. Uncertainty due to lack of specific information about the pest within the risk assessment area will therefore always feature in pest risk assessment.

3.4.3. Lack of specific information

Given the diversity of information types needed to inform a pest risk assessment, conventional scientific literature is unlikely to provide all the information required to make a fully informed assessment regarding pest risk (Kolar and Lodge, 2001; Baker and MacLeod, 2005; Devorshak, 2012). In particular there is often a lack of detailed information regarding events on pathways.

In many situations, risk assessors are constrained by data availability and need to use what information is available to inform judgments, for example extrapolating historical data, and data from where the pest occurs, to assess potential future events in a different geographic area (i.e. the risk assessment area); or taking information about one pest and applying it to the related pest being assessed, i.e. surrogacy.

Further guidance on making informed judgments due to lack of specific information is discussed further in section 3.5.

3.4.4. Transparency

The PLH Panel recognises the importance of, and requirement for, transparency in risk assessment. It is therefore necessary to provide a comprehensive description of the information examined in a risk assessment and the rational for its use (EFSA, 2009).

To ensure transparency in risk assessment, uncertainties should be identified, characterized and documented in the assessment process (see section 3.7.).

3.5. Obtaining probabilities and distributions to describe the uncertainty in the risk assessment

Probability and probability distributions are the mathematical tools available to represent uncertainty associated with a quantity in a risk assessment. This section provides guidance on how to obtain those probabilities or distributions, either by statistical analysis of suitable data if such data are available (section 3.5.1) or by estimation of the uncertainty by expert judgement (sections 3.5.2 and 3.5.3).

The probability estimates are used as parameter inputs within the risk assessment models.

3.5.1. Obtaining probabilities and distributions from data

When relevant data are available, use them to estimate probabilities (for events or outcomes) and probability distributions (for parameters) using appropriate statistical fitting methods (e.g. @Risk). There exist in general two statistical approaches for obtaining probabilities and probability distributions, respectively Bayesian methods which provide a probability distribution directly, and frequentist methods where probability distributions are derived from confidence intervals, or from samples of possible values produced by bootstrapping. See section 11.2 of EFSA (2018b) for more discussion of issues to consider when using probability distributions obtained by Bayesian and non-Bayesian methods.

Any additional uncertainties not addressed explicitly in the model components, either affecting the data (e.g. limitations in relevance or reliability) or its analysis (e.g. appropriateness of statistical model and validity of assumptions) should be recorded in text for consideration later, in the overall uncertainty assessment (see section 3.7.).

3.5.2. Obtaining parameter distributions by expert judgement

The absence of suitable data to estimate distributions by statistical analysis is the rule rather than the exception in plant health risk assessments, e.g. regarding future trade imports. Therefore, estimation of the uncertainty distribution by expert judgement of quantiles in a probability distribution, including documenting the justification for the values estimated, is a regular exercise when quantifying the uncertainty in the risk problem. Expert judgements must be based on evidence. The evidence may include quantitative data that are of limited quality or unsuitable for statistical analysis, and also other types of information (e.g. qualitative, anecdotal, expert experience and reasoning, etc.). The evidence may have varying degrees of relevance and reliability, which will be taken into account when making the judgements.

Expert judgement is subject to psychological biases, e.g. over-confidence (EFSA 2014). EFSA's (2014) Guidance on expert knowledge elicitation (EKE) describes formal methods that are designed to counter those biases: these maximise rigour, but require significant time and resource. EFSA (2014) also describes a method of 'minimal assessment', which is much simpler. This can be used to obtain approximate distributions and also to identify which parameters contribute most uncertainty, so that they can be subjected to the full EKE process. EFSA's uncertainty Guidance describes further variations on EKE methodology, including semi-formal EKE, 'expert discussion' and 'individual expert judgement' (EFSA, 2018a).

The present Guidance uses a semi-formal approach to eliciting probability distributions for parameters, based on the Sheffield method (EFSA, 2014a). In summary the approach is as follows:

1. Ensure that the parameter is well-defined (see section 10 of EFSA Scientific Committee, 2018a).
2. Review and summarise the evidence and uncertainties that are relevant to estimating the parameter.
3. Decide which experts will participate in making judgements about the parameter, i.e. those Working Group members with relevant expertise for this parameter. It is strongly recommended that at minimum two experts should make judgements for each parameter, as comparison and discussion will improve the rigour and quality of the judgements and help guard against bias and over-confidence. The selected experts should have received basic training in making probability judgements, or should receive it before proceeding (available via EFSA's Training). It is desirable, but not essential, that the elicitation process is facilitated by someone who is not contributing to the judgements, e.g. a Working Group chair. In all cases, the elicited distribution should be subject to review by the rest of the Working Group as part of the normal EFSA procedure for assessments.
4. Elicit first a 98% credibility (confidence) range for the parameter, then a median, then quartiles (the order is important, to avoid anchoring bias). It is recommended that the experts do this individually at first, then share their judgements and discuss the reasons for differences between them, and finally develop consensus judgements for the range, median and quartiles by group discussion.
5. The experts should then use appropriate software (e.g. @RISK, R4EU, MATCH, SHELF) to fit a range of distributions to their judgements, and choose the distribution that best represents their collective judgement of the uncertainty of the parameter. If necessary, they should adjust their judgements to further improve the distribution as a representation of their judgement.
6. The consensus distribution should not be a compromise between competing views: instead, the experts should consider what the judgements of a rational independent observer would be after seeing their individual judgements and hearing their discussion (see section 6.1.4 in EFSA, 2014a).
7. The final distribution is then used to represent the uncertainty of the parameter in the risk assessment model. The rationale for the final distribution should be documented at least briefly, with reference to supporting evidence, e.g. why are values near the peak of the distribution more probable, and why are higher and lower values less probable.

3.5.3. Obtaining probabilities by expert judgement

In first tier assessments (section 3.1), or when assessing overall uncertainty (section 3.7), the assessors might choose to express their judgement in terms of the probability of a specified event or outcome (e.g. the probability that no founder populations of a pest will enter the EU within a specified time period) rather than estimating a distribution for a quantity (e.g. the number of founder populations that will enter). Here, the uncertainty of the specified outcome is quantified as a probability that the outcome will occur. If suitable data exist, e.g. on the frequency of similar outcomes in the past, it may be possible to estimate this probability by statistical analysis (see section 3.5.1.). Otherwise, it will be necessary to obtain the probability by expert judgement.

Existing EFSA Guidance on expert elicitation (EFSA, 2014a) describes methods for eliciting distributions for parameters, but these can be adapted to elicit probabilities for outcomes (EFSA, Scientific Committee 2018a). In the present context, it is recommended to elicit probabilities following the same approach as outlined in section 3.5.2., with the following modifications:

1. Ensure that the outcome of interest is well-defined (see section 10 of EFSA, 2018a).
2. Review and summarise the evidence and uncertainties that are relevant to assessing the probability of that outcome.
3. As in section 3.5.2.

4. Elicit a probability for the specified outcome, i.e. a probability that would represent a fair bet for that outcome occurring, such that the expert would be equally happy to bet for or against the outcome on that probability. It may help to start at one end of the probability scale (0 or 100%) and move inwards to reach a first estimate, then make a second estimate starting from the other end of the probability scale, then take the midpoint of the two estimates. It is recommended that the experts make their judgements individually at first, then share them and discuss the reasons for differences between them, and finally develop a consensus judgement for the probability. Alternatively, if the outcome of interest is an event that could occur in the future, then assessors may find it easier to make judgements about the average waiting time for an event to occur, and derive a probability as the reciprocal of that.
5. No distribution fitting is needed.
6. As in section 3.5.2., but for consensus probability rather than distribution.
7. As in section 3.5.2., but for consensus probability rather than distribution.

3.6. Risk model implementation and calculation

Calculation of the risk model output requires implementation of the conceptual risk model defined for the risk assessment, eventually via a formal model definition (section 3.3) and its associated mathematical formulas, into computer readable format. There exist various software solutions available for this purpose, but this step in the risk assessment requires specific skills and experience on mathematical modelling and experience with the actual calculation tool chosen. Uncertainty in the model quantities are described using probability distributions. The uncertainty is propagated through the model by use of the so-called Monte Carlo method, where the information in the uncertainty distributions are calculated by randomly drawing sample values by simulation. The uncertainty calculations requires that the risk model is implemented in software that supports Monte Carlo simulation.

At the time of writing this Guidance, the procedure for risk model implementation and calculation is in a transition stage at EFSA. Currently, the model implementation and risk calculation is performed in the tool @Risk™ which is an add-in to Microsoft Excel™ spreadsheet software. For future risk model implementation and calculation, EFSA is developing an online and web-based risk model calculation tool based on the open source software platform R (R Core Team, 2014). The idea of the forthcoming tool is to allow the user to build the model in a web browser interface and it is a key objective to lower the barrier with respect to the technical skills required for model implementation and calculation. It is also important that users of the tool would not need to have any specialized or commercial software requiring a licence to operate the tool.

Furthermore, it is a key idea that the web-calculation tools should facilitate transparency and allow readers to repeat the risk calculations on their own. This is in line with EFSA policy of transparency, the risk model implementation and calculation procedure will be published as supplementary material along with the Panel Opinion.

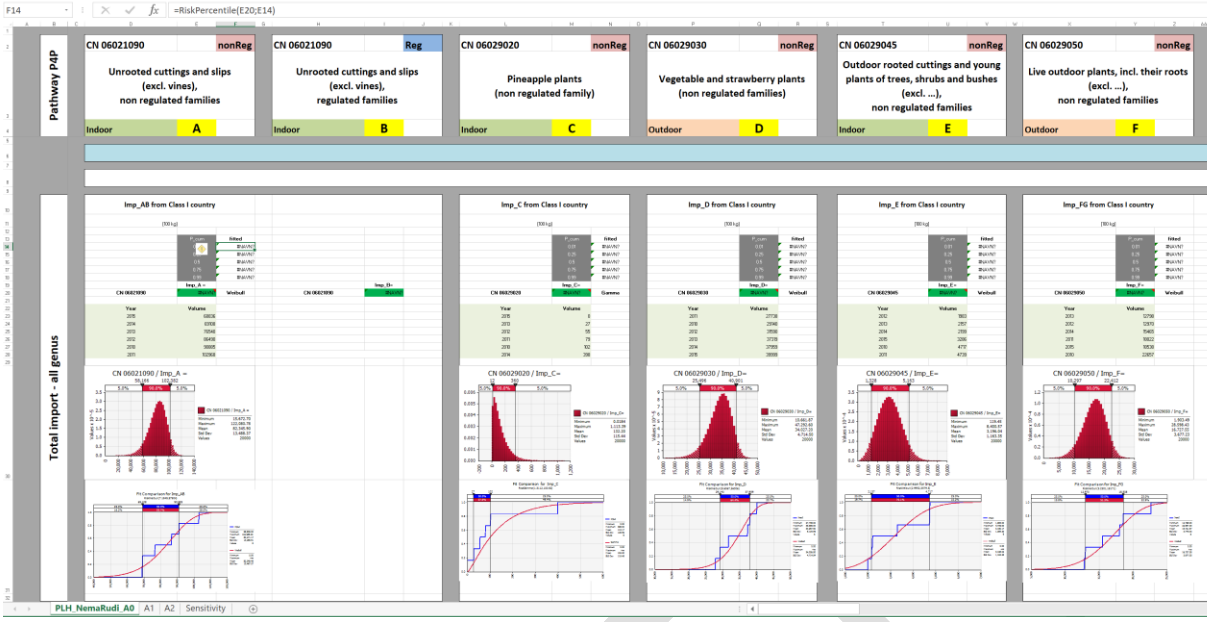


Figure 7: Screenshot of parameter specification for a part of a risk model using @Risk™ and Microsoft Excel™. The actual example is taken from the EFSA risk assessment of *Radopholus similis* (EFSA, 2017a)

Figure 7 shows an example user interface where @Risk™ and Microsoft Excel™ is used to fit uncertainty distributions to quantile value estimates obtained by expert elicitation during work on the EFSA risk assessment for *Radopholus similis* (EFSA, 2017). By interactive choice of distribution type by the user, the software will simulate a number of randomly drawn values from the distributions so that the shape of the uncertainty distributions can be visualised both by histogram of the randomly drawn values and by cumulative probability curves along with quantile estimates from expert elicitation.

3.7. Overall uncertainty assessment - taking account of additional uncertainties

When the assessment uses a quantitative model, some uncertainties will be quantified within it, as parameter distributions. Similarly, when the conclusion of a first tier assessment is expressed quantitatively, based on a simpler model or a weight of evidence approach, uncertainties are quantified within that. In both cases, however, there will be further uncertainties that are not quantified within the model or weight of evidence process. All these are referred to collectively here as 'additional uncertainties'. They include, but are not limited to:

- uncertainties that assessors chose not to quantify within the assessment, e.g. parameters for which a fixed value was assumed, and potentially relevant factors omitted from the model, e.g. omitting humidity and relying on temperature only for a development model;
- uncertainties about the identification and selection (or exclusion) of evidence used in the assessment (e.g. in cases of complex taxonomy there could be confusion in the literature regarding features of the species);
- uncertainties about the methods used to quantify uncertainty (e.g. validity of assumptions for statistical estimates, and quality of experts and elicitation process for expert judgements).

EFSA's Scientific Committee (2018a) uncertainty Guidance explains why it important that assessors quantify the combined impact of as many as possible of the identified uncertainties in each assessment, including the additional uncertainties. This is referred to as 'characterisation of overall uncertainty' in EFSA (2018b), which describes a general methodology. The following steps summarise how to perform overall uncertainty assessment in the context of the present Guidance:

1. Collate all uncertainties identified in earlier steps of the assessment into a single list or table, omitting those that have been quantified within the model or weight of evidence assessment, so that only the additional uncertainties remain.

2. Systematically review all steps of assessment for further sources of additional uncertainty (including those described in the bullets above) and add them to list. This is necessary to check for any uncertainties that may have been missed earlier in the assessment, or for uncertainties that only become apparent at the end (e.g. when interpreting the model output).

3. Optionally, reorder the list in any way the assessors find helpful for the following steps (e.g. group them by parameter or line of evidence, etc.). For example, it may be easier to judge the combined impact of uncertainties on the model output if assessors consider first the uncertainties affecting each parameter, and then how those parameters combine.

4. Adjust the output distribution or probability produced by the model or weight of evidence assessment by expert judgement to take account of the collective impact of the additional uncertainties. These judgements should be elicited using expert knowledge elicitation (EKE) methods appropriate to the importance of the result, the nature and magnitude of uncertainties involved, and the time and resources available for the mandate. If the impact of the additional uncertainties might be critical for decision-making, it should be assessed by semi-formal EKE (sections 3.5.2 and 3.5.3) or formal expert knowledge elicitation (see EFSA 2014a).

    a. When the assessment output is a distribution, there are three options:
        i. Elicit an adjusted distribution directly, by expert judgement, in the same way as for model parameters (see section 3.5.2). Assessors should review the output of the model or weight of evidence assessment and the list of additional uncertainties, and agree on a final, adjusted distribution to represent the experts' judgement of the overall uncertainty.
        ii. Elicit a distribution for impact of the additional uncertainties on the assessment output (i.e. how much they would change it), in the same way as for model parameters (see Section 3.5.2). Then combine this with the model output distribution by a probabilistic calculation.
        iii. Elicit the assessors' probability that the output of the assessment will exceed some value of interest (e.g. zero), taking account of both the distribution output by the assessment model and the additional uncertainties, and using the same elicitation procedure as for probabilities of conclusions in weight of evidence assessment (see Section 3.5.3). This is simpler than options (i) or (ii) above, but provides less information.

    b. When the assessment output is a probability for a particular outcome, elicit an adjusted probability for the outcome directly, using the same elicitation procedure as for probabilities of conclusions in weight of evidence assessment (see Section 3.5.). Assessors should review the probability produced by the model or weight of evidence assessment together with the list of additional uncertainties, and agree on a final, adjusted probability by expert judgement.

    In all of the above approaches (a and b), the assessors should take account of any dependencies between the additional uncertainties and those quantified in earlier steps of the assessment. In case a(ii), any dependencies should be quantified and incorporated into the probabilistic calculation. In cases a(i), a(iii) and b, any dependencies should be taken into account by expert judgement.

5. If the assessors identify any sources of uncertainty that they feel unable to include in their quantitative assessment, they should mark them as 'unquantifiable'. They should then complete their quantitative assessment of the other uncertainties, assuming the potentially unquantifiable uncertainties have no impact, and address the latter through the approach described in the following section (3.9).

The relation of the overall uncertainty assessment to the modelling output may be illustrated using an example. Suppose that the median estimate for the number of potential founder populations for scenario A0 was 142 with a 95% uncertainty interval from 70 to 200 (this example is also used later, in section 3.9). The assessment of overall uncertainty, taking account of additional uncertainties not quantified within the risk model, might lead to various outcomes as illustrated by the following examples:

- If the assessors concluded that the combined contribution of additional uncertainties was practically zero, then they would report the model results as overall uncertainty without further adjustment (median 142, 95% uncertainty interval 70-200).
- If the assessors concluded that the combined contribution of additional uncertainties would increase the overall uncertainty but not shift the distribution upwards or downwards, they might retain the median, perhaps rounded (e.g. 140 or 150) and would increase the width of the uncertainty interval to reflect their judgement of the overall uncertainty taking into account the additional uncertainties (e.g. a 95% interval of 50 -300).
- If the assessors concluded that the combined contribution of additional uncertainties would increase the overall uncertainty and also shift the distribution upwards or downwards, they would make both these adjustments in their overall assessment of uncertainty. For example, if the uncertainty arose from underestimation of some risk factor, or excluding a secondary pathway that would contribute additional founder populations, they might both increase the median estimate (e.g. from 142 to 200) and also increase the width of the uncertainty interval (e.g. from 70 – 200 to 50 – 500).
- The assessors might prefer to make an approximate probability judgement about specified outcomes of interest, instead of adjusting the median and uncertainty interval produced by the assessment model. For example, after considering the model output together with the additional uncertainties, they might judge that it is nearly certain (99-100% probability) that at least one founder population will occur in scenario A0, and likely (66%-90% probability) that there will be more than 100 founder populations. Judgements of this type could be made for any outcome that was thought to be of interest for decision-making.

Adjustments or judgements of the types illustrated above should be reasoned expert judgements based on evidence (including expert knowledge), and the basis for them should be documented in the Opinion. See section 3.5 for more information on methods for eliciting expert judgements.

3.8. Unquantified uncertainties

In principle, it should be possible for assessors to quantify uncertainty about any quantity or question using probability, at least approximately, provided that the quantity or question is well defined (see section 5.10 of EFSA, 2018b). However, assessors may sometimes feel unable to include all the uncertainties they have identified in their quantitative assessment of overall uncertainty.

If there are any identified sources of uncertainty that the assessors regard as unquantifiable, it is essential to describe them and consider their impact on the reporting and interpretation of the quantitative assessment. In general, not being able to quantify the impact of a source of uncertainty on a conclusion implies that there could be any amount of additional uncertainty in either direction, which makes it questionable whether any conclusion can be drawn. If assessors feel they can draw conclusions that could inform decision-making, this implies that they are able to provide at least a partial quantification of the collective impact of all the identified uncertainties. If so, they should revisit the quantitative assessment of overall uncertainty (section 3.7.) and try to include all these identified uncertainties. If they are unable to do this, the uncertainties in question may be regarded as unquantifiable.

When unquantifiable uncertainties are present, assessors should consider whether they can make the quantitative assessment conditional on assumptions about the unquantifiable uncertainties. For example, if uncertainty about future trade volume cannot be quantified, then the assessors might assume trade continues at its current level and the quantitative results would then be conditional on this being true. Any conditionality must be clearly stated wherever the quantitative result is presented; omitting it would be misleading and could lead to poor decisions. Conditional conclusions will be useful if risk managers can understand the conditionality and take account of it in decision-making. Otherwise, the assessors should report that no conclusion can be reached and describe the unquantifiable uncertainties that are responsible for this. In such situations, any quantitative assessment that was done could still be reported in the body of the opinion, provided it is clearly stated that the results are hypothetical and not a reliable basis for decision-making.

The approach described above applies to identified uncertainties, i.e. sources of uncertainty that assessors are aware of. It does not apply to 'unknown unknowns' – things that might change the assessment in future, but which assessors have no awareness of at the time of completing the assessment. It is, by definition, not possible to take account of unknown unknowns; at most, assessors might identify situations where they are more likely to be present (e.g. novel risks). All assessments are necessarily conditional on assuming that the collective impact of unknown unknowns is zero, and this should be understood and taken into account by risk managers

3.9. Presentation of results and conclusions

This section provides guidance on the presentation of results and conclusions. EFSA is developing general Guidance on communicating the outcomes of assessments involving uncertainty analysis, and this should also be taken into account when available.

3.9.1. Introduction to the communication of results

Previous EFSA PLH panel opinions expressed pest risk in entirely qualitative terms (e.g. EFSA Panel on Plant Health, 2011; 2013). In contrast, the current Guidance advocates the expression of risk in quantitative terms, by asking assessors to express (imperfect) knowledge and judgments in terms of probabilities specifically encouraging results to be expressed as numerical ranges (i.e., probability distributions). It encourages the use of graphs to support the communication of results. This different approach may present some challenges to whom are unfamiliar with interpreting risk information in such a way. Guidance is therefore provided here which aims to facilitate the communication of the quantitative aspects of the results from risk assessments and the evaluation of RROs. It is anticipated that harmonizing communication of results will improve the users' experience of the assessments, aid learning and improve the usefulness of the assessments. If future assessments follow a common approach regarding how results are presented outputs will be more consistent and users should more quickly come to terms with this approach.

Scope

The scope of this part of the Guidance is to focus on possible approaches that allow quantitative results to be presented in a consistent manner within and between assessments. Presenting results using a similar style of text, tables and graphics is proposed that aim to help to clearly present and communicate risk assessment results and to compare results between scenarios. Since the purpose of risk assessment is to inform risk managers about the nature and potential magnitude of risk, and thus inform their risk management decisions, it is essential to communicate the results of the risk assessment in an unambiguous and transparent way to facilitate understanding.

Focus of communication

The ToR may have identified specific issues to be addressed within an overall assessment and each issue must be clearly addressed when reporting results of an assessment. Regarding the quantitative results from an assessment, assessors should consider how to communicate results taking the guidance below into account.

Level of resolution varies according to section of the opinion

Different sections of an opinion, such as the abstract, the summary, and the main body of text serve a different purpose and they should report results at different level of detail. For example, in an abstract it may be desirable to express the results using a verbal description of a range, such as "several tens up to a couple of hundred" but in the main body of text, a graph of probability distribution could be provided which provides much more information and shows that the approximation is based on a 95% probability interval of 70 to 200 with a median of 125. When approximating results it is essential to ensure that readers can easily and reliably trace back from the rounded/approximated values to find the more precise results on which they are based. This may require the use of cross-references to the relevant sections of the opinion, or the inclusion of specific phrases in the communication that make it easy to locate the corresponding text and results in the body of the opinion. This is especially important after publication of the opinion if the communication format is changed from being quantitative to be expressed in a qualitative way, for example for the purposes of wider communication in press releases or a web story.

Terminology

The methodology represents a framework allowing novel tools and techniques to be used and 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.

3.9.2. Aspects to consider when presenting the results of the assessment

Model outputs for each step in the assessment, i.e. entry, establishment, spread and impact should be presented and commented upon. Within the main text of an opinion this is best done using tables, graphs and figures with some text to explain key features of the graphs (see section 3.9.3). If RROs have been evaluated it is important to highlight and comment on differences between scenarios (e.g. some pathways could be more affected by particular RROs than others).

The text should be kept to purely descriptive comments without discussing or interpreting the results before additional uncertainties (see section 3.7.) are taken into account.

Comparisons should refer to the estimated ranges of outputs, e.g. comparing 95% probability intervals between pathways for entry or between each step for each scenario (e.g. compare the baseline scenario to an alternative scenario where a specific combination of RROs has been applied). In doing this, it is essential to consider and document the things that affect the difference, e.g. effects of the RRO on parameters other than those they are intended to affect, and the nature and magnitude of dependencies of the uncertainties between the two scenarios. The effect of such complications should then be taken into account either by quantifying them within the model or as additional uncertainties in the overall uncertainty assessment, recognizing that judgements on this may be very uncertain.

When presenting the results of each assessment step, any assumptions and conditionality should be made clear (see section 3.7.). The following aspects should be reported:

- Entry should be reported as the distribution of the estimated number of potential founder pest populations arriving in the risk assessment area along each individual pathway assessed, and as the range of the sum of all pathways assessed for the defined scenarios and the selected temporal and spatial scales. This should be calculated probabilistically using supporting software (ref to software) or may be estimated without sub-steps using EKE.
- If RROs that act on a pathway are evaluated, then it will be important to give the equivalent ranges for each RRO scenario and highlight changes (reductions) in the range of the numbers of potential founder populations arriving in the risk assessment area as a consequence of the RROs. Depending on the specific ToR, it may be relevant to draw particular attention to the scenarios with the biggest differences. Comparison between two scenarios can be performed using the distributions for two scenarios in a Monte Carlo calculation of the difference between the two quantities, yielding a distribution for the difference. Assessors can then read off from the distribution what is the probability of any difference of interest, e.g. the probability that the RRO decreases the risk at all, or by some desired amount.
- Establishment should be described as the distribution of the estimated number of founder populations transferring to hosts for the selected temporal and spatial scales and surviving for the foreseeable future. If RROs that act on the likelihood or extent of establishment of potential founder populations are evaluated, then it will be important to give the equivalent ranges for each RRO scenario and highlight changes (reductions) in the range of numbers of founder populations establishing in the risk assessment area and highlight the influence that RROs have on the changes.
- Spread should be presented as an estimate of the increase in the numbers of spatial units (e.g., NUTS regions) or area occupied by the pest at the appropriate temporal and spatial scales. If RROs that inhibit pest spread are evaluated, then it will be important to give the

equivalent ranges for each RRO scenario and highlight changes (reductions) in the estimated range of spatial units or area occupied as a consequence of RROs.

- Several types of pest impact have to be considered and should be reported in terms of distributions for changes to crop output, yield or quality. Environmental impacts should be reported in terms of distributions for the changes of ecosystem services provision level and biodiversity due to the pest. If RROs that inhibit pest impacts are evaluated, then it will be important to give the equivalent ranges for each RRO scenario and highlight changes (reductions) in the estimated crop yield and/or ecosystem services and biodiversity, drawing attention to those RROs that provide the greatest reduction in pest impacts.

Reporting to an appropriate degree of precision or approximation

Applying this Guidance produces quantitative results which are estimates for specific steps within a risk assessment. As in all quantitative science, it is important to report the results in a manner that appropriately reflects the degree of precision or approximation of the data used. While precise data should be used when available, in plant health, risk assessment data are often limited and many input parameters must be assessed by expert judgment, which is necessarily approximate in nature. The risk assessment outputs are hence also approximate in nature. Therefore, although the outputs will be calculated to many significant figures, they must be rounded to an appropriate degree (see details under 3.9.3)to properly reflect the degree of approximation present in the assessment when reporting results. This applies to all parts of the opinion when reporting results, and is especially important in the conclusions, abstract and summary sections.

The approximate nature of the results may be further emphasized, when appropriate, by reporting the results in text form, provided that these have clear quantitative meaning. For example, the EFSA AHAW panel reported aspects of one quantitative model as "The […] model indicates that some hundreds of […] infected animals will be moved into the Region of Concern when an epidemic in the source areas occurs" (EFSA AHAW, 2013). Although model outputs provided more precise figures, for the purposes of communicating the results of the risk assessment, it was sufficient to report the result as "some hundreds of infected animals".

Expressions to avoid and qualifiers to include

Results should not be reduced to verbal expression that lacks a clear quantitative meaning, such as 'low', 'moderate' or 'high' as these expressions are ambiguous and will be interpreted differently by different people. Furthermore, they often carry risk management connotations, e.g. 'negligible' implies 'too small to warrant concern or action'. Adding verbal qualifiers such as 'about', 'approximately', or 'in the region of' to numbers may help to reduce the chance that readers interpret them with too much precision. However, assessors must be careful not to add verbal qualifiers which might be understood as implying value judgments (e.g. 'only').

Uncertainties affecting the assessment

To ensure transparency, it is important to identify and discuss uncertainties within each step of the assessment.

The following uncertainties should be considered (see sections 3.7 and 3.8):

1. Uncertainties quantified within the model

2. Additional uncertainties that are not quantified within the model, including uncertainties relating to the model itself (see section 3.7).

   The impact of the additional uncertainties on the results should be discussed, e.g. how much they might alter the uncertainty interval and/ or median produced by the model (see section 3.7).

3. Overall uncertainty, combining those quantified in the model and the additional uncertainties (see section 3.7).

4. Unquantified uncertainties (see section 3.8)

Uncertainty in the results for each step or sub-step (e.g. entry, establishment, etc.) is indicated by the range and distribution of the results, derived from input estimates. (see relevant tables and graphs/figures described below).

The contribution to uncertainty of the various sub-steps considered in the different steps can be shown as a decomposition of uncertainty as shown in Figure 15.

Additional uncertainties affecting the assessment but not quantified within the assessment model should be listed in a table. Their impacts on interpretation of the model outputs are discussed below (see section 3.9.7).

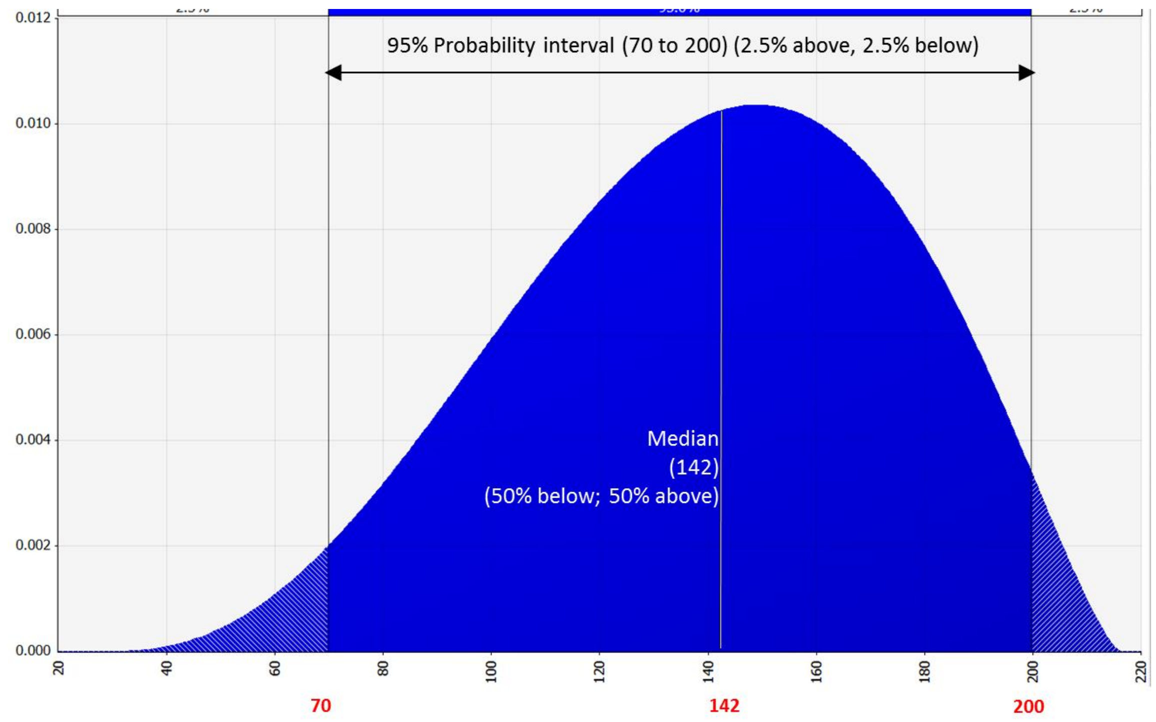
Additional uncertainties affecting the previous step should also be taken into account when assessing overall uncertainty for the relevant/current step, but can be listed as a single item in the uncertainty table for that relevant step, with a reference back to the table in the previous section.

3.9.3. Documentation and interpretation of results (distributions)

In this methodology results are expressed in terms of probability distributions; therefore it is essential that the information conveyed by the probability distributions is understood and interpreted identically by both risk assessors and managers. A good introductory text is provided by Morgan et al., (2010). Graphs showing probability density distributions and cumulative descending probability are recommended. Figure 8 is an example of a probability density. The 95% probability interval and median are marked. Figure 9 shows the same data presented as a descending cumulative probability with the same points marked.

Much information can be obtained from such graphs. The curve describes the shape of the distribution. Rare or unlikely events (numbers) are represented at the shallow tails of the curve. The area between two points on the curve is the probability that an unknown value will fall between the two points. Thus in Figure 8 there is a 95% probability that the value is between 70 and 200. There is a 2.5% probability that the value is below 70 and a 2.5% probability that the value is above 200. The median value is the point separating the upper 50% of probability (area under the curve) from the lower 50% of probability (area under the curve).

Graphs or charts are provided as an aid to formulate conclusions; they are not themselves the conclusions. Verbal terms and relevant numbers (rounding) should be used so as to reflect uncertainty.

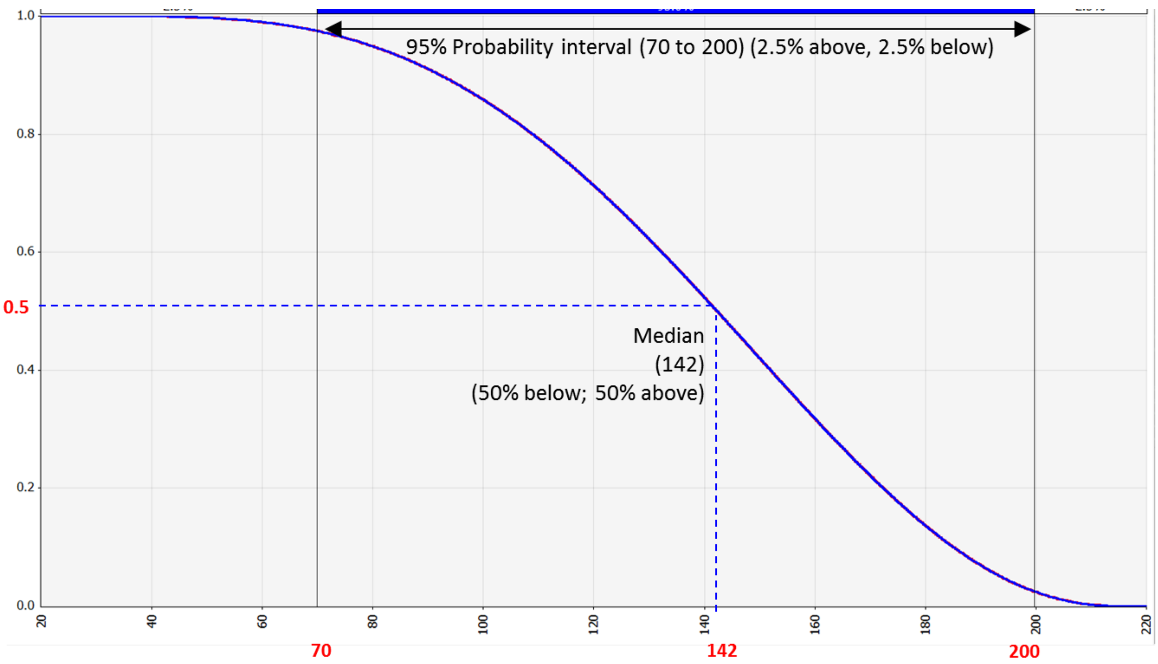


X-axis label: Number of potential founder populations (Scenario A0)

Y-axis label: Probability density

Figure legend: In this probability density plot, the area to the left of point 70 on the horizontal axis represents 2.5% of the blue area under the curve and represents the probability that founder populations are less than or equal to 70; the area to the left of 142 represents 50% of the area of the curve and indicates that there is a 0.5 probability that the number of potential founder populations is up to, or equal to 142; equally the probability that the number of potential founder populations is more than 142 is 0.5; The area to the right hand side of 200 represents 2.5% of the area under the curve and indicates that the probability that the number of potential founder populations is greater than or equal to 200 is 0.025, equally the probability that the number of potential founder populations is less than or equal to 200 is 0.975.

Figure 8: Probability density of the number of potential founder populations in Scenario A0.



X-axis label: Number of potential founder populations (Scenario A0)

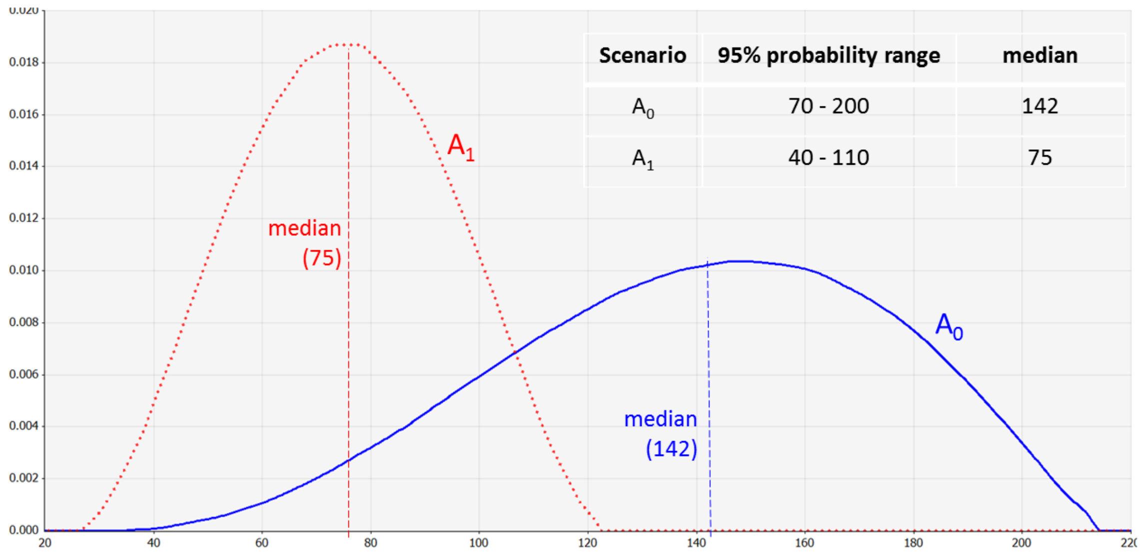
Y-axis label: Cumulative probability

Figure legend: Here the data from Figure 13 are shown as a descending cumulative probability plot. Reading across from 0.975 on the vertical axis, indicates that there is a 0.975 probability that the number of potential founder populations is greater than or equal to 70; equally the probability that the number of potential founder populations is less than or equal to 70 is 0.025 (1-0.975). On the vertical axis 0.5 indicates that there is a 0.5 probability that the number of potential founder populations is greater than or equal to 142; equally there is a 0.5 probability that the number of potential founder populations is less than 142. Reading across from 0.025 on the vertical axis indicates that the probability that the number of potential founder populations is greater than or equal to 200 is 0.025, equally the probability that the number of potential founder populations is less than or equal to 200 is 0.975. There is a 0.95 probability that the potential founder population is within the range 70 to 200.

Figure 9: Descending Probability density of the number of potential founder populations in Scenario A0.

For the comparison of the results from different scenarios, it is useful to plot the result distributions on the same chart.

Overlaying the results of a distribution from one scenario on the results from another scenario may help communicate how scenarios compare (Figures 10, 11, 12) Comparison of the ranges in distributions should then be made. A default uncertainty range of 95% is suggested but the Commission can be asked for an alternative (during the interpretation of ToR) if useful.

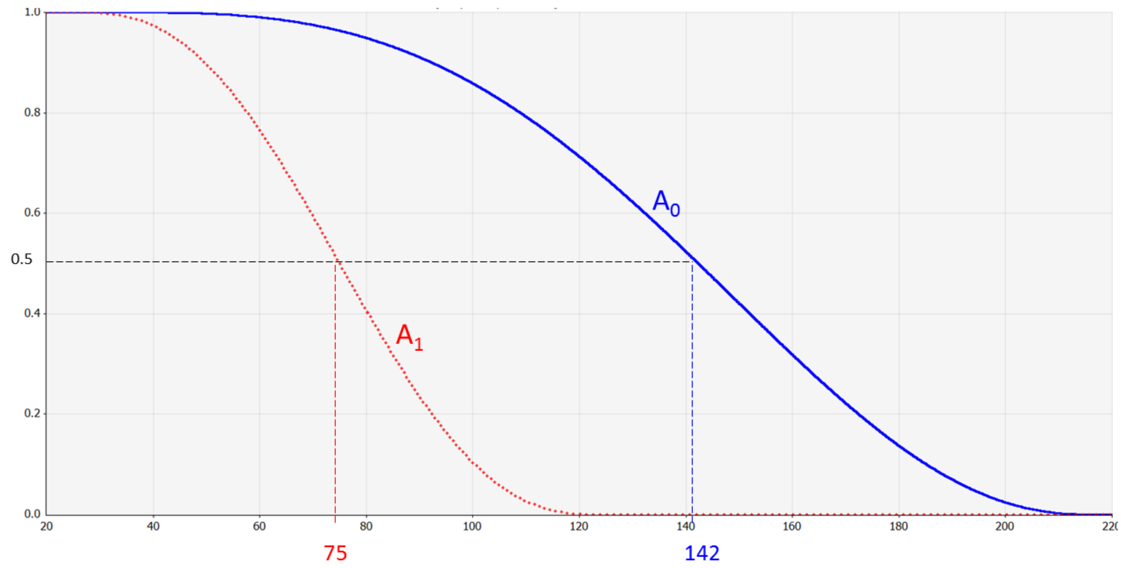


X-axis label: Number of potential founder populations (Blue line Scenario A0, Red Line Scenario A1)
Y-axis label: Probability density

Figure legend: A probability density plot for potential founder populations in scenario A0, without RROs and A1, with RROs. Note that the median for the number of potential founder populations in A0 (142) is greater than the median for the number of potential founder populations in A1 (75) although there is some overlap in the distributions.

Figure 10: Probability density plots of the number of potential founder populations in Scenario A0 and Scenario A1.

The results data used to generate the probability density in Figure 14 are expressed as cumulative descending probability in Figures 15 with the medians highlighted and in Figure 16 with the 95% probability range marked.

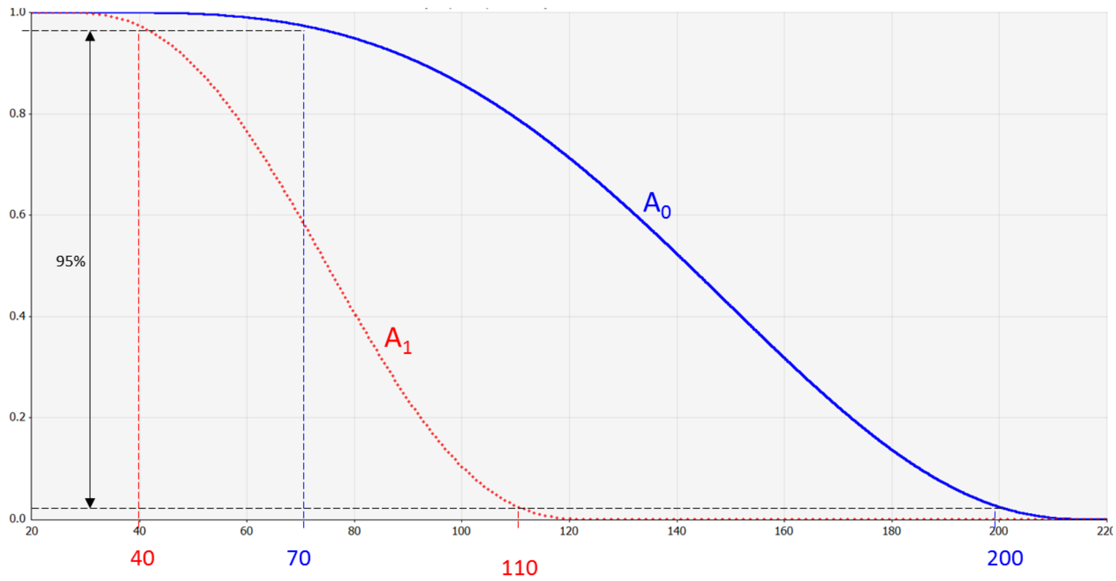


X-axis label: Number of potential founder populations

Y-axis label: Probability

Figure legend: Here the data from Figure 15 are shown as descending cumulative probability plots. For Scenario A_0 this corresponds to up to 142 potential founder populations; for Scenario A_1 this corresponds to up to 75 potential founder populations. Note that the RROs used in A_1 shift the curve to the left. The greater the shift to the left, the more effective the RROs used in the scenario.

Figure 11: Descending cumulative probability distribution of the number of potential founder populations in Scenarios A0 and A1.



X-axis label: Number of potential founder populations
Y-axis label: Cumulative probability

Figure legend: Here the data from Figure 16 are reproduced with the addition of the 95% probability range for each scenario. Scenario A0 95% probability interval that the number of potential founder populations is between 70 and 200; Scenario A1 95% probability interval that the number of potential founder populations is between 40 and 110.

Figure 12: Descending cumulative probability distribution of the number of potential founder populations in Scenario A0 and A1.

When reporting any of the results, they should be rounded to an appropriate number of significant figures. This is a matter of judgement, but will take account of the widths of the intervals being reported. A possible starting point might be to report the upper and lower bound of each range to the minimum number significant figures needed to differentiate them. For example, a range of 34 to 76 might be expressed as 30 to 80, and 462 to 878 might be expressed as 500 - 900. However, assessors should use their judgement to deviate from this rule where they consider it appropriate, for example if rounding results in a range that is markedly shifted up or down relative to the original numbers, or conveys less precision than the assessors consider is merited.

Examples:

1,220 = Median: Approximately twelve hundred

810 to 1,760 = 95% Uncertainty interval (interval between 2.5% and 97.5%): In the range of eight to eighteen hundred.

For all steps, tables should be provided, showing relevant quantiles of the uncertainty distribution for the resulting numbers (suggested quantiles are 2.5th, 50th and 97.5th) See Table 3 as an example. Show the full table with all relevant quantiles produced by the software in an Appendix (consider adding a distribution of differences between scenarios as well).

Table 3: Selected quantiles (2.5th, 50th and 97.5th) of the uncertainty distribution for the number of potential founder populations of pest name expected per month/year/etc. due to new entries in the EU calculated in the time horizon of x years for scenarios A0 - An (all pathways combined).

Quantile	2.5% quantile	Median (50%)	97.5% quantile
Number of potential founder populations for scenario A_0	70	142	200
Number of potential founder populations for scenario A_1	40	75	110
Number of potential founder populations for scenario A_2 …			

3.9.4. Comparing distributions

When an assessment results in distributions quantifying risk for different scenarios, A0, A1...etc., there will often be interest in comparing them. Since the risk for each scenario is uncertain, the difference between any pair of scenarios is also uncertain. This uncertainty can be quantified by calculating the difference (or ratios in logarithmic scales) between the two scenarios, expressed either as an absolute difference (e.g. subtract the calculated outcomes under scenario A0 from those of A1) or a relative magnitude of effect (e.g. the ratio of the outcomes under A1 and A0). This is best done by Monte Carlo simulation, repeatedly calculating pairs of outcome values for A0 and A1 for the same stochastic draws, and calculating the difference or ratio between them, resulting in a distribution for the difference or ratio.

Figure 13 shows an example of the effect of changing the rigour of import inspections/pest control. Compared to a baseline scenario A0, scenario A2 represents stricter import inspection, whereas scenario A1 represents less strict import inspection. In this example, the scenario A2 has lowered each of the 10,000 stochastic simulation outcomes, such that the entire distribution of ratios of the outcomes under A2 and A0 is below 1 (denoted at 1.0E+00 on the figure X-axis). On the other hand, the scenario A1 has increased most of the stochastic simulation outcomes compared to A0 (ratios larger than 1), while it has lowered the stochastic simulation outcome in other instances (ratios smaller than 1). Figure 14 is showing the same results as cumulative distributions. In this figure, it is easy to see that all ratios A2/A0 are all less than 1, whereas approximately 30% of the ratios A1/A0 are less than 1, while 70% are greater than 1. Thus, with a high level of confidence the scenario A2 reduces the risk, whereas the scenario A1 increases the median value of the uncertainty distribution of the number of impacted plants, while the probability of an increase in the impact is assessed as 70%.The technical implementation of the risk model affects the calculated distributions. If a risk reducing option is added as an additional sub-step, and provided its impact is a reduction, then the resulting outcomes will always be lowered, resulting in a distribution of the ratio below 1, with no uncertainty. However, if a risk reducing option is implemented in the risk model by eliciting a changed distribution for a sub-step that is already in the risk model, the ratio of outcomes is determined by a ratio of two stochastic outcomes from two independent draws from two different probability distributions, making the result more difficult to predict, and potentially different from the risk assessors expectations. The uncertainties contained in the two elicitations for the same sub-step –

with or without RRO – may result in a reduction as well as in an increase in the calculated outcome after the step.

The choice between the two options (to implement the RRO as an additional sub-step or as a different elicited distribution for an existing sub-step) depends on if the assessor consider the RRO to be an add-on or a replacement of an existing practice.

Advice may be requested from statistical support. The resulting distribution for the difference or ratio illustrates how a change in risk management affects the relative effect sizes calculated by the model including uncertainty in this measure. Such a distribution may be interpreted and communicated in the same way as the distributions of outcomes for individual scenarios: e.g. by reporting the median ratio or difference and its 95% uncertainty interval.

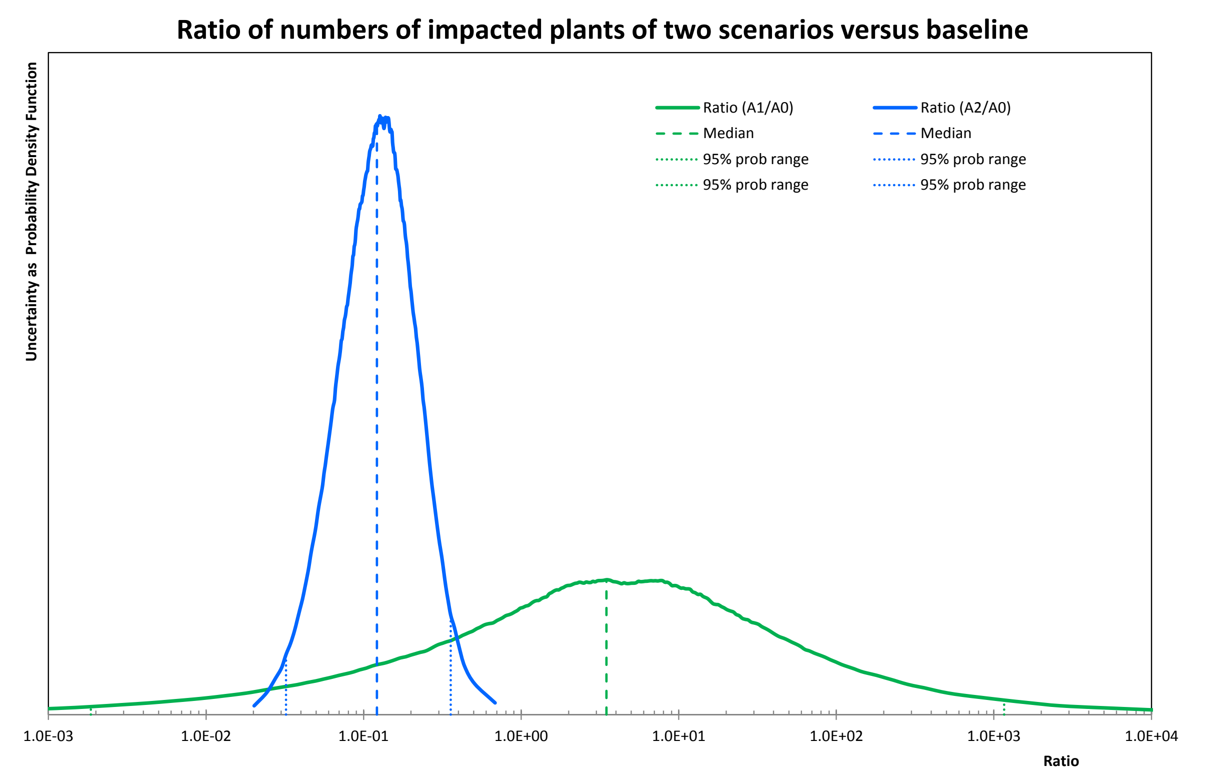


Figure 13: Comparison of scenarios by assessment of the ratio of the outcome variables under two scenarios. This figure shows the uncertainty distribution (density form) of the ratios for two scenarios A2 (stricter import inspection) and A1 (less strict import inspection) in comparison to a common baseline A0. The distribution for scenario A2 is entirely below 1, indicating very high certainty that stricter import inspection will lower the risk. The distribution of the ratio for the comparison of scenario A1 to A0 is only partly above 1, indicating uncertainty whether loosening import inspections will increase risk. The same data are shown in cumulative distribution form in Fig. 14.

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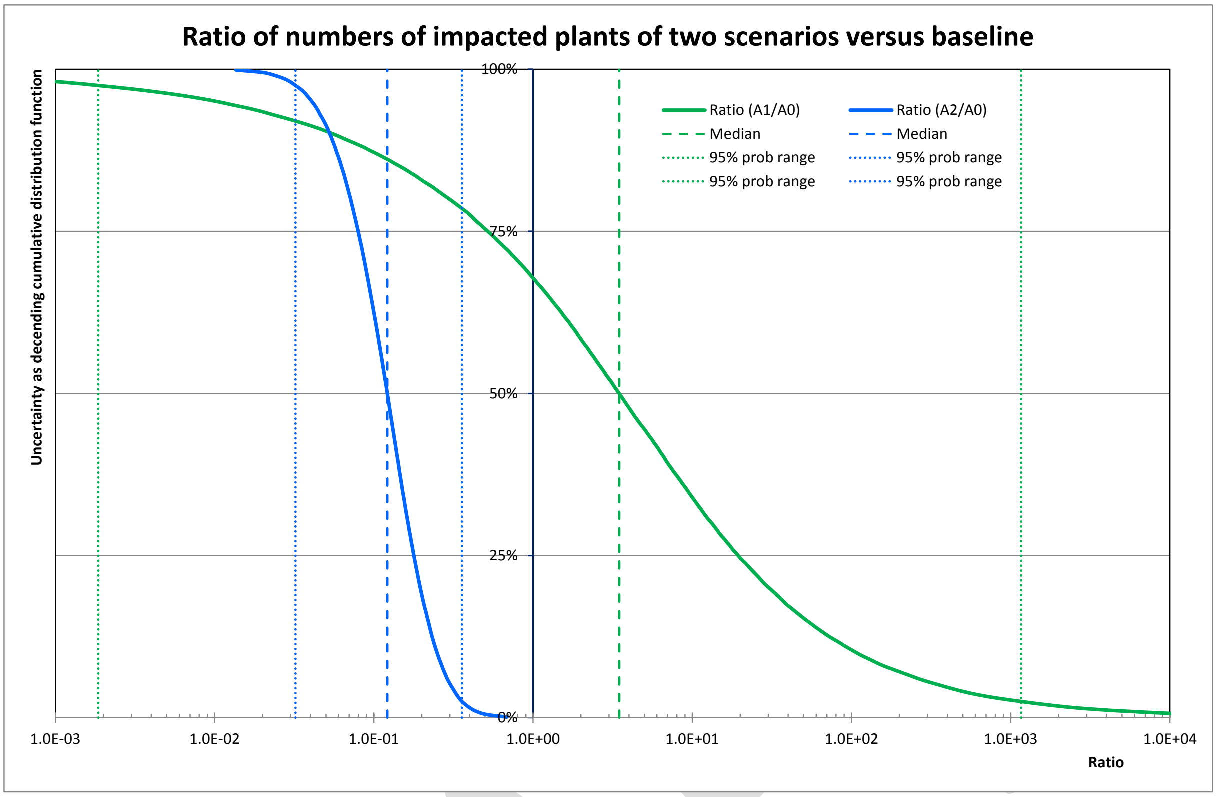

Figure 14: Comparison of scenarios by assessment of the ratio of the outcome variables under two scenarios. This figure shows the uncertainty distribution (cumulative form) of the ratios for two scenario's A2 (stricter import inspection) and A1 (less strict import inspection) in comparison to a common baseline A0. The distribution for scenario A2 is entirely below 1, indicating very little uncertainty that stricter import inspection will lower the risk. The distribution of the ratio for the comparison of scenario A1 to A0 is only partly above 1, indicating substantial uncertainty that loosening import inspections will increase risk. The same data are shown in probability density form in Fig. 13.

3.9.5. Overall uncertainty

When communicating the conclusion of the assessment, primary emphasis should be given to the assessment of overall uncertainty, as this includes both the uncertainties quantified within the assessment and any additional (i.e. unquantified) uncertainties identified by the assessors (section 3.7). Graphical and numerical outputs from the assessment model should be presented as a second level of information, which supports and contributes to the assessment of overall uncertainty.

Methods for assessing the overall uncertainty are described in section 3.7. A consensus conclusion on the overall uncertainty should be sought in the Working Group and the Panel. If giving a fully-specified probability distribution for overall uncertainty is considered to be over-precise, then a more approximate quantitative expression should be found that appropriately communicates what the Panel is able to say about the conclusion, while minimizing the degree to which it becomes ambiguous. Options for this include giving imprecise or bounded probabilities for values of interest for decision-making (e.g. 'less than 10% probability of exceeding zero') or using verbal qualifiers (e.g. 'about', 'approximately', 'some tens', etc.) although the latter are ambiguous and should be used only when necessary and with care. If assessors found it impossible to include some of the additional uncertainties in the quantitative expression (see section 3.6), then these should be described qualitatively side by side with the quantitative uncertainties.

Any additional information that may aid understanding of the conclusion should be added, e.g. factors contributing to the location of the median estimate, factors or circumstances contributing to the range of uncertainty, and reasons why values outside the uncertainty interval are less likely.

It should be identified which of the uncertainties contribute most to the overall uncertainty, including those quantified in the model and the additional uncertainties. Any actions that could be taken to try to reduce those uncertainties (e.g. further data collection or modelling) should be identified as well. If possible, an indication of their feasibility should be given, how much time they would take, and how much they might reduce the uncertainty, as these factors may be relevant for decision-making.

3.9.6. Decomposition of the uncertainties

A feature of the quantitative model is the propagation of uncertainty through the model. Uncertainty analysis is conducted by storing during model simulation the randomly drawn input variables for the model as well as the outputs (e.g. 10,000 iterations). A regression analysis is then done on these data to determine how the calculated output changes with each of the inputs. The relative contributions of different input variables to the variance of the output are then calculated and presented as a pie chart (Figure 15). This decomposition of the variance of the output allows the user to identify which sub-steps contribute the most to the uncertainty of the calculated output.

Each section of a pie-chart represents the relative contribution of each factor to the overall uncertainty affecting the result for a step in the risk assessment. The larger the area of a pie-chart section the more that factor contributes to the uncertainty. Changes to values of estimates for sub-steps that contribute only a small amount to overall uncertainty (i.e. small slices of pie chart) will not greatly affect the overall result for the step. However, changes to estimates of values for sub-steps with larger slices will have a greater effect on results.

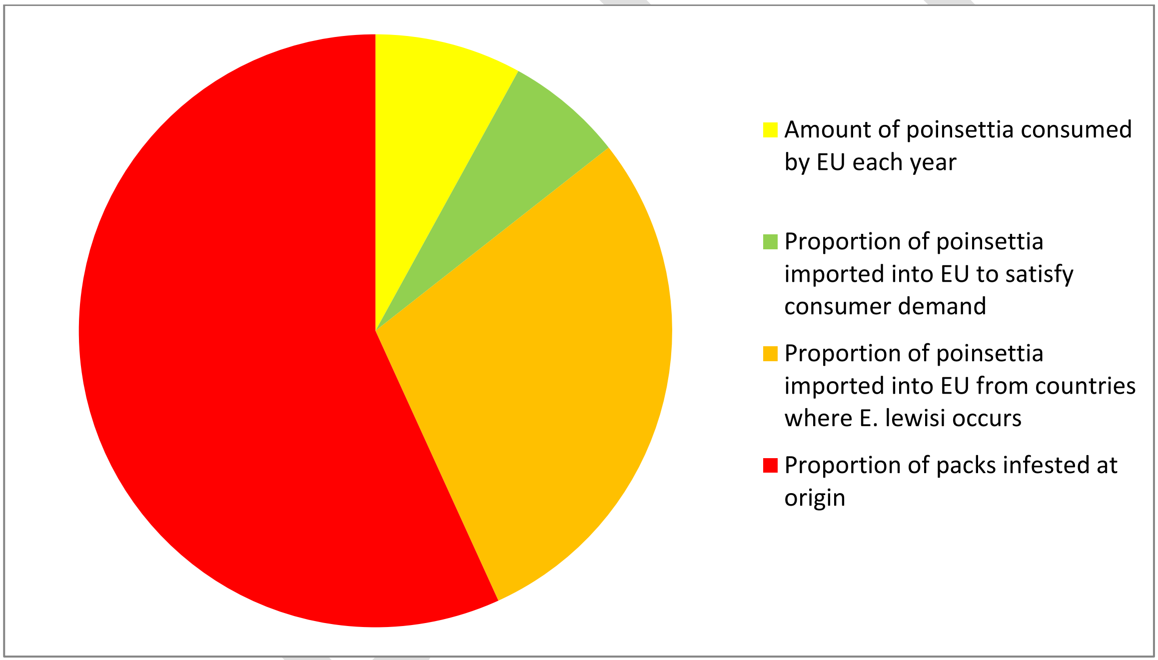

Figure 15: Example on decomposition uncertainties from the EFSA opinion on *Eotetranychus lewisi* (EFSA, 2017d). Entry sub-steps whose estimates contribute the most to overall uncertainty regarding the mean number of packs of poinsettia entering the EU each year infested with *E. lewisi*. Within the model for entry via poinsettia, there are four major sub-steps that contribute the most to uncertainty. Three of the four sub-steps are not related to the biology of *E. lewisi* but concern the international trade in poinsettia. The uncertainties are about the average amount of poinsettia 'consumed' each year in the EU, the amount that is imported, and the amount that is imported from countries where E. lewisi occurs. Improved knowledge about the future trends of where poinsettia could be sourced from, and the amount imported would narrow uncertainty in the estimate of the number of packs arriving each year in the EU infested with *E. lewisi*. The single greatest uncertainty regarding entry is the level of infestation of the commodity at pathway origin.

3.9.7. Unquantified uncertainties

Assessors should express in quantitative terms the combined impact of as many as possible of the identified uncertainties (EFSA Scientific Committee, 2018a). Only those uncertainties that the assessors feel unable to include in their quantitative assessment of overall uncertainty should remain unquantified (see section 3.8).

If there are any unquantified uncertainties, the result of the quantitative assessment will be conditional on the assumptions that have been made about the unquantified uncertainties (section 3.8). Therefore, the quantitative assessment of overall uncertainty should be presented together with a qualitative description of any uncertainties that remain unquantified. Assessors should describe (either in the conclusion of the opinion or another section, as appropriate) in which step(s) of the assessment each unquantified uncertainty arises, the cause or reason for the uncertainty, how it affects the assessment (but not how much, see below), why it is difficult to quantify, what assumptions have been made about it in the assessment, and what could be done to reduce or better characterise it. If the assessors feel able to use words that imply a judgement about the magnitude or likelihood of the unquantified sources of uncertainty during describing these uncertainties, they should revisit the quantitative assessment and try to include them.

3.9.8. Discussion and conclusions of the different steps/sections

The conclusions should clearly respond and answer the questions within the ToR. Conclusions regarding each scenario should be provided, as should the effect of RROs. The time horizon and spatial units should be clear. The key interpretations based on the results sections should appear in the conclusion. The primary message should focus on the assessment of overall uncertainty (3.9.4); if intermediate results (e.g. model outputs) are included in the conclusions then any difference between them and the overall uncertainty assessment must be explained clearly. Since a large part of the results will have been reported mainly in the form of probability ranges, the conclusions should also focus on ranges rather than medians; conclusions should be reported with an appropriate degree of approximation (as in the results sections). If more than one range from a single distribution is being reported, wider ranges should be communicated before narrower ones. The standard range reported should be the 95% probability interval, between the 2.5th and 97.5th quantile of the distribution. This should be reported before the median. Again the intent of this is to avoid excessive anchoring on the central region (median). If more than one range is referred to, it is also important to state clearly what probability is covered by each range, to avoid readers assuming they relate to intervals they are familiar with (e.g. 95% confidence intervals). The purpose of this is to encourage the readerto understand that the true value of the quantity is uncertain. The median should be described as the central estimate, it should never be described as a ‘best estimate’.

3.9.9. Summary

Table 4 summarises the types of communication and appropriate degree of approximation best suited for each section of a published risk assessment opinion. As a reader progresses from abstract to summary to main body, the level of detail increases, while maintaining a consistent message.

1. <u>Opinion Abstract</u>

The fundamental issues requested in the ToR for assessment must be clearly addressed in the abstract. Numerical estimates should be rounded and ranges given, from the assessment of overall uncertainty (i.e. including additional uncertainties). If this is expressed in the abstract as a verbal interpretation of the ranges from the assessment of overall uncertainty, then it is recommended to repeat the same phrase in the summary and main body of the opinion, in order to provide a clear link between the verbal expression and the quantitative assessment, as illustrated in Table 4. Comparisons and differences (or not) between scenarios should be provided. If the quantitative assessment is conditional on uncertainties that the assessors were unable to quantify, this should be clearly stated. If the word limit for the abstract permits, the unquantified uncertainties should be briefly described.

2. Summary

There is more space in the summary than in the abstract so assessors can go into more detail and be more precise regarding the figures on which ranges given in the abstract are based. Ranges given in the abstract should also be referred to in the summary, together with median values if appropriate. If there are several pathways and scenarios being assessed it may be appropriate to provide a table showing the ranges for the results for each step in each scenario. Primary place should be given to results including overall uncertainty. If model results are included, then any differences between these and the final conclusions due to consideration of additional uncertainties should be briefly summarised. If any uncertainties were considered unquantifiable, they should be listed and it should be stated clearly that the quantitative results are conditional on them.

3. Main body of opinion

The graphs (probability density and / or descending cumulative probability) should appear in the main body and be appropriately annotated to draw attention to key parts of each graph to help readers interpret the information provided by such graphs. The ranges used in the abstract and summary should also appear, allowing readers to see how key results appear in each section of the opinion.

Pie charts illustrating the sub-steps and /or steps providing the greatest uncertainty in the overall assessment should also appear in the main body of the opinion, together with other relevant outputs from the bespoke software supporting the probabilistic assessment

Table 4: Summary highlighting the appropriate and relevant style of communication of results to use in sections of a risk assessment

Section	What to communicate	Example	Comparison between scenarios
Abstract	verbal interpretation of ranges from the assessment of overall uncertainty	several tens up to a couple of hundred	*Three to four times more*
	if any uncertainties were unquantified, state that the result is conditional on them	…however, this assessment is conditional on assumptions about some uncertainties that could not be quantified	
Summary	verbal interpretation of ranges from the assessment of overall uncertainty	several tens up to a couple of hundred	*Three to four times more*
	Numbers on which verbal interpretation is based (median and 95% range)	median 125 , 95% probability range 70 – 200 (e.g. table in Appendix with all relevant quantiles, see section 3.9.3 above)	?

	if any uncertainties were unquantified, state that the result is conditional on them	…however, this assessment is conditional on assumptions about the following uncertainties, which could not be quantified: [insert list]	
Main body	verbal interpretation of ranges from the assessment of overall uncertainty	several tens up to a couple of hundred	*Three to four times more*
	Numbers on which verbal interpretation is based (median and 95% range)	median 125 , 95% probability range 70 – 200 (e.g. table in Appendix with all relevant quantiles, see section 3.9.3 above)	?
	Charts and numerical results from modelling	From the @risk tools (charts)	
	List of additional uncertainties not quantified within the model		
	Summary of overall uncertainty assessment		
	Detailed description of any quantified uncertainties and the conditionalities/assumptions, made about them in the quantitative assessment		
Appendices and/or Annexes	Case by case		

4. Conclusions

The EFSA PLH Panel developed a two phase framework for the assessment of risk from plant pests that potentially threaten the territory of the EU. The framework aligns with international phytosanitary standards and takes into account broader risk assessment guidance developed by the EFSA Scientific Committee.

This Guidance focusses on how to implement the second phase of the framework, the process of pest risk assessment. For completeness a template for phase one, pest categorisation, the process to determine whether an organism has the characteristics of a regulated pest, is provided as an Annex.

The Guidance provides a framework built upon agreed principles of pest risk assessment and includes flexibility allowing assessors to design conceptual and formal models at appropriate levels of sophistication and resolution to suit the needs of each assessment. The development of the Guidance benefited from eight trial pilot case studies that applied the principles on which the guidance for phase two was built. The Guidance proposed by the EFSA Panel on Plant Health provides a means to produce a fit for purpose assessment of pest risk that expresses risk and uncertainty in quantitative terms as far as is scientifically achievable. It seeks to avoid the use of ambiguous expressions of risk to clearly inform risk managers' decision making. Depending on the exact nature of the assessment request, outputs will inform risk managers of the nature and potential magnitude of pest entry, establishment, spread and impact, and the effectiveness of risk management options at agreed relevant temporal and spatial scales.

As with all EFSA guidance, this Guidance should be regularly reviewed (EFSA Scientific Committee, 2015) to take into account the experiences of the EFSA Plant Health Panel and the needs of those requesting pest risk assessments.

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Glossary and Abbreviations

Glossary of terms

In addition to the terms already defined in ISPM 5 (FAO, 2017), it is necessary to clearly define other terms used in this Guidance:

Abundance	
Baseline scenario	The Risk Assessment Scenario representing the current situation, prolonged for a specified time horizon, including all active pathways and currently implemented phytosanitary regulations (including Council Directive 2000/29/EC, Emergency measures, Control Directives, Marketing Directives, etc.) The complexity of the scenario design might vary depending on whether the phytosanitary measures could be specifically implemented for the pest being assessed or whether the phytosanitary measures could also affect one or more other regulated pests not being assessed.
Conceptual model	
Control measures	
Dependence	Dependence is often found between variables, e.g. height and body weight. Dependence also occurs between uncertain parameters, in cases where obtaining more information about one parameter would change one's uncertainty about others. It is important to take account of such dependencies when combining uncertain parameters in a calculation, because they may substantially alter the uncertainty of the calculation result. See section 5.3 of the EFSA uncertainty Guidance for further information (EFSA Scientific Committee, 2018a).
Effectiveness	The degree to which something is successful in producing a desired result; success. (Online Oxford dictionary, https://en.oxforddictionaries.com). The effectiveness of an RRO combination corresponds to measurement of the reduction of the level of risk, or of the likelihood or of the specific risk assessment unit.
Formal model	
Measures	Control (of a pest) is defined in ISPM 5 as "Suppression, containment or eradication of a pest population (FAO, 2010)". Control measures are measures that have a direct effect on pest abundance. Supporting measures are organisational measures or procedures supporting the choice of appropriate RROs that do not directly affect pest abundance.
Model	
Phytosanitary measures (PMs)	Any legislation, regulation or official procedure having the purpose to prevent the introduction or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests (FAO, 2017, ISPM 5)
Prevalence	Prevalence is a general term expressing how frequently something occurs. Prevalence is usually quantified in terms of density (abundance), but in the context of prevalence of pest in a trade, it may also be thought of in terms of the proportion of units of the product that carry the pest.
Probability	Defined depending on philosophical perspective: 1) the frequency with which samples arise within a specified range or for a specified category; 2) quantification of uncertainty as degree of belief regarding the likelihood of a particular range or category. The latter definition applies to the probabilities used in this document. Probabilities are often expressed as proportions but in this document

	are expressed as percentages.
Quantile	Quantiles are values that divide the range of a probability distribution into contiguous intervals with equal probabilities. There is one less quantile than the number of intervals created. Thus quartiles are the three cut points that will divide a distribution into four equal-size intervals, each with a probability of 25%.
Risk reduction options (RROs)	RROs are measures acting on pest introduction and/or pest spread and/or the magnitude of the biological impact of the pest should the pest be present. A RRO may become (or not) a phytosanitary measure, action or procedure according to the decision of the risk manager.
Risk reduction option (RRO)	A measure acting on pest introduction and/or pest spread and/or the magnitude of the biological impact of the pest should the pest be present. A RRO may become (or not) a phytosanitary measure, action or procedure according to the decision of the risk manager (Jeger et al., 2012)
Risk Reduction Option Combination (RRO Combination)	a set of complementary risk reduction options (Control measures and Supporting measures) applied in one risk assessment sub-step to reduce the risks posed by the pest.
Risk Reduction Option Scenario (RRO Scenario)	The description of the complete sequence of RRO combinations for all sub-steps of the risk assessment reducing the overall risk posed by the pest.
Eradication	Application of phytosanitary measures to eliminate a pest from an area [FAO, 1990; revised FAO, 1995; formerly "eradicate"] (ISPM 5, FAO, 2017) ISPM 09 provides Guidelines for pest eradication programmes
	Application of phytosanitary measures in and around an infested area to prevent spread of a pest [FAO, 1995] (ISPM 5)
Low pest prevalence	22 provides requirements for the establishment of areas of low pest prevalence
Protected zones	A protected zone is the denomination of a Pest Free Area within the EU territory.
Pest Free Area	An area in which a specific pest is absent as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained [ISPM 2, 1995; revised CPM, 2015] (ISPM 5, FAO, 2017)
Pest Free Place of Production	Place of production in which a specific pest is absent as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained for a defined period [ISPM 10, 1999; revised CPM, 2015] (ISPM 5, FAO, 2017) ISPM 10 indicates the requirements for the establishment of pest free places of production and pest free production sites
Pest Free Production Site	A production site in which a specific pest is absent, as demonstrated by scientific evidence, and in which, where appropriate, this condition is being officially maintained for a defined period [ISPM 10, 1999; revised CPM, 2015] (ISPM 5, FAO, 2017) ISPM 10 (FAO, 1999) indicates the requirements for the establishment of pest free places of production and pest free production sites
Uncertainty	In this document, as in the guidance on uncertainty (EFSA, 2018a), uncertainty is used as a general term referring to all types of limitations in available knowledge that affect the range and probability of possible answers to an assessment question. Available knowledge refers here to the knowledge (evidence, data, etc.) available to assessors at the time the assessment is conducted and within the time and resources agreed for the assessment. Sometimes 'uncertainty' is used to refer to a source of uncertainty, and

	sometimes to its impact on the outcome of an assessment.
Uncertainty distribution	Technically, a mathematical function that relates probabilities with specified intervals of a continuous quantity or values of a discrete quantity (EFSA, 2016). Distributions are used in this document to quantify the uncertainty of model parameters and outputs.

Abbreviations

EC	European Commission
EFSA	European Food Safety Authority
EKE	Expert knowledge elicitation
EPPO	European and Mediterranean Plant Protection Organization
EU	European Union
IPPC	International Plant Protection Convention
ISPM	International Standards for Phytosanitary Measures
MS	Member State
NPPO	National Plant Protection Organisation
NUTS	Nomenclature of territorial units for statistics
PAFF	EU Standing Committee of Plants, Animals, Food and Feed
PFA	Pest Free Area
PFC	Pest free consignment
PFPP	Pest Free Place of Production
RRO	Risk reduction option
ToR	Terms of Reference

Appendix A – Pest categorisation template

Pest categorisation of *X.y.*

EFSA Panel on Plant Health (PLH),
Michael Jeger, Claude Bragard, David Caffier, Thierry Candresse, Elisavet Chatzivassiliou, Katharina Dehnen-Schmutz, Gianni Gilioli, Jean-Claude Grégoire, Josep Anton Jaques Miret, Alan MacLeod, Maria Navajas Navarro, Björn Niere, Stephen Parnell, Roel Potting, Trond Rafoss, Vittorio Rossi, Gregor Urek, Ariena Van Bruggen, Wopke Van der Werf, Jonathan West, Stephan Winter, [WG members in alphabetical order by surname], [EFSA staff members in alphabetical order by surname], [trainees in alphabetical order by surname] and [WG chair]

Abstract

(Max. 300 words, no paragraph breaks; no tables, footnotes, graphs or figures. Note that the abstract should end with the copyright)

Keywords: European Union, pest risk, plant health, plant pest, quarantine

Requestor: European Commission

Question number: EFSA-Q-YYYY-NNNNN

Correspondence: alpha@efsa.europa.eu

Panel [or Scientific Committee] members: Claude Bragard, David Caffier, Thierry Candresse, Elisavet Chatzivassiliou, Katharina Dehnen-Schmutz, Gianni Gilioli, Jean-Claude Grégoire, Josep Anton Jaques Miret, Michael Jeger, Alan MacLeod, Maria Navajas Navarro, Björn Niere, Stephen Parnell, Roel Potting, Trond Rafoss, Vittorio Rossi, Gregor Urek, Ariena Van Bruggen, Wopke Van der Werf, Jonathan West and Stephan Winter.

Minority opinion: In case of a minority opinion, please add: [Part of this/This] scientific output is not shared by the following member(s) of the Panel: [add names in the format Name Surname, Name Surname and Name Surname].

Competing interests: In case of identified conflict(s) of interest, please add: In line with EFSA's policy on declarations of interest, Panel member(s) [add names in the format Name Surname, Name Surname and Name Surname] did not participate in the development and adoption of this scientific output.

Acknowledgements: The [Panel or Scientific Committee or EFSA] wishes to thank the following for the support provided to this scientific output: [staff members or others who made a contribution but are not eligible as authors]. The Panel [Panel/Scientific Committee/EFSA] wishes to acknowledge all European competent institutions, Member State bodies and other organisations that provided data for this scientific output.

Amendment: In case of amendment, please add: An editorial correction was carried out that does not materially affect the contents or outcome of this scientific output. To avoid confusion, the older version has been removed from the EFSA Journal, but is available on request, as is a version showing all the changes made.

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Suggested citation: [EFSA ACRONYM Panel (EFSA Panel name)] [or EFSA (European Food Safety Authority)] [or EFSA Scientific Committee], [add individual author names in the same order as it is on the first page, followed by a comma, in the format: Surname Initial(s), Surname Initial(s) and Surname Initial(s)], 20YY. [Full title, including output category]. EFSA Journal 20YY;volume(issue):NNNN, 20 pp. doi:10.2903/j.efsa.20YY.NNNN

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Table of contents

1. Introduction

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

1.1.1. Background

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

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

1.1.2. Terms of reference

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

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

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

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

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

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

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

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

1.1.2.1. Terms of Reference: Appendix 1

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

Annex IIAI

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

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

(b) Bacteria

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

(c) Fungi

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

(d) Virus and virus-like organisms

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

Annex IIB

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

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

(b) Bacteria

Curtobacterium flaccumfaciens pv. flaccumfaciens (Hedges) Collins and Jones

(c) Fungi

Glomerella gossypii Edgerton

Gremmeniella abietina (Lag.) Morelet

Hypoxylon mammatum (Wahl.) J. Miller

1.1.2.2. Terms of Reference: Appendix 2

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

Annex IAI

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

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

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

Group of Tephritidae (non-EU) such as:

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

(c) Viruses and virus-like organisms

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

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

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

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

Annex IIAI

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

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

1) *Margarodes vitis* (Phillipi)
2) *Margarodes vredendalensis* de Klerk
3) *Margarodes prieskaensis* Jakubski

1.1.2.3. Terms of Reference: Appendix 3

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

Annex IAI

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

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

(b) Fungi

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

(c) Viruses and virus-like organisms

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

(d) Parasitic plants

Arceuthobium spp. (non-EU)

Annex IAII

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

Meloidogyne fallax Karssen
Popillia japonica Newman
Rhizoecus hibisci Kawai and Takagi

(b) Bacteria

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

(c) Fungi

Melampsora medusae Thümen

Synchytrium endobioticum (Schilbersky) Percival

<u>Annex I B</u>

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

Leptinotarsa decemlineata Say

Liriomyza bryoniae (Kaltenbach)

(b) Viruses and virus-like organisms

Beet necrotic yellow vein virus

1.2. Interpretation of the Terms of Reference

If needed, provide here information on how the ToR is interpreted, in particular concerning the interpretation of the term "non-European", if relevant for the species.

Xy is one of a number of pests listed in the Appendices to the Terms of Reference (ToR) to be subject to pest categorisation to determine whether it fulfils the criteria of a quarantine pest or those of a regulated non-quarantine pest for the area of the EU excluding Ceuta, Melilla and the outermost regions of Member States referred to in Article 355(1) of the Treaty on the Functioning of the European Union (TFEU), other than Madeira and the Azores.

Since *Xy* is regulated in the protected zones only, the scope of the categorisation is the territory of the protected zone (…), thus the criteria refer to the protected zone instead of the EU territory.

1.3. Additional information (if appropriate)

2. Data and Methodologies

2.1. Data

2.1.1. Literature search

If the literature on the pest is limited and a complete review of it was performed, modify the text below to indicate this.

A literature search on *Xy* was conducted at the beginning of the categorisation in the ISI Web of Science bibliographic database, using the scientific name of the pest as search term. Relevant papers were reviewed and further references and information were obtained from experts, as well as from citations within the references and grey literature.

2.1.2. Database search

Pest information, on host(s) and distribution, was retrieved from the European and Mediterranean Plan Protection Organization (EPPO) Global Database (EPPO, 2017) and relevant publications.

Data about the import of commodity types that could potentially provide a pathway for the pest to enter the EU and about the area of hosts grown in the EU were obtained from EUROSTAT (Statistical Office of the European Communities).

The Europhyt database was consulted for pest-specific notifications on interceptions and outbreaks. Europhyt is a web-based network run by the Directorate General for Health and Food Safety (DG SANTÉ) of the European Commission, and is a subproject of PHYSAN (Phyto-Sanitary Controls) specifically concerned with plant health information. The Europhyt database manages notifications of interceptions of plants or plant products that do not comply with EU legislation, as well as notifications of plant pests detected in the territory of the Member States (MS) and the phytosanitary measures taken to eradicate or avoid their spread.

If other databases were used, indicate here. If any of the databases listed above were not used, please delete the related text. If additional information from literature on distribution was used, please indicate here.

2.2. Methodologies

The Panel performed the pest categorisation for *Xy*, following guiding principles and steps presented in the EFSA guidance on the harmonised framework for pest risk assessment (EFSA PLH Panel, 2010) and as defined in the International Standard for Phytosanitary Measures No 11 (FAO, 2013) and No 21 (FAO, 2004).

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

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

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

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

Criterion of pest categorisation	Criterion in Regulation (EU) 2016/2031 regarding Union quarantine pest	Criterion in Regulation (EU) 2016/2031 regarding protected zone quarantine pest (articles 32-35)	Criterion in Regulation (EU) 2016/2031 regarding Union regulated non-quarantine pest
Identity of the pest (Section 3.1)	Is the identity of the pest established, or has it been shown to produce consistent symptoms and to be transmissible?	Is the identity of the pest established, or has it been shown to produce consistent symptoms and to be transmissible?	Is the identity of the pest established, or has it been shown to produce consistent symptoms and to be transmissible?
Absence/ presence of the pest in the EU territory (Section 3.2)	Is the pest present in the EU territory? If present, is the pest widely distributed within the EU? Describe the pest distribution briefly!	Is the pest present in the EU territory? If not, it cannot be a protected zone quarantine organism.	Is the pest present in the EU territory? If not, it cannot be a regulated non-quarantine pest. (A regulated non-quarantine pest must be present in the risk assessment area).

Criterion of pest categorisation	Criterion in Regulation (EU) 2016/2031 regarding Union quarantine pest	Criterion in Regulation (EU) 2016/2031 regarding protected zone quarantine pest (articles 32-35)	Criterion in Regulation (EU) 2016/2031 regarding Union regulated non-quarantine pest
Regulatory status (Section 3.3)	If the pest is present in the EU but not widely distributed in the risk assessment area, it should be under official control or expected to be under official control in the near future.	The protected zone system aligns with the pest free area system under the International Plant Protection Convention (IPPC). The pest satisfies the IPPC definition of a quarantine pest that is not present in the risk assessment area (i.e. protected zone).	Is the pest regulated as a quarantine pest? If currently regulated as a quarantine pest, are there grounds to consider its status could be revoked?
Pest potential for entry, establishment and spread in the EU territory (Section 3.4)	Is the pest able to enter into, become established in, and spread within, the EU territory? If yes, briefly list the pathways!	Is the pest able to enter into, become established in, and spread within, the protected zone areas? Is entry by natural spread from EU areas where the pest is present possible?	Is spread mainly via specific plants for planting, rather than via natural spread or via movement of plant products or other objects? Clearly state if plants for planting is the main pathway!
Potential for consequences in the EU territory (Section 3.5)	Would the pests' introduction have an economic or environmental impact on the EU territory?	Would the pests' introduction have an economic or environmental impact on the protected zone areas?	Does the presence of the pest on plants for planting have an economic impact, as regards the intended use of those plants for planting?
Available measures (Section 3.6)	Are there measures available to prevent the entry into, establishment within or spread of the pest within the EU such that the risk becomes mitigated?	Are there measures available to prevent the entry into, establishment within or spread of the pest within the protected zone areas such that the risk becomes mitigated? Is it possible to eradicate the pest in a restricted area within 24 months (or a period longer than 24 months where the biology of the organism so justifies) after the presence of the pest was confirmed in the protected zone?	Are there measures available to prevent pest presence on plants for planting such that the risk becomes mitigated?

Criterion of pest categorisation	Criterion in Regulation (EU) 2016/2031 regarding Union quarantine pest	Criterion in Regulation (EU) 2016/2031 regarding protected zone quarantine pest (articles 32-35)	Criterion in Regulation (EU) 2016/2031 regarding Union regulated non-quarantine pest
Conclusion of pest categorisation (Section 4)	A statement as to whether (1) all criteria assessed by EFSA above for consideration as a potential quarantine pest were met and (2) if not, which one(s) were not met.	A statement as to whether (1) all criteria assessed by EFSA above for consideration as potential protected zone quarantine pest were met, and (2) if not, which one(s) were not met.	A statement as to whether (1) all criteria assessed by EFSA above for consideration as a potential regulated non-quarantine pest were met, and (2) if not, which one(s) were not met.

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

3. Pest categorisation

3.1. Identity and biology of the pest

3.1.1. Identity and taxonomy

Is the identity of the pest established, or has it been shown to produce consistent symptoms and to be transmissible? (Yes or No)

Xy is a insect/mite/nematode/virus/bacteria/phytoplasma/fungus/plant of the family xxxxxx.

Provide justification in case the answer is negative.

3.1.2. Biology of the pest

Summarise the key biological features influencing the risk assessment. Stay concise!

- *For fungi/bacteria address here disease cycle, living stages, infection mechanisms, incubation period, and survival parameters.*
- *For insects, mites and nematodes life cycle and the key elements of the life history strategies (development, survival, reproduction, feeding and dispersal) can be described mentioning also the ecological requirements of the organisms.*
- *For viruses and vectored diseases present in broad terms the epidemiology, transmission mechanisms including the list of the vectors.*

3.1.3. Intraspecific diversity

Intraspecific diversity (lower than taxonomical species), when of particular interest for e.g. virulence, pesticide resistance, invasiveness, etc. can be described here.

3.1.4. Detection and identification of the pest

Sources: Literature, EPPO standards and/or others (e.g PERSEUS)

Are detection and identification methods available for the pest?

List key reference(s)!

Provide justification in case the answer is negative.

3.2. Pest distribution

3.2.1. Pest distribution outside the EU

Source: EPPO GD.

If other sources were used, indicate it!

Figure 1: Global distribution map for *Xy* (extracted from the EPPO Global Database accessed on …….).

3.2.2. Pest distribution in the EU

Source: EPPO GD.

If other sources were used, indicate!

Is the pest present in the EU territory? If present, is the pest widely distributed within the EU?

If the pest is not present in the EU territory, it cannot be a RNQP. An RNQP must be present in the risk assessment area.

Table 2: Current distribution of *Xy* in the 28 EU MS based on information from the EPPO Global Database and other sources if relevant

Country	EPPO Global Database Last update: Date accessed:	Other sources
Austria		
Belgium		
Bulgaria		
Croatia		
Cyprus		
Czech Republic		
Denmark		
Estonia		
Finland		
France		
Germany		
Greece		
Hungary		
Ireland		
Italy		

Country	EPPO Global Database Last update: Date accessed:	Other sources
Latvia		
Lithuania		
Luxembourg		
Malta		
Netherlands		
Poland		
Portugal		
Romania		
Slovak Republic		
Slovenia		
Spain		
Sweden		
United Kingdom		

3.3. Regulatory status

Sources: 2000/29/EC (+ emergency measures when applicable)

This section only transcribes the relevant content from legislation without discussing and analysing.

3.3.1. Council Directive 2000/29/EC

Xy is listed in Council Directive 2000/29/EC. Details are presented in Tables 3 and 4.

Table 3: *Xy* in Council Directive 2000/29/EC

Annex II, Part A		
Section II		
(a)	Insects, mites and nematodes, at all stages of their development	
	Species	Subject of contamination
5.		

3.3.2. Legislation addressing the hosts of *xy*

Annex I pests: if the pest has a single host or a restricted host range, fill in Table 4 with the relevant legislation on the host(s). If the pest is highly polyphagous, delete the section and the table as it becomes irrelevant.

Annex II pests: fill in Table 4 with the relevant legislation concerning the regulated hosts mentioned in Table 3.

Table 4: Regulated hosts and commodities that may involve *Xy* in Annexes III, IV and V of Council Directive 2000/29/EC

Annex III, Part A	**Plants, plant products and other objects the introduction of which shall be prohibited in all Member States**	
	Description	Country of origin

Annex IV, Part B	**Special requirements which shall be laid down by all member states for the introduction and movement of plants, plant products and other objects into and within certain protected zones**	
	Plants, plant products and other objects	Special requirements	Protected zone(s)

Annex V	**Plants, plant products and other objects which must be subject to a plant health inspection (at the place of production if originating in the Community, before being moved within the Community—in the country of origin or the consignor country, if originating outside the Community) before being permitted to enter the Community**
Part A	Plants, plant products and other objects originating in the Community
Section II	Plants, plant products and other objects produced by producers whose production and sale is authorised to persons professionally engaged in plant production, other than those plants, plant products and other objects which are prepared and ready for sale to the final consumer, and for which it is ensured by the responsible official bodies of the Member States, that the production thereof is clearly separate from that of other products

3.3.3. Legislation addressing the organisms vectored by *Xy* (Directive 2000/29/EC)

Remove if not relevant!

3.4. Entry, establishment and spread in the EU

3.4.1. Host range

Sources: literature (use EPPO GD and CABI as starting point for the collection of evidence)

Indicate whether the hosts and/or commodities for which the pest is regulated are comprehensive of the host range. If not, list potential phytosanitary measures under section 3.6.1.

3.4.2. Entry

Is the pest able to enter into the EU territory? (Yes or No) If yes, identify and list the pathways!

Provide supporting evidence.

Information on interceptions can also be presented here.

Between (start date) and (search date) there were n records of interception of *Xy* in the Europhyt database.

List in bullet points the main pathways of entry without considering existing legislation. After listing the pathways, indicate if a pathway is closed due to existing legislation!

3.4.3. Establishment

Is the pest able to become established in the EU territory? (Yes or No)

3.4.3.1. EU distribution of main host plants

Sources: EUROSTAT and/or other sources (previous opinions, forestry JRC maps etc.)

3.4.3.2. Climatic conditions affecting establishment

Provide supporting evidence!

If you have answered YES, briefly describe the areas of the EU where the pest could establish.

Here the current distribution of the pest should be compared with the suitability of the environment in the eu; e.g. comparing hardiness/climate zones where the pest occurs with host distribution in the EU.

The purpose here is to document the availability of hosts. If a widely distributed host is identified, there is no need to describe the distribution of all the hosts of polyphagous pests.

Discuss also protected cultivation. Tables and figures on host plants from previous opinions can be used when available. (e.g JRC maps or maps from previous opinions).

3.4.4. Spread

3.4.4.1. Vectors and their distribution in the EU (if applicable)

Is the pest able to spread within the EU territory following establishment? (Yes or No) How? *RNQPs: Is spread mainly via specific plants for planting, rather than via natural spread or via movement of plant products or other objects?*

Sources: EPPO GD; CABI, Fauna Europaea and/or Literature

Present the geographical distribution of the vectors in the EU!
The purpose here is to document the availability of vectors. If a widely distributed vector is identified, there is no need to describe the distribution of all the vectors.

This section should briefly address in general terms spread mechanisms (natural spread and human assisted), spread pattern (short vs long distance spread) and spread rate.

Indicate if plants for planting are main means of spread of the pest. For a pest to be a RNQP its main means of spread must be via plants for planting.

It can be for many pests a very short section (e.g for a pest that has already been shown to spread throughout Europe very fast in few years, e.g. Dryocosmus, Tuta absoluta, Rhyncophorus ferrugineus etc.)

3.5. Impacts

Sources: impact reports and other literature

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

RNQPs: Does the presence of the pest on plants for planting have an economic impact, as regards the intended use of those plants for planting?[4]

If the pest is present in the EU, focus on impacts in the EU, but briefly refer to impacts in third countries to give a more complete overview of impacts if necessary. Remain concise.

If the pest is not present in the EU, describe impacts outside the EU especially where environmental conditions are similar to those in the EU so as to indicate the potential impacts in the EU if the pest entered and established.

If impact is well documented on an important host, there is no need to describe the impact on other hosts. Briefly describe symptoms, yield and quality losses. Information on environmental consequences is to be added only if there is no likelihood of crop impact, because impact on crops is sufficient information to satisfy the criterion for consequences. If it is not reasonable to expect crop impacts (e.g. pest is a non-crop plant pest), then do consider whether environmental impact is recorded. Indirect pest effects on trade, society are excluded from this section, because they are outside the current remit of the EFSA PLH Panel.

Also, please briefly list here the pathogens (e.g. viruses or bacteria) transmitted by the pest and their significance (indirect impact).

3.6. Availability and limits of mitigation measures

Are there measures available to prevent the entry into, establishment within or spread of the pest within the EU such that the risk becomes mitigated? *RNQPs: Are there measures available to prevent pest presence on plants for planting such that the risk becomes mitigated?*

3.6.1. Phytosanitary measures

Referring back to existing phytosanitary measures (see section 3.3.2.), are there additional phytosanitary measures available (e.g. for other hosts or pathways)? If so, . For definitions on phytosanitary measures, please consult the Guidance of the EFSA PLH Panel on quantitative pest risk assessment (xxxx).

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

Appropriate only for organisms which fulfil the other criteria (see sections 3.1.–3.6. above) for Union quarantine pests.

List briefly - as bullet points - the key elements limiting the effectiveness of the quarantine regulation (e.g. asymptomatic phase, dormant stage, lack of rapid diagnostic, rapid and long distance dispersal etc.)

3.6.1.2. Biological or technical factors limiting the ability to prevent the presence of the pest on plants for planting

Appropriate only for organisms which fulfil the other criteria (see sections 3.1.-3.6. above) for regulated Union RNQPs.

List briefly - as bullet points - the key elements limiting the ability to produce healthy plants for planting (e.g. asymptomatic phase, lack of efficient diagnostic, rapid and long distance dispersal etc.)

[4] See section 2.1 on what falls outside EFSA's remit.

3.6.2. Pest control methods

List briefly - as bullet points - cultural practices and control methods currently used with success to reduce the spread and the impact of the pest (do not list experimental findings).

3.7. Uncertainty

List the main sources of uncertainty only when they may affect the pest categorisation conclusions. If uncertainty does not affect the categorisation conclusions, explain why.

4. Conclusions

In order for the risk manager to decide the listing of the pests, a statement as to whether the criteria required to satisfy the definition of a Union quarantine pest or a Union RNQP have been fulfilled should be stated clearly, indicating the associated uncertainty.

e.g.:

D. micans meets the criteria assessed by EFSA for consideration as a potential protected zone quarantine pest for the territory of the protected zones: Greece, Ireland and the United Kingdom (Northern Ireland, Isle of Man and Jersey).

Table 5: The Panel's conclusions on the pest categorisation criteria defined in Regulation (EU) 2016/2031 on protective measures against pests of plants (the number of the relevant sections of the pest categorisation is shown in brackets in the first column)

Criterion of pest categorisation	**Panel's conclusions against criterion in Regulation (EU) 2016/2031 regarding Union quarantine pest**	**Panel's conclusions against criterion in Regulation (EU) 2016/2031 regarding protected zone quarantine pest (articles 32-35)**	**Panel's conclusions against criterion in Regulation (EU) 2016/2031 regarding Union regulated non-quarantine pest**	**Key uncertainties**
Identity of the pest (section 3.1)	Is the identity of the pest established, or has it been shown to produce consistent symptoms and to be transmissible?	Is the identity of the pest established, or has it been shown to produce consistent symptoms and to be transmissible?	Is the identity of the pest established, or has it been shown to produce consistent symptoms and to be transmissible?	
Absence/presence of the pest in the EU territory (section 3.2)	Is the pest present in the EU territory? If present, is the pest widely distributed within the EU? Describe the pest distribution briefly!	Is the pest present in the EU territory? If not, it cannot be a protected zone quarantine organism.	Is the pest present in the EU territory? If not, it cannot be a regulated non-quarantine pes. (A regulated non-quarantine pes must be present in the risk assessment area).	
Regulatory status (section 3.3)	If the pest is present in the EU but not widely distributed in the risk assessment area, it should be under official control or expected to be under official control in the near future.	The protected zone system aligns with the pest free area system under the International Plant Protection Convention (IPPC). The pest satisfies the IPPC definition of a quarantine pest that is not present in the risk assessment area (i.e. protected zone).	Is the pest regulated as a quarantine pest? If currently regulated as a quarantine pest, are there grounds to consider its status could be revoked?	
Pest potential for entry, establishment and spread in the EU territory (section 3.4)	Is the pest able to enter into, become established in, and spread within, the EU territory? If yes, briefly list the pathways!	Is the pest able to enter into, become established in, and spread within, the protected zone areas? Is entry by natural spread from EU areas where the pest is present possible?	Is spread mainly via specific plants for planting, rather than via natural spread or via movement of plant products or other objects? Clearly state if plants for planting is the main pathway!	
Potential for consequences in the EU territory (section 3.5)	Would the pests' introduction have an economic or environmental impact on the EU territory?	Would the pests' introduction have an economic or environmental impact on the protected zone areas?	Does the presence of the pest on plants for planting have an economic impact, as regards the intended use of those plants for planting?	

Criterion of pest categorisation	Panel's conclusions against criterion in Regulation (EU) 2016/2031 regarding Union quarantine pest	Panel's conclusions against criterion in Regulation (EU) 2016/2031 regarding protected zone quarantine pest (articles 32-35)	Panel's conclusions against criterion in Regulation (EU) 2016/2031 regarding Union regulated non-quarantine pest	Key uncertainties
Available measures (section 3.6)	Are there measures available to prevent the entry into, establishment within or spread of the pest within the EU such that the risk becomes mitigated?	Are there measures available to prevent the entry into, establishment within or spread of the pest within the protected zone areas such that the risk becomes mitigated? Is it possible to eradicate the pest in a restricted area within 24 months (or a period longer than 24 months where the biology of the organism so justifies) after the presence of the pest was confirmed in the protected zone?	Are there measures available to prevent pest presence on plants for planting such that the risk becomes mitigated?	
Conclusion on pest categorisation (section 4)	A statement as to whether (1) all criteria assessed by EFSA above for consideration as a potential quarantine pest were met and (2) if not, which one(s) were not met.	A statement as to whether (1) all criteria assessed by EFSA above for consideration as potential protected zone quarantine pest were met, and (2) if not, which one(s) were not met.	A statement as to whether (1) all criteria assessed by EFSA above for consideration as a potential regulated non-quarantine pest were met, and (2) if not, which one(s) were not met.	
Aspects of assessment to focus on / scenarios to address in future if appropriate				

References

Alderman G and Stranks MH, 1967. The iodine content of bulk herd milk in summer in relation to estimated dietary iodine intake of cows. Journal of the Science of Food and Agriculture, 18(4), 151–153.

EFSA PLH Panel (EFSA Panel on Plant Health), 2010. PLH Guidance on a harmonised framework for pest risk assessment and the identification and evaluation of pest risk management options by EFSA. EFSA Journal 2010;8(2):1495, 66 pp. doi:10.2903/j.efsa.2010.1495.

EPPO (European and Mediterranean Plant Protection Organization), online. EPPO Global Database. Available online: https://gd.eppo.int [Accessed Date]

FAO (Food and Agriculture Organization of the United Nations), 2004. ISPM (International Standards for Phytosanitary Measures) 21—Pest risk analysis of regulated non-quarantine pests. FAO, Rome, 30 pp. Available online: https://www.ippc.int/sites/default/files/documents//1323945746_ISPM_21_2004_En_2011-11-29_Refor.pdf

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Abbreviations

EPPO	European and Mediterranean Plant Protection Organization
FAO	Food and Agriculture Organization
IPPC	International Plant Protection Convention
MS	Member State
PLH	EFSA Panel on Plant Health
TFEU	Treaty on the Functioning of the European Union
ToR	Terms of Reference

Appendix B: Pest risk assessment template

Introduction to the template document

The template is an "empty shell" whose purpose is to provide a structure for compiling the risk assessment. By completing the template, risk assessors will step by step build the pest risk assessment. When the template is completely filled, the PRA is the result. Accordingly, the template has the same structure as a completed PRA. The following sections are present:

Abstract

The abstract is a very short extract of the main findings of the opinion (300 words). It should state the purpose of the PRA, the most important points addressed, the main findings and the conclusions.

Summary

The summary is 2-3 page extract of the opinion, detailing the main aspects of each part of the whole PRA.

1. Introduction

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

This section is prepared by literally citing the request by the European Commission/the requestor.

1.2. Interpretation of the Terms of Reference (if appropriate)

1.2.1. Pest categorisation

Refer here to the published Opinion of the Pest Categorisation of the assessed organism.

1.2.2. Interpretation of the Terms of Reference and recommendations

This section details how the panel has interpreted the terms of reference and elaborated the request from the commission in a feasible workflow for elaborating the PRA.

The formulation of the objectives necessary for the assessment can be done here, detailing the questions that should then be addressed by the literature review, data retrieval and modeling in line with the ToR.

1.3. Additional information (if appropriate)

In case it is necessary, additional information can be put here.

2. Data and Methodologies

2.1. Data

This section details methods for literature search and other data retrieval efforts, e.g. surveys of pest presence in EU member countries. Full details may be given. Appendices may be used if needed.

2.2. Methodologies

Some introductory text (e.g. reference to the Guidance of the EFSA PLH Panel on quantitative pest risk assessment, the Guidance on Uncertainty and case studies) can be given here. This section should explain the conceptual model for interpretation of the ToR. In case expert knowledge elicitation was used this should be explained here.

2.2.1. Specification of the scenarios

In this section, the different scenarios that have to be assessed to address properly the ToR are described.

2.2.2. Definitions for the scenarios

To define the scenarios to be assessed, the information requested in the following sections (2.2.2.1. to 2.2.2.6) need to be assembled.

2.2.2.1. Definition of the pathways

2.2.2.2. Definition of different units used

2.2.2.3. Definition of abundance of the pest

2.2.2.4. Potential RROs of the steps and identification of the RROs for the sub-steps

2.2.2.5. Ecological factors and conditions in the chosen scenarios

2.2.2.6. Temporal and spatial scales

2.2.3. Summary of the different scenarios

The different scenarios can be summarised here, e.g. in form of a table.

3. Assessment

3.1. Entry

3.1.1. Assessment of entry for the different scenarios

Here, the conceptual model and the formal model for the assessment of entry are presented and the results for the different scenarios are provided. Details (distributions, justifications) can be put in the appendix.

3.1.2. Uncertainties affecting the assessment of entry

Uncertainties quantified in the quantitative model (as parameter distributions) or in the conclusion of a first tier assessment (based on a simpler model or a weight of evidence approach), can be described/commented here. Furthermore, uncertainties that are not quantified within the model or weight of evidence process should be outlined. All these are referred to collectively here as 'additional uncertainties'.

3.1.3. Conclusion on the assessment of entry for the different scenarios

The conclusion should include the number of founder populations and summarise the uncertainties.

3.2. Establishment

3.2.1. Assessment of establishment for the different scenarios

Here, the conceptual model and the formal model for the assessment of establishment are presented and the results for the different (relevant) scenarios are provided. Details (distributions, justifications) can be put in the appendix.

3.2.2. Uncertainties affecting the assessment of establishment

Uncertainties quantified in the quantitative model (as parameter distributions) or in the conclusion of a first tier assessment (based on a simpler model or a weight of evidence approach), can be described/commented here. Furthermore, uncertainties that are not quantified within the model or weight of evidence process should be outlined. All these are referred to collectively here as 'additional uncertainties'.

3.2.3. Conclusions on establishment for the different scenarios including the area of potential establishment

The conclusion should include the number of established populations and summarise the uncertainties.

3.3. Spread

3.3.1. Assessment of spread for the different scenarios

Here, the conceptual model and the formal model for the assessment of spread are presented and the results for the different (relevant) scenarios are provided. Details (distributions, justifications) can be put in the appendix.

3.3.2. Uncertainties affecting the assessment of spread

Uncertainties quantified in the quantitative model (as parameter distributions) or in the conclusion of a first tier assessment (based on a simpler model or a weight of evidence approach), can be described/commented here. Furthermore, uncertainties that are not quantified within the model or weight of evidence process should be outlined. All these are referred to collectively here as 'additional uncertainties'.

3.3.3. Conclusions on Spread for the different scenarios

The conclusion should include a quantitative statement on the area or number of plants affected by the pest across the European territory, as a result of spread, either from newly established founder populations from entry, or from pockets of infestation of the pest if it is already present in Europe. and summarise the uncertainties.

3.4. Impact

3.4.1. Assessment of impact for the different scenarios

Here, the conceptual model and the formal model for the assessment of impact are presented and the results for the different (relevant) scenarios are provided. Details (distributions, justifications) can be put in the appendix.

3.4.2. Uncertainties affecting the assessment of impact

Uncertainties quantified in the quantitative model (as parameter distributions) or in the conclusion of a first tier assessment (based on a simpler model or a weight of evidence approach), can be described/commented here. Furthermore, uncertainties that are not quantified within the model or weight of evidence process should be outlined. All these are referred to collectively here as 'additional uncertainties'.

3.4.3. Conclusions on impact for the different scenarios

The conclusion should include a quantitative statement on the yield loss in agriculture and the pest's effect on ecosystem services and biodiversity across the European territory and summarise the uncertainties.

4. Conclusions

An overall conclusion of the pest risk assessment should be given.

The template is not prescriptive. Modifications may be made to suit the needs of a clear and logical presentation of the PRA.

Title of the output

[EFSA Panel name (acronym)] [or EFSA Scientific Committee] [or European Food Safety Authority (EFSA)],
Authors (format Name Surname) listed in the following order: [Panel chair], [Panel members in alphabetical order by surname], [WG members in alphabetical order by surname], [EFSA staff members in alphabetical order by surname], [trainees in alphabetical order by surname] and [WG chair]

Abstract

(Max. 300 words, no paragraph breaks; no tables, footnotes, graphs or figures. Note that the abstract should end with the copyright)

Keywords: (max. seven keywords)

Requestor: add requesting party

Question number: EFSA-Q-YYYY-NNNNN

Correspondence: alpha@efsa.europa.eu

Panel [or Scientific Committee] members: [add names in the format Name Surname, Name Surname and Name Surname].

Minority opinion: In case of a minority opinion, please add: [Part of this/This] scientific output is not shared by the following member(s) of the Panel: [add names in the format Name Surname, Name Surname and Name Surname].

Competing interests: In case of identified conflict(s) of interest, please add: In line with EFSA's policy on declarations of interest, Panel member(s) [add names in the format Name Surname, Name Surname and Name Surname] did not participate in the development and adoption of this scientific output.

Acknowledgements: The [Panel or Scientific Committee or EFSA] wishes to thank the following for the support provided to this scientific output: [staff members or others who made a contribution but are not eligible as authors]. The Panel [Panel/Scientific Committee/EFSA] wishes to acknowledge all European competent institutions, Member State bodies and other organisations that provided data for this scientific output.

Amendment: In case of amendment, please add: An editorial correction was carried out that does not materially affect the contents or outcome of this scientific output. To avoid confusion, the older version has been removed from the EFSA Journal, but is available on request, as is a version showing all the changes made.

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ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.

Summary

The summary should not include tables, footnotes, graphs or pictures or references.

A summary should reflect the full scope of the opinion. It should include:

- the requestor;
- the request and the questions;
- the methodologies and the data used;
- the assessment and its results (including uncertainty, if applicable);
- the main conclusions and, if appropriate, recommendations.

In case the summary does not contain any additional information compared to the abstract, it can be omitted.

Table of contents

5. Introduction

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

5.2. Interpretation of the Terms of Reference (if appropriate)

5.2.1. Pest categorisation

5.2.2. Interpretation of the Terms of Reference and recommendations

5.3. Additional information (if appropriate)

6. Data and Methodologies

6.1. Data

6.2. Methodologies

6.2.1. Specification of the scenarios

6.2.2. Definitions for the scenarios

6.2.2.1. Definition of the pathways

6.2.2.2. Definition of different units used

6.2.2.3. Definition of abundance of the pest

6.2.2.4. Potential RROs of the steps and identification of the RROs for the sub-steps

6.2.2.5. Ecological factors and conditions in the chosen scenarios

6.2.2.6. Temporal and spatial scales

6.2.3. Summary of the different scenarios

7. Assessment

7.1. Entry

7.1.1. Assessment of entry for the different scenarios

7.1.2. Uncertainties affecting the assessment of entry

7.1.3. Conclusion on the assessment of entry for the different scenarios

7.2. Establishment

7.2.1. Assessment of establishment for the different scenarios

7.2.2. Uncertainties affecting the assessment of establishment

7.2.3. Conclusions on establishment for the different scenarios including the area of potential establishment

7.3. Spread

7.3.1. Assessment of spread for the different scenarios

7.3.2. Uncertainties affecting the assessment of spread

7.3.3. Conclusions on Spread for the different scenarios

7.4. Impact

7.4.1. Assessment of impact for the different scenarios

7.4.2. Uncertainties affecting the assessment of impact

7.4.3. Conclusions on impact for the different scenarios

8. Conclusions

9. Recommendations (if appropriate)

Documentation provided to EFSA (if appropriate)

1. Dossier name. Month YYYY. Submitted by [name of the company]

References

Alderman G and Stranks MH, 1967. The iodine content of bulk herd milk in summer in relation to estimated dietary iodine intake of cows. Journal of the Science of Food and Agriculture, 18(4), 151–153.

Glossary [and/or] Abbreviations

Glossary: an alphabetical list of words relating to a specific subject with explanations; a brief dictionary.

Abbreviation: a shortened form of a word or phrase (such as Mr, Prof). It also includes acronyms (a group of initial letters used as an abbreviation for a name or expression, each letter being pronounced separately – such as DVD, FDA – or as a single word – such as EFSA, NATO).

XXX	Dsadsadsadsa
YYY	Sdsdsadsad
ZZZ	Fdsfsafasdf

Appendix A – Model formulation and formalisation

A.1. Notation

A.2. Model for Entry

A.2.1. Conceptual model for entry

A.2.2. Formal model for entry

A.3. Model for Establishment

A.3.1. Conceptual model for establishment

A.3.2. Formal model for establishment

A.4. Model for Spread

A.4.1. Conceptual model for spread

A.4.2. Formal model for spread

A.5. Model for Impact

A.5.1. Conceptual model for impact

A.5.2. Formal model for impact

Appendix B – Formal model and parameter estimates

B.1. Entry

B.1.1. Assessment of entry for the different scenarios

B.1.2. Conclusion on the assessment of entry for the different scenarios

B.2. Establishment

B.2.1. Assessment of establishment for the different scenarios

B.2.2. Conclusions on the assessment of establishment for the different scenarios

B.3. Spread

B.3.1. Assessment of spread for the different scenarios

B.3.2. Conclusions on the assessment of spread for the different scenarios

B.4. Impact

B.4.1. Assessment of impact for the different scenarios

B.4.2. Conclusions on the assessment of impact for the different scenarios

Appendix C - Inventory of risk reduction options

The Panel has identified a collection of risk reduction options (RROs) that embrace all types of phytosanitary measures that could be implemented for acting on a pest injurious to plants.

The measures are divided into two main categories:

i. the control measures that are measures that have a direct effect on pest abundance. Control (of a pest) is defined in ISPM 5 (FAO, 2017) as "Suppression, containment or eradication of a pest population (FAO, 1995)".
ii. the supporting measures that are organisational measures or procedures supporting the choice of appropriate RROs that do not directly affect pest abundance.

For each one of these RROs an information sheet information sheet was developed. In these documents, the Panel does not pretend providing a monography of the measures neither providing a full review of the measures. The aim of the RRO information sheets is to support and assist the risk assessor in the identification of potential measures under the different scenarios for risk assessment and to provide some key information to consider in the evaluation of effectiveness of measures. These documents should undergo a frequent adjustment and update when new data and information have been found by the Panel in the context of its risk assessments. The RRO information sheets are all articulated along the following sections:

i. Description of the RRO;
ii. Risk factors for consideration when implementing the measure;
iii. Parameters to consider regarding the effectiveness of the RRO;
iv. Limitations to the feasibility or applicability of the measure;
v. Combinations of measures that include this RRO;
vi. Conclusion with synoptic table
vii. The RRO information sheets are available at http://doi.org/10.5281/zenodo.1164805

Table 1: Inventory of RRO information sheets

N°	RRO Information sheet title	Brief description of the RRO
	CONTROL MEASURES	
1.01	Growing plants in isolation	Description of possible exclusion conditions that could be implemented to isolate the crop from pests and if applicable relevant vectors. E.g. a dedicated structure such as glass or plastic greenhouses.
1.02	Timing of planting and harvesting	The objective is to produce phenological asynchrony in pest/crop interactions by acting on or benefiting from specific cropping factors such as: cultivars, climatic conditions, timing of the sowing or planting, and level of maturity/age of the plant seasonal timing of planting and harvesting.
1.03	Chemical treatments on crops including reproductive material	Use of chemical compounds that may be applied to plant propagation material or to plants prior to planting and during the vegetation cycle.
1.04	Chemical treatments on consignments or during processing	Use of chemical compounds that may be applied to plants or to plant products after harvest, during process or packaging operations and storage. The treatments addressed in this information sheet are: a) fumigation; b) spraying/dipping pesticides; c) surface

		disinfectants; d) process additives; e) protective compounds
1.05	Cleaning and disinfection of facilities, tools and machinery	The physical and chemical cleaning and disinfection of facilities, tools, machinery, transport means, facilities and other accessories (e.g., boxes, pots, pallets, palox, supports, hand tools). The measures addressed in this information sheet are: washing, sweeping and fumigation.
1.06	Soil treatment	The control of soil organisms by chemical and physical methods listed below: a) Fumigation; b) Heating; c) Solarisation; d) Flooding; e) Soil suppression; f) Augmentative Biological control; g) Biofumigation
1.07	Use of non-contaminated water	Chemical and physical treatment of water to eliminate waterborne microorganisms. The measures addressed in this information sheet are: chemical treatments (e.g. chlorine, chlorine dioxide, ozone); physical treatments (e.g. membrane filters, ultraviolet radiation, heat); ecological treatments (e.g. slow sand filtration).
1.08	Physical treatments on consignments or during processing	This information sheet deals with the following categories of physical treatments: irradiation /ionisation; mechanical cleaning (brushing, washing); sorting and grading, and; removal of plant parts (e.g. debarking wood). This information sheet does not address: heat and cold treatment (information sheet 1.14); roguing and pruning (information sheet 1.12).
1.09	Controlled atmosphere	Treatment of plants by storage in a modified atmosphere (including modified humidity, O2, CO2, temperature, pressure).
1.10	Waste management	Treatment of the waste (deep burial, composting, incineration, chipping, production of bio-energy…) in authorized facilities and official restriction on the movement of waste.
1.11	Use of resistant and tolerant plant species/varieties	Resistant plants are used to restrict the growth and development of a specified pest and/ or the damage they cause when compared to susceptible plant varieties under similar environmental conditions and pest pressure. It is important to distinguish resistant from tolerant species/varieties.
1.12	Rogueing and pruning	Rogueing is defined as the removal of infested plants and/or uninfested host plants in a delimited area, whereas pruning is defined as the removal of infested plant parts only without affecting the viability of the plant.
1.13	Crop rotation, associations and density, weed/volunteer control	Crop rotation, associations and density, weed/volunteer control are used to prevent problems related to pests and are usually applied in various combinations to make the habitat less favourable for pests. The measures deal with (1) allocation of crops to field (over time and space) (multi-crop, diversity cropping) and (2) to control weeds and volunteers as hosts of pests/vectors.
1.14	Heat and cold treatments	Controlled temperature treatments aimed to kill or inactivate pests without causing any unacceptable prejudice to the treated material itself. The measures addressed in this information sheet are: autoclaving; steam; hot water; hot air; cold treatment
1.15	Conditions of transport 1.	Specific requirements for mode and timing of transport of commodities to prevent escape of the pest and/or contamination. a) physical protection of consignment b) timing of transport/trade

1.16	Biological control and behavioural manipulation	other pest control techniques not covered by 1.03 and 1.13 a) Biological control b) Sterile Insect Technique (SIT) c) Mating disruption d) Mass trapping
1.17	Post-entry quarantine and other restrictions of movement in the importing country	This information sheet covers post-entry quarantine (PEQ) of relevant commodities; temporal, spatial and end-use restrictions in the importing country for import of relevant commodities; Prohibition of import of relevant commodities into the domestic country. 'Relevant commodities' are plants, plant parts and other materials that may carry pests, either as infection, infestation, or contamination.
SUPPORTING MEASURES		
2.01	Inspection and trapping	Inspection is defined as the official visual examination of plants, plant products or other regulated articles to determine if pests are present or to determine compliance with phytosanitary regulations (ISPM 5, FAO, 2017). The effectiveness of sampling and subsequent inspection to detect pests may be enhanced by including trapping and luring techniques.
2.02	Laboratory testing	Examination, other than visual, to determine if pests are present using official diagnostic protocols. Diagnostic protocols describe the minimum requirements for reliable diagnosis of regulated pests.
2.03	Sampling	According to ISPM 31 (FAO, 2008), it is usually not feasible to inspect entire consignments, so phytosanitary inspection is performed mainly on samples obtained from a consignment. It is noted that the sampling concepts presented in this standard may also apply to other phytosanitary procedures, notably selection of units for testing. For inspection, testing and/or surveillance purposes the sample may be taken according to a statistically based or a non-statistical sampling methodology.
2.04	Phytosanitary certificate and plant passport	An official paper document or its official electronic equivalent, consistent with the model certificates of the IPPC, attesting that a consignment meets phytosanitary import requirements (ISPM 5, FAO, 2017) a) export certificate (import) b) plant passport (EU internal trade)
2.05	Certified and approved premises	Mandatory/voluntary certification/approval of premises is a process including a set of procedures and of actions implemented by producers, conditioners and traders contributing to ensure the phytosanitary compliance of consignments. It can be a part of a larger system maintained by the NPPO in order to guarantee the fulfilment of plant health requirements of plants and plant products intended for trade. Key property of certified or approved premises is the traceability of activities and tasks (and their components) inherent the pursued phytosanitary objective. Traceability aims to provide access to all trustful pieces of information that may help to prove the compliance of consignments with phytosanitary requirements of importing countries.
2.06	Certification of reproductive material (voluntary/official)	The reproductive material of several species can be commercialised in the EU only if submitted to a process of official certification under the responsibility of the competent public organisations of each Member State. This process

		guaranties the identity, health and quality of seeds and propagating material coming from internal production or from outside the EU before marketing. The certification is mandatory for the reproductive material (seed and propagating material) of the main crops (cereal, fodder plants, beet, oil and fibre plants, and potatoes), fruit plants, vegetables, vine, ornamental and forest plants.
2.07	Delimitation of Buffer zones	ISPM 5 (FAO, 2017) defines a buffer zone as "an area surrounding or adjacent to an area officially delimited for phytosanitary purposes in order to minimize the probability of spread of the target pest into or out of the delimited area, and subject to phytosanitary or other control measures, if appropriate" (ISPM 5). The objectives for delimiting a buffer zone can be to prevent spread from the outbreak area and to maintain a pest free production place (PFPP), site (PFPS) or area (PFA).
2.08	Surveillance	

Appendix D - Examples for pathways

Table 1: Examples for pathways (from EPPO Express PRA Scheme, see EPPO, 2012)

Examples of pathways are:	
Plants for planting	*Wood and wood products*
○ plants for planting (except seeds, bulbs and tubers) with or without soil attached	○ non-squared wood
○ bulbs or tubers	○ squared wood
○ seeds	○ bark
Plant parts and plant products	○ wood packaging material
○ cut flowers or branches	○ chips, firewood
○ cut trees	*Natural spread*
○ fruits or vegetables	*Other possible pathways*
○ grain	○ other packaging material
○ pollen	○ soil/growing medium as such
○ stored plant products	○ conveyance and machinery
	○ passengers
	○ hitchhiking
	○ plant waste
	○ manufactured plant products
	○ intentional introduction (e.g. scientific purposes)

Appendix E - Elaboration of a pathway model for entry (second tier)

Table 1: Variables involved in the entry model

Variable	Explanation	Sub-step
P_1	<u>Definition</u> Abundance (P is for population abundance) of the pest when leaving the place of production in the baseline scenario (A_0) in the country of origin. <u>Meaning/Example</u> E.g. nematode-infested potatoes per ton, proportion (%) of CBS-infected oranges in an orchard, proportion of thrips infested orchids in a box. <u>Value</u> To be estimated by the experts. <u>Units</u> Percentage of affected units or sub-units, or number of individuals per units or sub-units. To be operationalized by the risk assessor.	E_1
P_2	<u>Definition</u> Abundance of the pest when crossing the border of the exporting country. <u>Meaning/Example</u> See example for P_1. <u>Value</u> $P_2 = P_1 \times m_1 \times m_2 \times m_3$ <u>Units</u> Percentage of affected units or sub-units, or number of individuals per units or sub-units. To be operationalized by the risk assessor.	E_2
P_3	<u>Definition</u> 5.1.1. Abundance when arriving at the EU point of entry <u>Meaning/Example</u> See example for P_1 <u>Values</u> $P_3 = P_2 \times m_4$ <u>Units</u> Percentage of affected units or sub-units, or number of individuals per units or sub-units. To be operationalized by the risk assessor.	E_3
P_4	<u>Definition</u> 5.1.2. Abundance when leaving the EU point of entry. <u>Meaning/Examples</u> Here the abundance of the pest has to be assessed when leaving the EU point of entry. To calculate the abundance of the pest when leaving the point of entry, use the following formula, where P_4 is the pest abundance, and m_5 is the multiplication factor changing the abundance throughout the transition from sub-step E_3 to sub-step E_4. <u>Value</u> $P_4 = P_3 \times m_5$ <u>Units</u> Percentage of affected units or sub-units, or number of individuals per units	E_4

	or sub-units. To be operationalized by the risk assessor.	
N_0	<u>Definition</u> Number of pathway units potentially carrying the pest from the place of production in the country of origin to the risk assessment area per time unit in the different scenarios. <u>Meaning/Examples</u> Tons of seed potato per year, number of oranges per year, number of orchids (potted plants) per year. <u>Value</u> To be assessed by the experts. <u>Units</u> Units (tons, crates, numbers etc.) of product per year.	E_4
N_1	5.1.3. Definition Total number of new potential founder populations within the EU territory as a result of entry of the pest from third countries for the selected temporal and spatial scales. <u>Meaning/Examples</u> 10 new founder populations in the risk assessment area per year. <u>Value</u> $N_1 = P_4 \times N_0 \times m_6 \times m_7$ <u>Units</u> Number of transfers occurring per year in the EU	E_5
m_1	<u>Definition</u> Multiplication factor changing the abundance of the pest before leaving the place of production in the different scenarios (A_1, …, A_n). <u>Meaning/Examples</u> Proportion of the pest propagules that survive RROs applied before the product leaves the place of production. <u>Values</u> In A_0 this is not assessed and is therefore put equal to 1 in the calculation tool. In a scenario where additional measures are applied this factor could be ≤ 1. In a scenario where measures are removed this factor could be ≥ 1. <u>Units</u> Dimensionless	E_1
m_2	<u>Definition</u> Units conversion coefficient. It changes the units from the abundance of the pest when leaving the place of production to the pathway unit/sub-unit along the pathway (i.e. it changes the way in which pest propagules are defined). <u>Meaning/Examples</u> After the product leaves the place of production, it may be processed such that the original units of measurement of the pest are no longer applicable. For instance, when wood is converted into crates, the units of pest abundance change from pest propagules per unit of wood (#/kg) to pest propagules per crate. The multiplication factor m_2 ("unit conversion coefficient") accounts for this change of units of measurement. <u>Values</u>	E_1

	To be estimated by the experts. Units "New" propagule units per "old" propagule units, e.g. % of pine wood nematodes infested pellets per m^3 of wood infested by pine wood nematodes.	
m_3	Definition Multiplication factor changing the abundance from sub-step E_1 (after having left the place of production) to sub-step E_2 (before crossing the border of the export country) in the different scenarios, i.e. during transport in the country of origin. Meaning/Examples The abundance could remain the same and then the value is 1. It could also decrease (e.g. insects dying between E_1 and E_2) and then it would be < 1, or increase (e.g. due to fungal growth), and then it would be > 1. Values To be estimated by the experts. Units Dimensionless.	E_1
m_4	Definition Multiplication factor changing the abundance from sub-step E_2 (after having left the border of the export country) to sub-step E_3 (before arriving at the EU point of entry) in the different scenarios, i.e. during transport to the importing country. Meaning/Examples This could mean that the abundance decreases (e.g. insects dying between E_2 and E_3) or also increases (e.g. due to fungal growth). Values To be estimated by the experts. Units Dimensionless.	E_2
m_5	Definition Multiplication factor changing the abundance from sub-step E_3 (after arriving at the point of entry) to sub-step E_4 (before leaving the EU point of entry) in the different scenarios. Meaning/Examples It represents the proportion of pest propagules passing export inspection or surviving or escaping measures carried out to guarantee pest freedom. Due to the reliability and effectiveness of inspection measures at the point of entry, the proportion of pest propagules could be reduced and then it would be < 1. Values To be estimated by the experts. Units Dimensionless.	E_3
m_6	Definition Aggregation/disaggregation coefficient transforming the pathway units/sub-	E_4

	units into the transfer units in the different scenarios. Meaning/Examples 1 container of potted plants is regrouped into 10 boxes of potted plants sent to 10 nurseries. Values To be estimated by the experts. Units Dimensionless.	
m_7	Definition Multiplication factor changing the abundance from sub-step E_4 (after leaving the point of entry) to sub-step E_5 (transferring to the host) in the different scenarios. Meaning/Examples Average number of successful transfers of the pest obtained from a single affected transfer unit comes into contact with the host plant in the risk assessment area. For example, a bonsai plant affected by an Asian Longhorned beetle is a transfer unit. Each of these transfer units has the capacity to come in contact and transfer the pest to 0.01 host plants. 0.01 is the multiplication factor changing the abundance from sub-step E_4 to sub-step E_5. Values To be estimated by the experts. Units Dimensionless.	E_4

Appendix F - Examples of risk model implementation and calculation

The intention of providing examples is to explain the concepts and to indicate the competence and technical skills required. It is not the intention of this text to provide full technical instructions or serve as a tutorial.

Risk model implementation and calculation

The step from defining the conceptual risk model formula and implementing it into a risk model calculation software tool is a step requiring skills and experience on mathematical modelling and experience with the actual risk calculation tool chosen.

At the time of writing this guidance, the procedure for risk model implementation and calculation at EFSA is in a transition stage. Currently, the model implementation and risk calculation is performed in the tool @Risk™ which is a software add-in to Microsoft Excel™ spreadsheet. For future risk model implementation and calculation, EFSA is developing an online and web-based risk model calculation tool based on the open source software platform R (R Core Team, 2014).

The idea of the forthcoming tool is to allow the user to build the model and implement it through in a web browser interface (see Figure 1 and Figure 2). It is a key objective of the development of this tool to lower the barrier with respect to the technical skills required for model implementation and operation. Another advantage is that users of the tool would not need to have any specialized or commercial software requiring a licence to operate the tool. It must be noted that the development is still at the stage of work in progress, but the reason it is presented here is to introduce the reader to the ideas and principles applied. This appendix is not intended to be a textbook or a full tutorial, but rather serve as a minimum introduction for the risk assessor to the way of working and the challenges that will emerge and what type of decisions that needs to be taken e.g. model forming; uncertainty distribution fitting and selection of simulation approach.

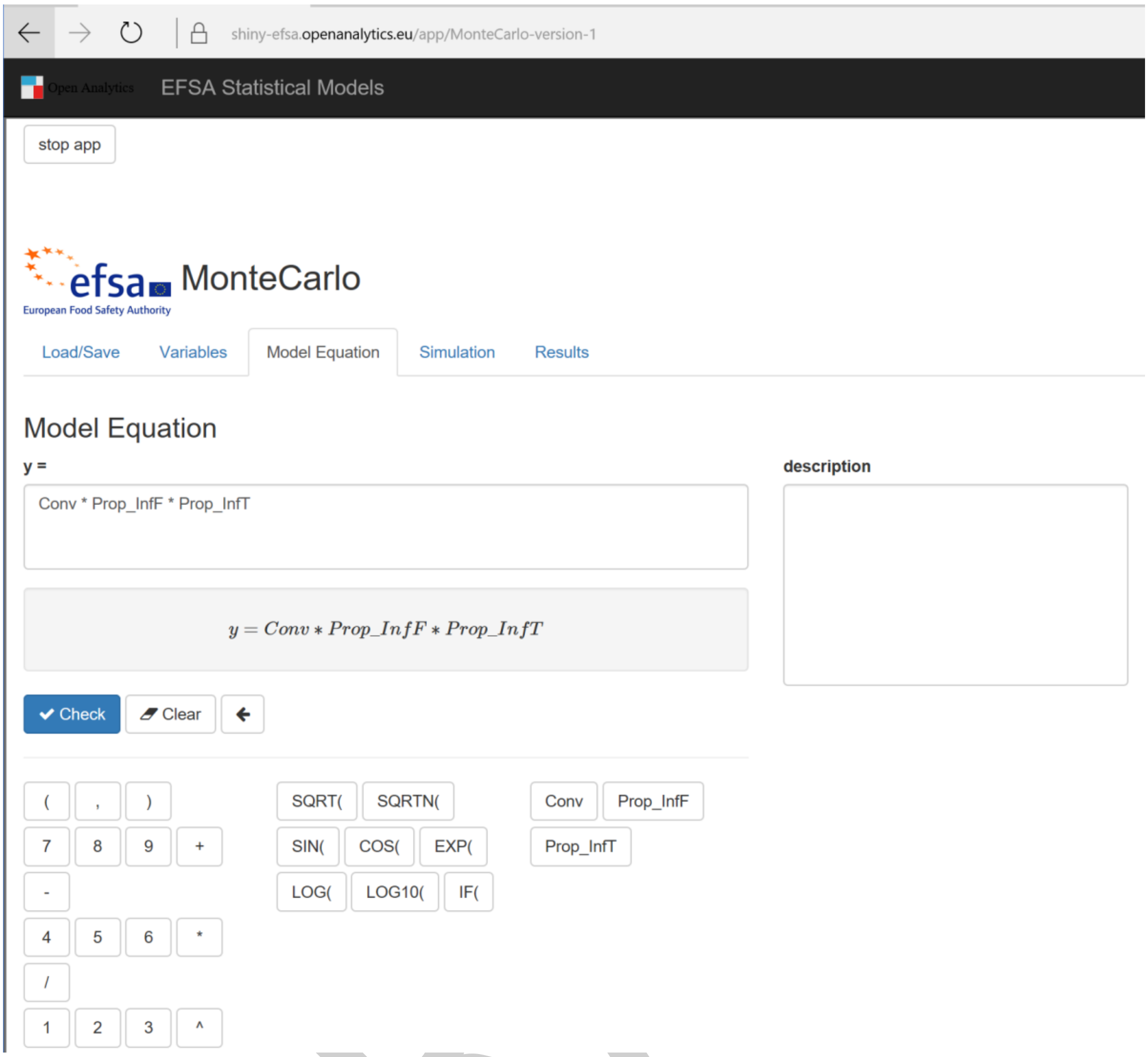

Figure 1: Example on model definition in the forthcoming risk model calculation tool at EFSA

Furthermore, it is a key idea that the web-calculation tools should facilitate transparency and allow readers to actually repeat the risk calculations on their own. In line with the EFSA policy of transparency, the risk model implementation and calculation procedure will be published as supplementary material along with the Panel Opinion.

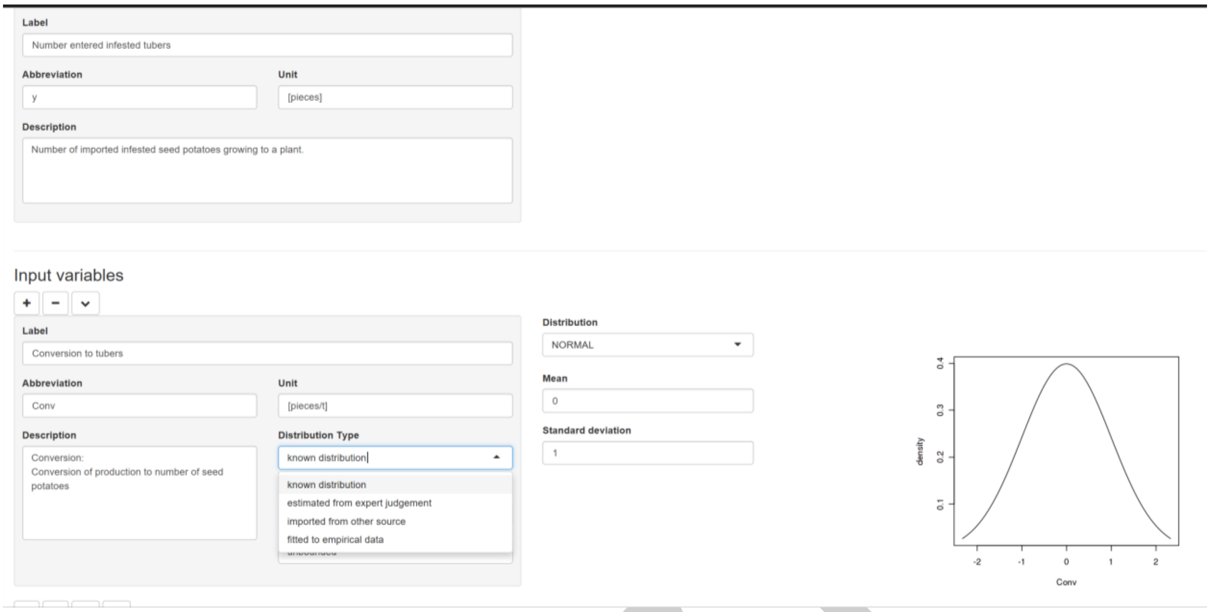

Figure 2: Model quantities (variables) definition interface

Although EFSA is not going to use the @Risk™ add-in for Microsoft Excel spreadsheet software as the future risk model implementation and calculation platform, it is still being used, as long as the new tool is not ready. Therefore, the examples provided here are based on the current practice of using @Risk™, both for risk model implementation and calculation, as well as uncertainty propagation through the risk model.

Estimation of uncertain quantities

<u>Introduction</u>

In this exercise you will assess and make an estimate of a quantity and its associated uncertainty, given the available evidence, for the following quantities of the risk assessment for *Phyllosticta citricarpa* the cause of citrus black spot disease (CBS) (EFSA PLH Panel, 2014a).

Uncertainty in the model quantities is described using probability distributions. The uncertainty is propagated through the model by use of Monte Carlo simulation

Learning outcomes of this exercise

1. How to use the concept of mathematical probability and probability distributions to describe/represent the uncertainty you have about a quantity in the risk assessment.
2. How to estimate the uncertainty by expert elicitation of quantiles, write justification for the values estimated and draw textual conclusions from the estimated uncertainty distribution for the uncertain quantity.

Procedure and material needed

The exercise guides you through the task by asking helping questions. For each task there is also provided a Data annex of supporting evidence.

- Answer the questions below first individually
- After finalisation of the individual assessment, we will have a group discussion

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Practical activity

Exercise 1: Estimate your uncertainty distribution for the proportion of total imported oranges that are infected with *P. citricarpa* arriving in EU ports in the timeframe of 1 year (2017) by assigning values to the following quantiles:

Lower	1st Q	Median	3rd Q	Upper

Helping questions:

- What do you think would be the extreme upper infestation rate? In other words, what do you think would be the **99th percentile**? The number for which there is a 99% chance that the true infestation rate is less and 1% chance that that it is more?
- What do you think would be the **first percentile**? That is the number for which there is a 1% chance that the true value is less and 99% chance that it is more.
- What do you think would be the middle value for the infestation rate? That is the **median infestation rate**? The number for which there is a 50% percent chance that the true value is smaller and 50% percent chance that the true infestation rate is greater?
- What do you think would be the **first quartile**? The number for which there is a 25% chance that the true value is less and 75% chance that it is more?
- What do you think would be the **third quartile**? The number for which there is a 75% chance that the true value is less and 25% chance that it is more

Supporting data: Meta-analysis of studies from fungicide treatment trials with control plots from CBS infested orange orchards. EU interception data for CBS symptoms on imported oranges. This information is compiled as supplementary material in Data annex.

Exercise 2: Estimate your uncertainty distribution for the trade flow of imported citrus into Spain in number of fruits per year in the timeframe of 1 coming year (2017).

Lower	1st Q	Median	3rd Q	Upper

Helping questions:

- What is the **99th percentile**? The number for which there is a 99% chance that the true value is less and 1% chance that that it is more
- What is the **first percentile**? The number for which there is a 1% chance that the true value is less and 99% chance that it is more

- What is the **median number** of fruits imported per year? The number for which there is a 50% percent chance that the true value is smaller and 50% percent chance that the true value is greater?
- What is the first quartile? The number for which there is a 25% chance that the true value is less and 75% chance that it is more?
- What is the third quartile? The number for which there is a 75% chance that the true value is less and 25% chance that it is more

Supporting data (Data annex 1): In the exercise you can use the trade import numbers from the countries with known presence of P*. citricarpa*. These data are prepared as a supplementary material in the form of an excel file. Please note that the numbers in the excel file are provided in 100 kg units citrus consignments (approximately equivalent to 500 fruit but, depending on their weight, this can range from 300 to 1 000 fruit).

Forming a model

Learning outcomes of the exercise

1. Participants understand that a simple multiplicative model may be run using Monte Carlo simulation, whereby a trade-flow and proportion of infestation are drawn many times randomly from fitted distributions, and a number of infested units entering the PRA area is calculated each time. The outcome of the Monte Carlo simulation is a probability distribution of the number of infested units entering the PRA area
2. Participants have seen how a very basic Monte Carlo simulation (multiplying two numbers) is conducted in @Risk
3. Participants understand how the simple learning outcome #2 can be scaled up to construct a quantitative PRA framework in which entry, establishment, spread and impact are calculated

This exercise requires a computer with Excel and @Risk installed

This exercise is based on the work done by EFSA on the risk of entry of citrus black spot, caused by the fungus *P. citricarpa* (https://www.efsa.europa.eu/en/efsajournal/pub/3557).

The task in this exercise is to calculate the **total next year's (2017) flow of infected oranges to the country of Spain**. **First**, this flow is calculated by a simple multiplication of the total flow into Spain of oranges from countries having the pathogen and the proportion of infected fruit in this flow, whereby both numbers are assumed to be **fixed constants, known exactly**. **Secondly**, this flow is calculated by performing the calculation using **random draws from two distributions** in @Risk. The first distribution characterizes the yearly total import volume into Spain of oranges originating from countries having the pathogen, and the second characterizes knowledge (uncertain) on the proportion of infected fruit within this flow.

The flow of infected oranges is calculated as:

$$N_{inf} = N * p_{inf}$$

Where

N_{inf} is the number of **infected** oranges imported **in 2017** by Spain from countries that are infested by *P. citricarpa*.

P_{inf} is the proportion of oranges that are infected with *P. citricarpa*. Both latently and visibly infected fruit are counted as infected because both may lead to transfer to the pathogen. Obviously, it is very difficult to get information on the proportion of infected fruit!

N_{inf} is the number of oranges imported **in 2017** by Spain from countries that are infested by *P. citricarpa,* via the official trade.

a. Calculate the yearly flow of **infected** oranges into the EU from countries with *P. citricarpa,* assuming **perfect** knowledge on N and p_{inf}

No further instructions are given on part a of this exercise as it is a simple multiplication.

Suppose the trade values are given in the table below, and the estimated value of p_{inf} is 0.0001 (1 in 10,000).

Tradeflow, N	
Year	Value
2010	107020476
2011	95876617
2012	92583227
2013	104697240
2014	94653893

Then, using the average trade volume of the last five years as the prediction for 2017 (98966291 oranges) and a proportion of infected oranges of 0.0001 (1 in 10,000), we obtain a total entry of 990 infected oranges in 2017. As we have no uncertainty about this number, we do not have to use language to qualify the exactness of the value obtained. There are exactly 990 infected oranges coming into Spain in 2017.

b. Calculate the yearly flow of **infected** oranges into the EU from countries with *P. citricarpa,* assuming **perfect** knowledge of N but imperfect knowledge of p_{inf}. Practically speaking, use the average trade 2012-2016 to make a prediction for 2017.

This calculation requires the use of @Risk, and proceeds according to the following steps:

1. Enter the information on trade flows into @Risk. This information could, e.g., look like:

Tradeflow, N	
Year	Value
2010	107020476
2011	95876617
2012	92583227
2013	104697240
2014	94653893

The numbers in the above table are fictitious. Please use your own numbers estimated in Exercise 2.

2. Take the mean trade flow, and use it as next year's trade flow (assumed to be known without uncertainty)

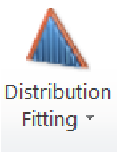
In this example, the average is 98966291 oranges per year

3. Enter the elicited estimates of the proportion of infected oranges in @Risk. This information could, e.g., look like:

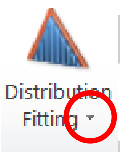
p	
Value	Quantile
0.00001	0.01
0.00003	0.25
0.0001	0.5
0.0002	0.75
0.001	0.99

Use your own numbers estimated in Exercise 2.

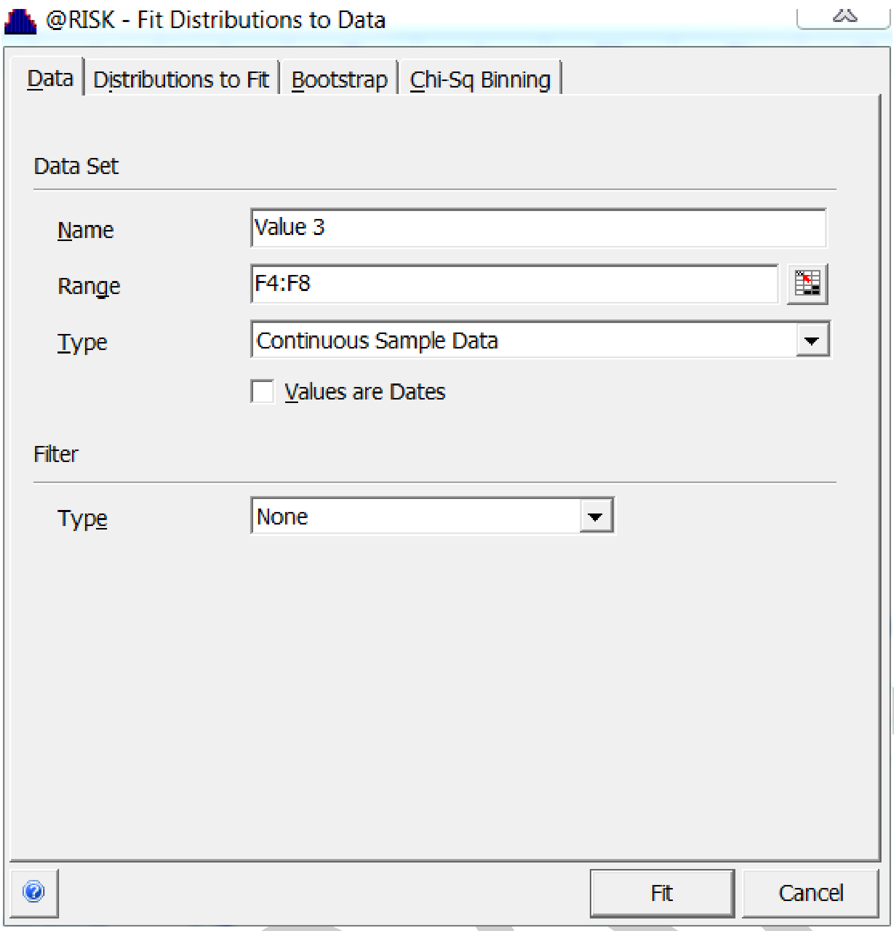
4. Put your mouse cursor on the cell containing the values from 0.00001 in the left upper corner to 0.99 in the right lower corner and select "Distribution Fitting" from the @Risk menu in the ribbon at the top of the @Risk window. The icon for Distribution Fitting looks like:



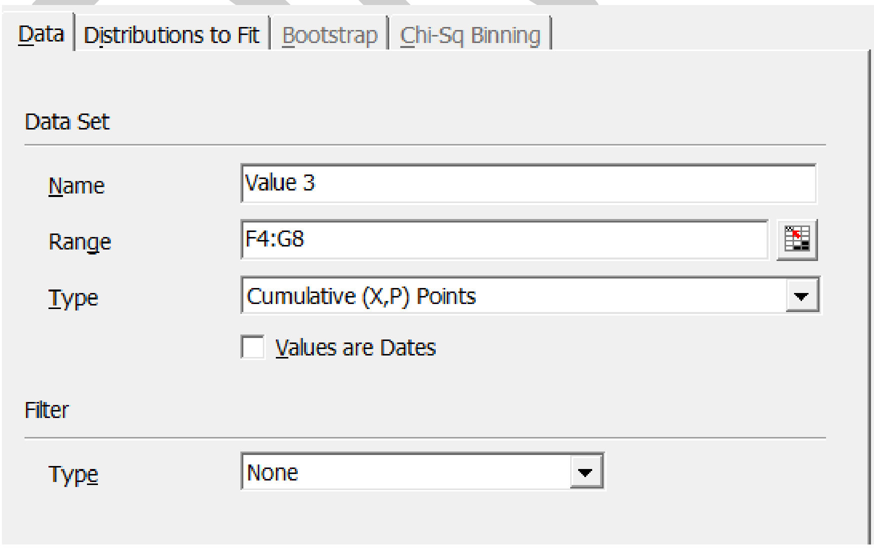
The tiny triangle in the bottom right corner of "Distribution Fitting"



produces a drop down menu if you click on it. Choose from this drop down menu "Fit". This should produce a window looking like the one below:

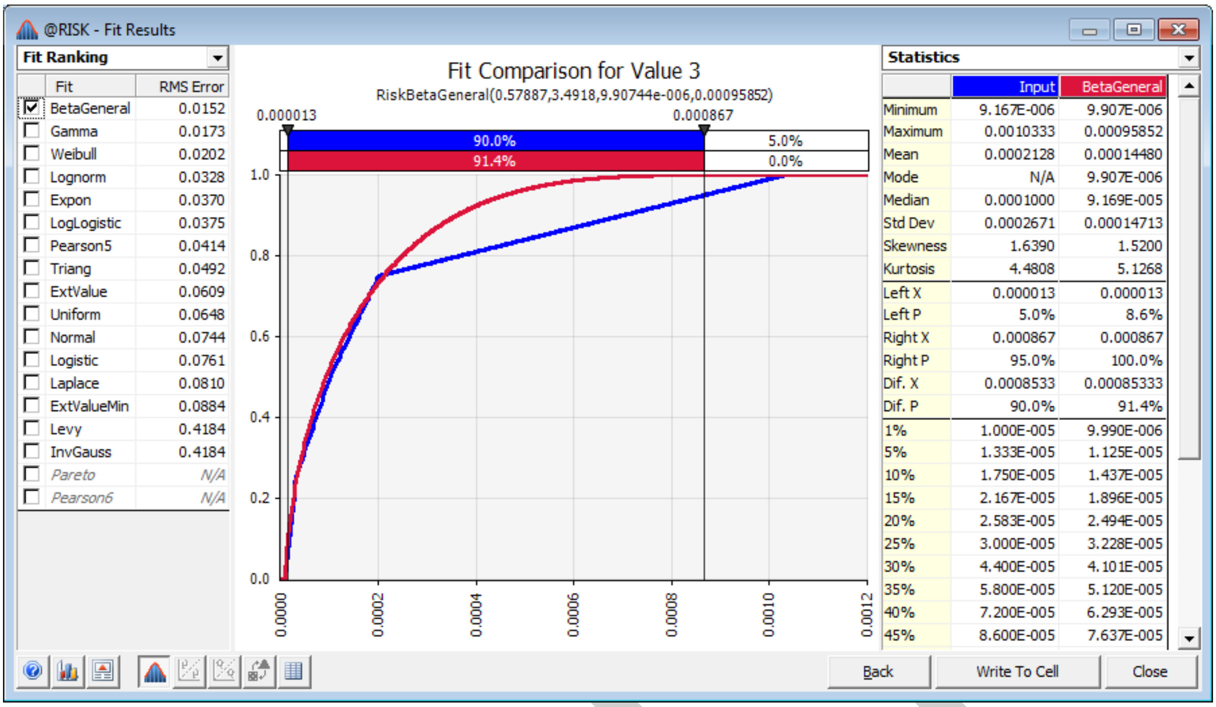


This window is set by default to fit a continuous distribution to a sample. However, we don't have a sample but five quantiles. To fit a distribution, change the Type of the data to Cumulative (X,P) Points:

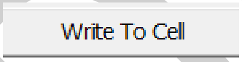


And choose "Fit". A window with the fitted distribution will then appear.

EFSA Journal



The panel at the left hand side above indicates that a generalized beta distribution (BetaGeneral) has been fitted. The generalized beta distribution is a flexible distribution with a defined minimum and maximum which if often used in risk assessment, and which is also known as the PERT distribution. In the middle panel, the fitted distribution is given by the smooth red curve while the elicited quantiles are represented by the blue "curve". Both the fitted distribution and the quantiles provided by the risk assessor represent cumulative probabilities, therefore, both curves are ascending. The blue curve is not smooth, because it simply connects the given quantiles. In the graph above, for instance, you can find the third quartile of 0.0002 at the point (0.0002, 0.75). **Check whether you can identify the other quantiles in the graph.** The right panel gives statistical metrics for the input data and for the fitted distribution.

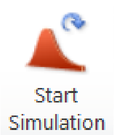
5. Choose 

from the bottom right hand corner of the window. This will write a formula for the fitted distribution in the chosen cell (G11 in the example spreadsheet). This formula looks like:

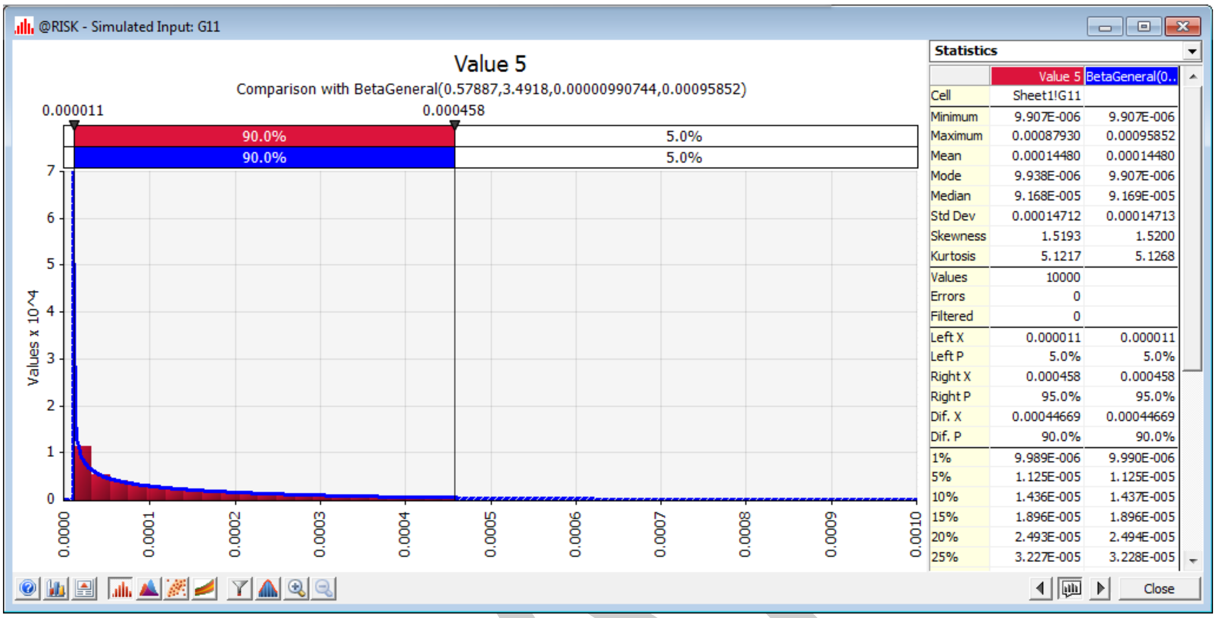
   =RiskBetaGeneral(0.57887,3.4918,0.00000990744,0.00095852,RiskName("Value 3"))

   (Readers who are familiar with the beta distribution will be helped by the information that 0.57887 is the value of the parameter α of the beta distribution, 3.4918 is the value of the parameter β, 0.00000990744 is the minimum value of p_{inf} and 0.00095852 is the maximum value.)

6. To generate random numbers from the fitted distribution, click the cell in which you placed the formula, and then select from the ribbon "Start simulation"



   This will generate random draws from the fitted beta distribution, and the results will be displayed as a histogram. The graph appears in a new window. On Windows computers, you can copy this window to the clipboard using <CTRL><ALT><PRINT SCREEN>, and then you can past it anywhere you like. The random draws are shown in red, while the fitted distribution is shown in blue.



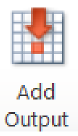
You can set the number of random draws by changing the number of iterations, just to the left of the "start simulation" button: Iterations 10000

Our objective is to generate a distribution of values for the number of infected oranges entering Spain in 2017. To generate this result, we first have to define a simple multiplication of the trade flow with the proportion of infected oranges in a new cell. In the example worksheet, the multiplication is in cell J10, and the formula is

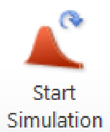
=D10 * G11

Where the trade flow is in cell D10 and the proportion of infestation is in cell G10.

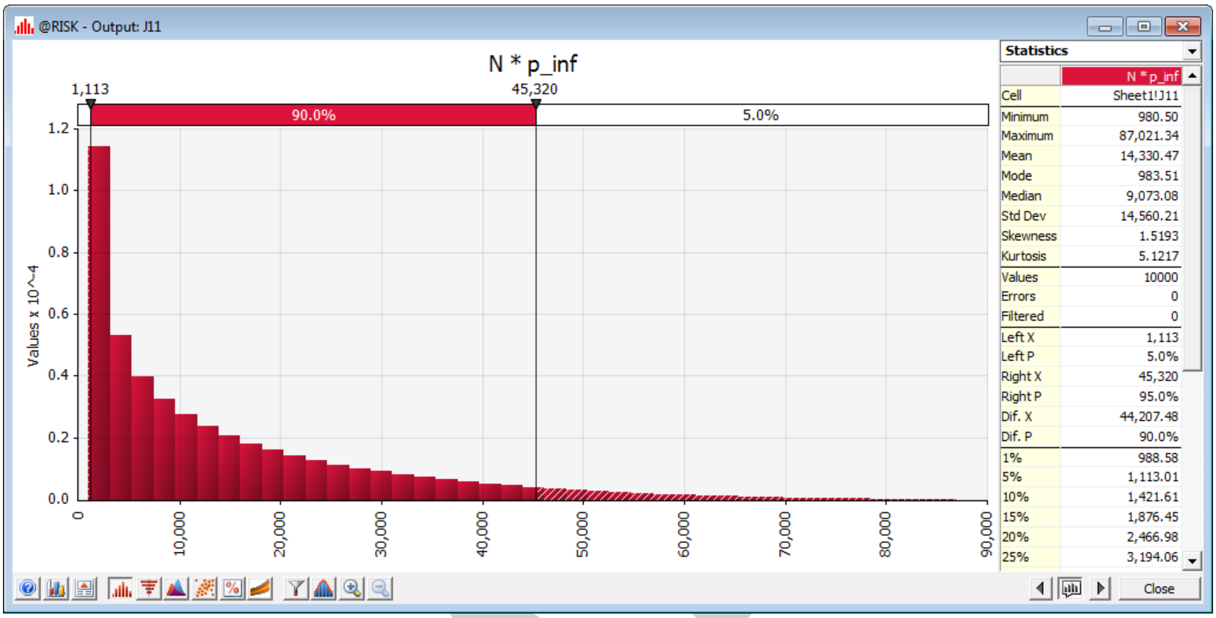
To generate random outcomes for the total number of infected oranges entering (N*p), we must define cell J11 as output, using the Add Output button in the ribbon. Place the cursor on cell J10, and click



From the ribbon. Then click again

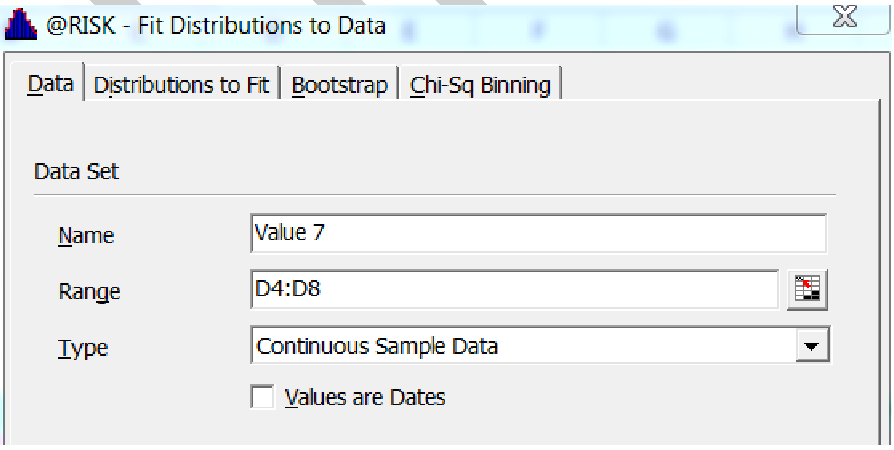


A new window will appear with a chart that looks like this:

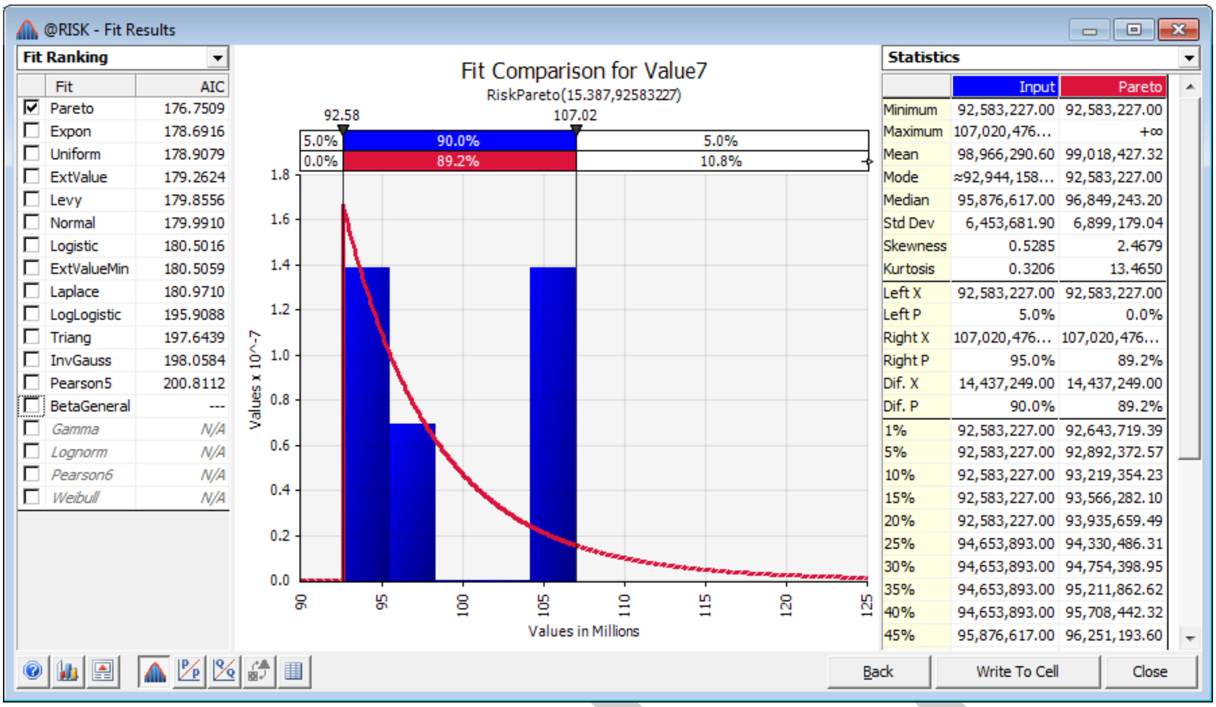


The forecasted number of oranges arriving varies from 980 to 89330, with a mean of 14330. The range is very wide, indicating high uncertainty. As only the p_{inf} was made stochastic in the calculations, we know that this uncertainty is due to our imperfect knowledge of p_{inf}. We can redo the calculations making the forecasted trade flow in 2017 also uncertain (it *is* uncertain of course).

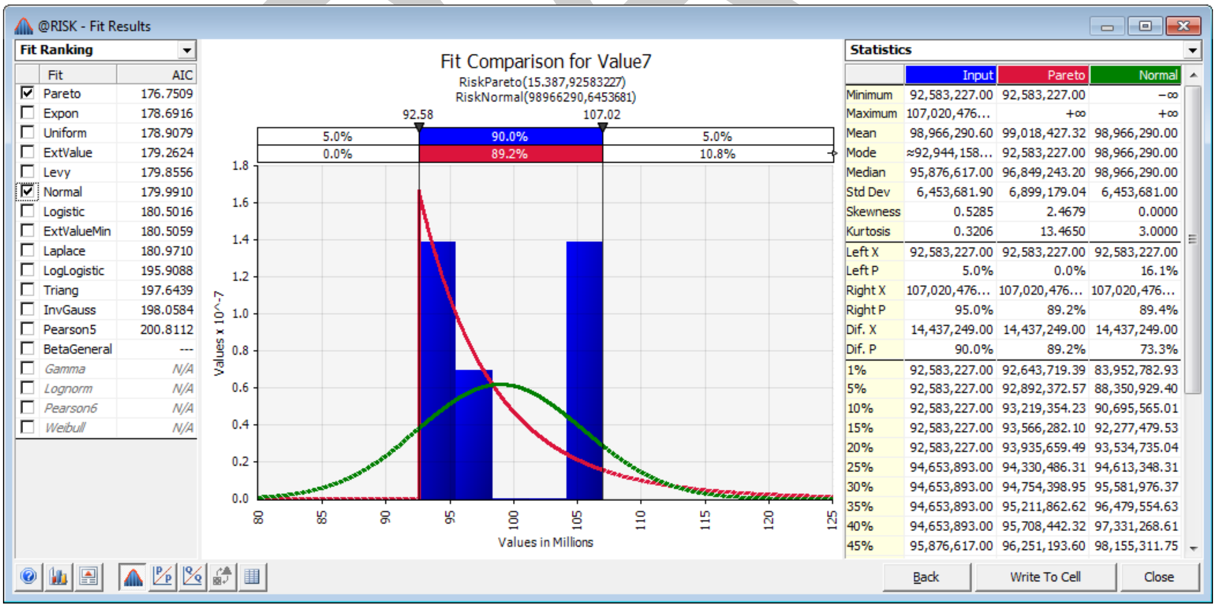
To do so, select cells D4:D8 containing the trade volumes to Spain in 2012-2016. As before, choose fit distribution from the Fit menu. Now, we can leave the field containing the text "continuous sample data" unchanged, because the observed trade flow in 2012-2016 are now regarded as sample from a distribution of trade volumes that covers both the trade in the past, the present and the future.



Choosing fit produces the following outcome:



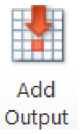
The fitted distribution for this small sample produces an unexpecte result with a sharp minimum and a long upper tail. This distribution does not conform with prior knowledge about the variability of trade over years, which should have a more bell-shaped curve. Tick "Normal" in the left panel of the window to fit the normal distribution to the data.



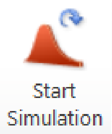
Choosing the normal distribution to fit the sample produces a more credible description of the variability in the trade (and hence our uncertainty about Spain's 2017 import of oranges). We proceed to untick the Pareto distribution, and write the normal distribution to cell D11.

Now we combine the uncertain trade flow in 2017 with the uncertain proportion of infested fruit in this trade flow.

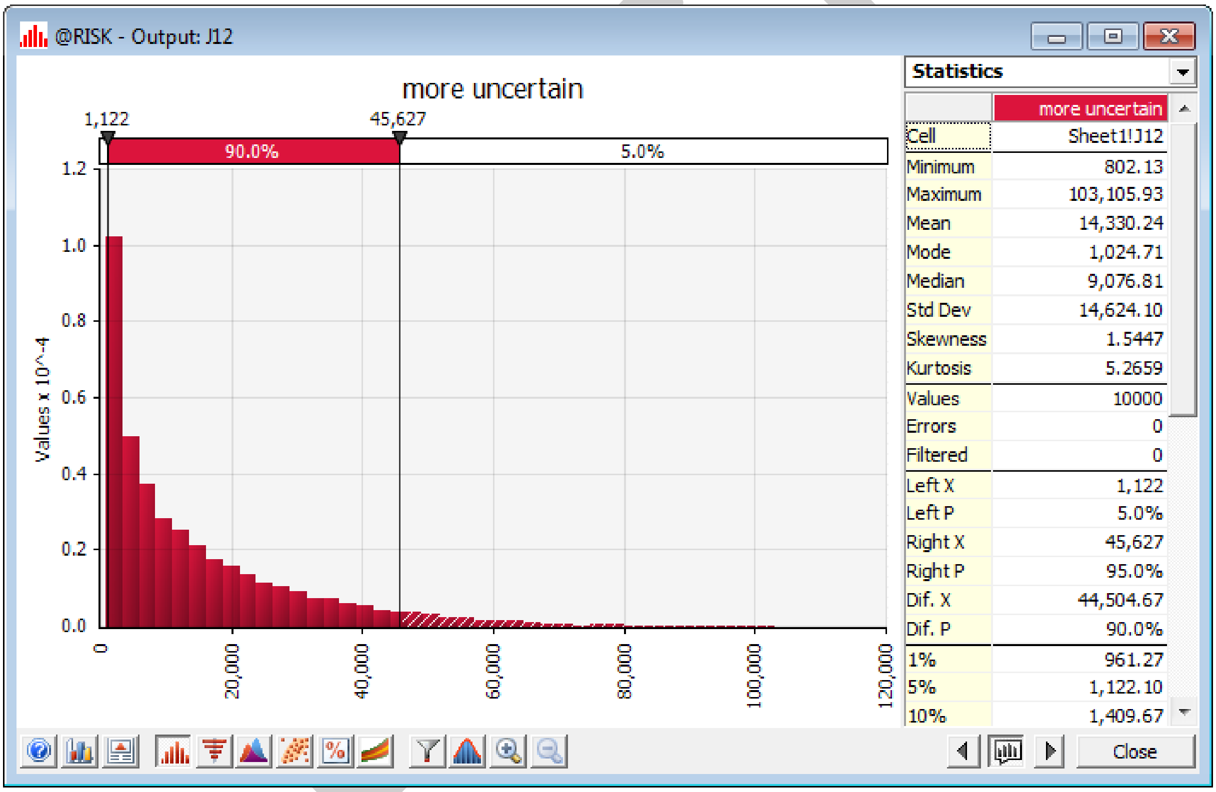
We write D11 * G11 in cell J12, and designate the cell J12 as risk output by placing the cursor in this cell and clicking in the ribbon on the icon "Add Output".



From the ribbon. Then click again



The new results appear. They look virtually unchanged compared to previously. Can you explain why?



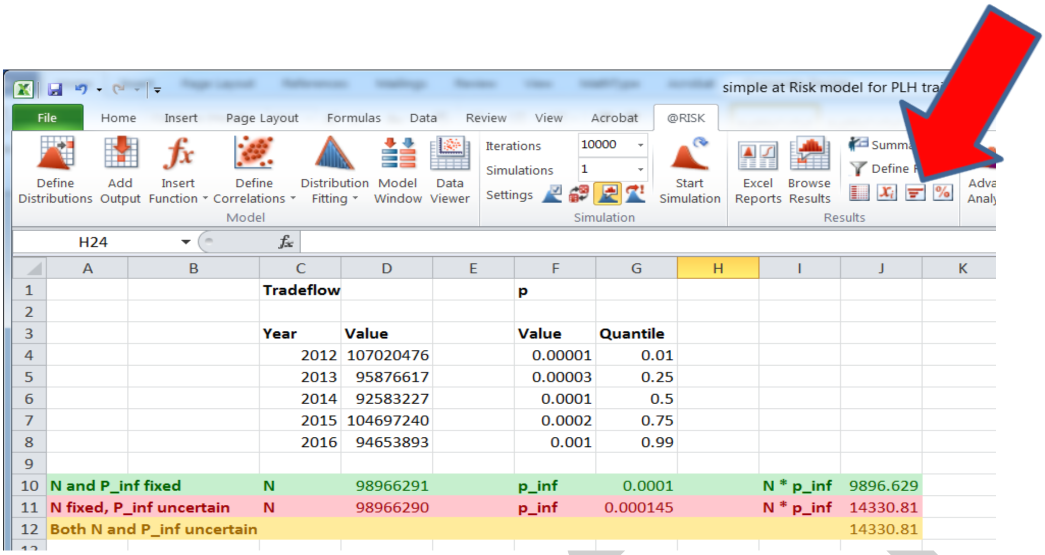
Results look similar as before because the uncertainty in trade flow is relatively small when compared to the orders of magnitude uncertainty in p_{inf}, and the uncertainty is symmetric around the mean. Therefore, this uncertainty does not affect the expected entry of infected fruit into the Spain, and it also does not greatly increase uncertainty about entry.

Uncertainty analysis

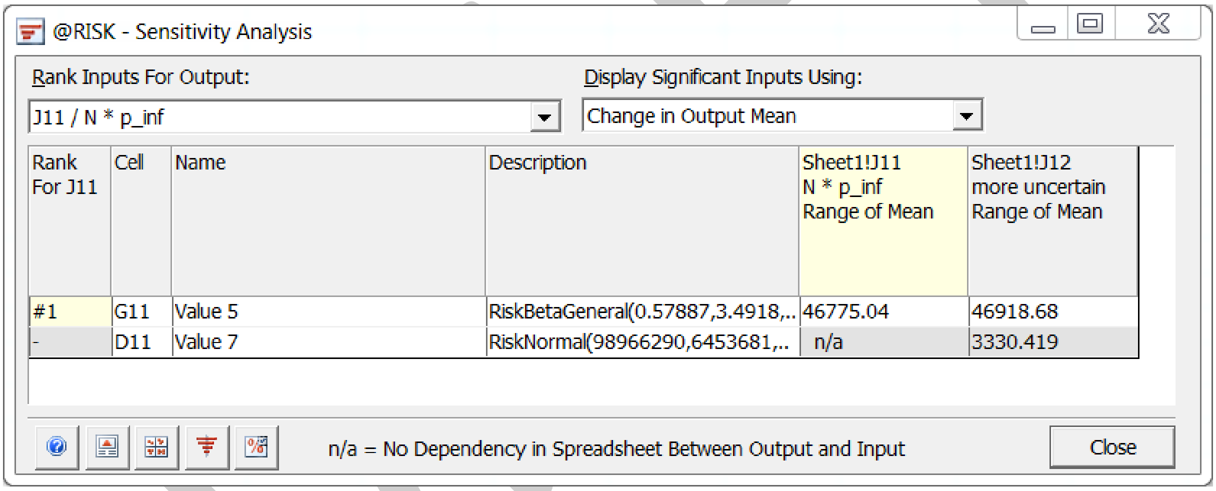
An uncertainty analysis can be conducted in @Risk to further analyse the contribution of different elements in the model on the uncertainty in the final result.

To conduct an uncertainty analysis, follow the following steps:

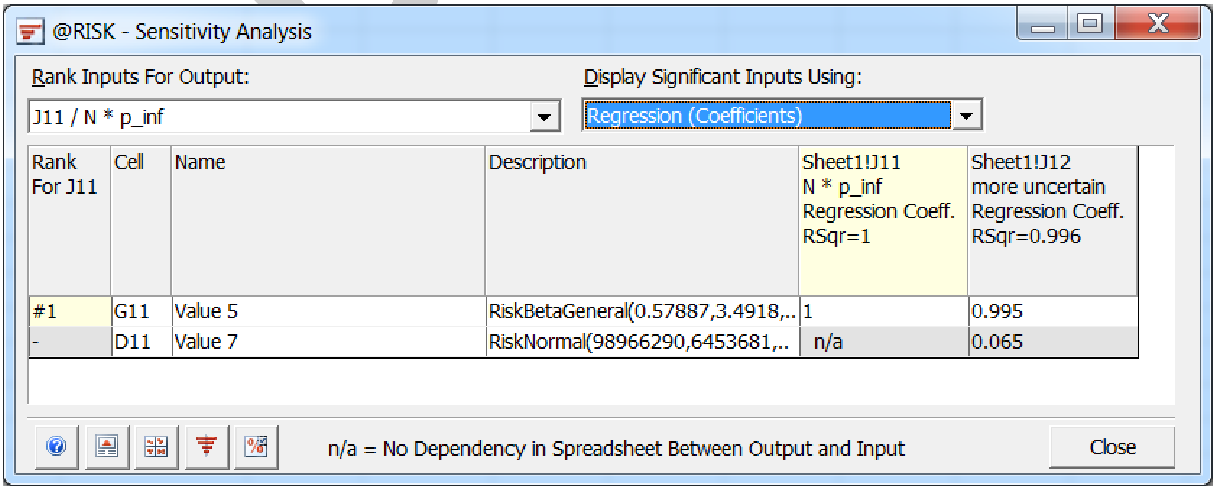
1. Click the "Tornado" button in the ribbon. It is found at the tip of the red arrow in the picture below:



This will produce the following window:



In the second drop down menu in this window, choose "Regression coefficients"



The regression coefficient indicate that variation in the final outcome of the model is strongly related to the variation in the value of G11 (the probability of infestation) but only weakly related to variation in the value of D11 (the trade flow). To express this difference in sensitivity between the two factors in the model, we make a few calculation steps. Unfortunately, these steps are a bit cumbersome in @Risk.

1. Within @Risk, click in the window illustrated above the second icon at the bottom left "Edit & export" 

2. Choose the option "Report in Excel" This produces the following output:

@RISK Sensitivity Analysis

Rank For J11	Cell	Name	Description	Sheet1!J11 N * p_inf Regression Coeff. RSqr=1	Sheet1!J12 more uncertain Regression Coeff. RSqr=0.996
#1	G11	Value 5	RiskBetaGeneral(0.57887,3.4918,0.00000990744,0.00095852,RiskName("Value 5"))	1.00	1.00
-	D11	Value 7	RiskNormal(98966290,6453681,RiskName("Value 7"))	n/a	0.07

Note that this output is in a different Excel worksheet. You can copy it back to your original sheet if you wish.

3. The last column contains regression coefficients. Their squared values are a measure of the relative sensitivity. Percent values for influence of uncertainty in different variables in the model on final output uncertainty can be calculated by hand, as shown below. For instance, 99.6 is calculated as 100 * (0.990/0.994). This uncertainty can also be shown as a tornado plot.

@RISK Sensitivity Analysis

Performed By: Wopke van der Werf

Date: Tuesday, November 08, 2016 1:18:23 PM

Rank For J11	Cell	Name	Description	Sheet1!J11 N * p_inf Regression Coeff. RSqr=1	Sheet1!J12 more uncertain Regression Coeff. RSqr=0.996	squares	% influence
#1	G11	Value 5	RiskBetaGene	1.00	0.995	0.990	99.6
-	D11	Value 7	RiskNormal(9	n/a	0.065	0.004	0.4
						0.994	

EFSA Journal

Data annex to the Appendix F on Supporting evidence

Supporting evidence in trade data

Living stages of *P. citricarpa* are frequently found on imported citrus fruit during border inspections at the EU points of entry (see Figure 3 and Table 1). This shows that *P. citricarpa* is associated with the citrus fruit pathway and is able to survive transport and storage as well as existing pest management procedures. During 1999–2012 there were 859 interceptions of *P. citricarpa* on citrus fruit consignments from third countries to the EU. Most interceptions were made by the Netherlands (65 %), but approximately 18 % (160) were from Spain, and a few interceptions were made by France, Greece and Portugal, three other EU citrus-growing countries.

All trade data shown for this pathway correspond to the Eurostat category "Citrus fruit, fresh or dried" detracted of the Eurostat category "Fresh or dried limes 'citrus aurantifolia, citrus latifolia'".

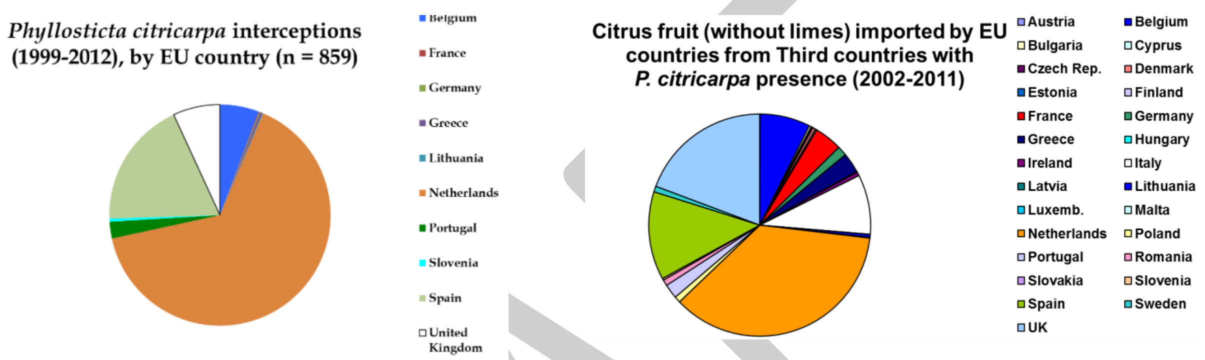


Figure 3: Distribution by EU country of (left) the 859 *Phyllosticta citricarpa* EU interceptions on citrus fruit consignments imported from third countries where *P. citricarpa* is present (1999–2012) (excluded pomelo) and (right) citrus fruit imported from third countries with *P. citricarpa* presence (2002–2011) excluded limes (*C. latifolia* and *C. aurantifolia*) (from EFSA PLH Panel, 2014a).

Table 1: Proportion of positive diagnoses in imported citrus fruit in The Netherlands and United Kingdom where pycnidia of *Phyllosticta citricarpa* were detected

Year	Positive diagnoses of *P. citricarpa*			
	The Netherlands		United Kingdom	
	Total No	Proportion with pycnidia	Total No	Proportion with pycnidia
2004	21	95.2	0	
2005	82	93.9	0	
2006	124	87.9	12	–*
2007	75	80.0	9	–*
2008	111	85.6	12	–*
2009	36	63.9	14	–*
2010	21	61.9	15	–*
2011	89	79.8	1	–*
2012	40	80.0	15	66.7
2013	66	86.4	27	51.9

Source: Europhyt, J. Meffert (NFCPSA, The Netherlands) and R. McIntosh (FERA, UK), personal communications.
Legend: *= no data available

For the EU MSs which intercepted *P. citricarpa* over the period 2002-2011, with the exclusion of interceptions on pomelo, there is a strong correlation between the number of *P. citricarpa* interceptions and the volume of citrus fruit, excluded limes, imported by the same EU MS from third countries with reported presence of *P. citricarpa*.

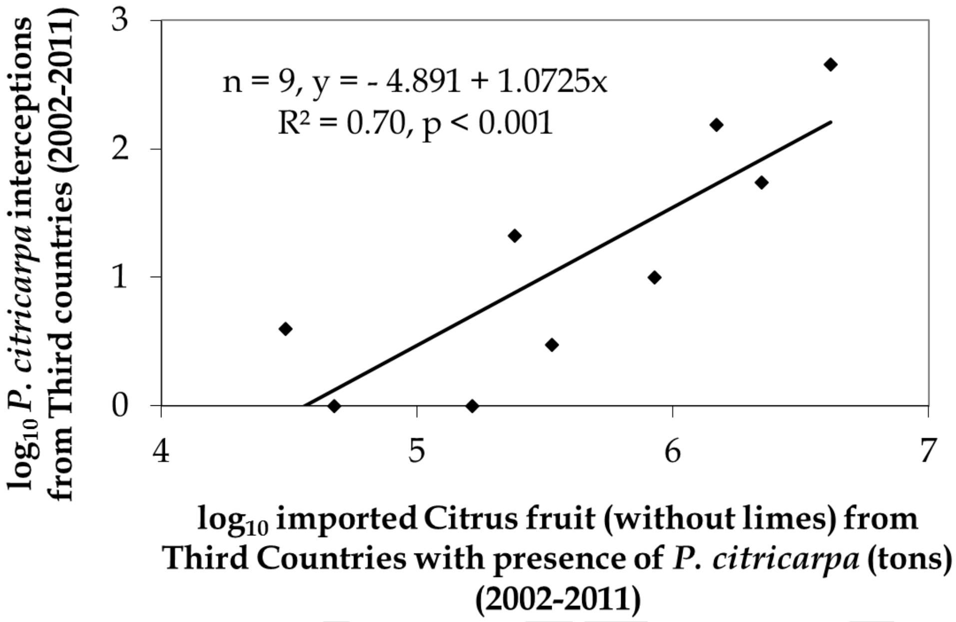


Figure 4: Log–log correlation of number of *Phyllosticta citricarpa* interceptions made by EU MSs (2002–2011), excluded interceptions on pomelo, and imported volumes of citrus fruit from third countries with reports of *P. citricarpa* (2002–2011), excluded limes, for the EU MSs which intercepted *P. citricarpa* at their borders. This figure covers the period 2002-2011, however the correlation was found to be just as strong when using all interception data (1999–2012) and when not log-transforming the data (from EFSA PLH Panel, 2014a)

Most (approximately 87 %) P. *citricarpa* interceptions on citrus fruit consignments imported into the EU from third countries were made on shipments of sweet orange. About 8 % (70) of interceptions were made on shipments of lemon (Figure 5), the citrus species most susceptible to P. *citricarpa*, of which more than half (43) originated from South Africa.

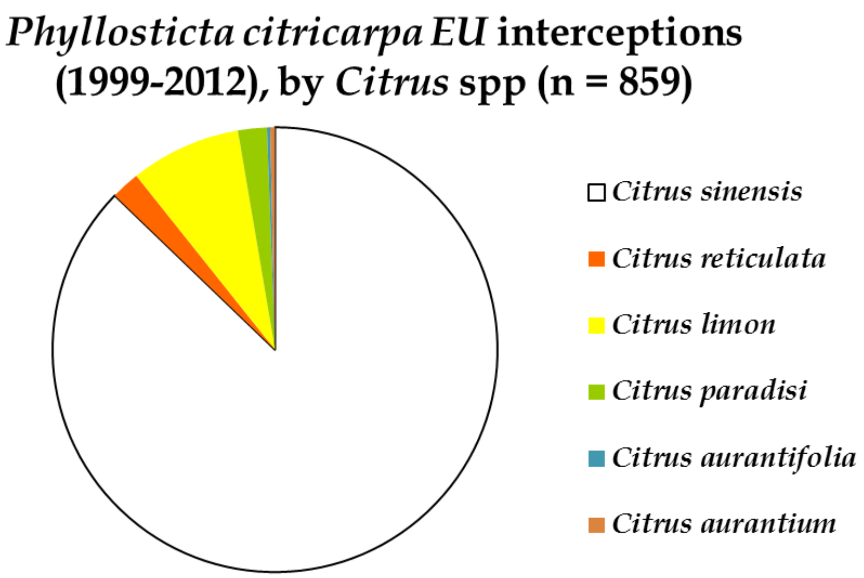


Figure 5: Distribution by citrus species of the 859 *Phyllosticta citricarpa* EU interceptions on citrus fruit consignments, excluded pomelo (*C. maxima*), imported from third countries between 1999 and 2012(from EFSA PLH Panel, 2014a)

Cultural practices and pre- and/or post-harvest treatments applied in the current area of P. citricarpa distribution may reduce the incidence and severity of CBS infection in citrus fruit imported into the pest risk assessment (PRA) area, but they will not completely eliminate the pathogen.

Volume of the movement along the pathway

Every year a large volume of citrus fruit is imported into the EU from third countries where *P. citricarpa* is present. The main exporters of citrus fruit into the EU are Argentina, Brazil, China, the United States, Uruguay, South Africa and Zimbabwe. Minor imports originate from Australia, Cuba, Ghana, Mozambique and New Zealand. Very small quantities of citrus fruit have been imported into the EU from Kenya, the Philippines, Taiwan, Uganda and Zambia.

EU import data for citrus for recent years are provided in a separate excel file.

Most EU interceptions of *P. citricarpa* on citrus fruit consignments imported from third countries over the period 1999–2012 originated from Brazil and South Africa. The number of countries from which interceptions originated (13) provides evidence that citrus fruit can be considered as a major potential pathway of entry for the pathogen.

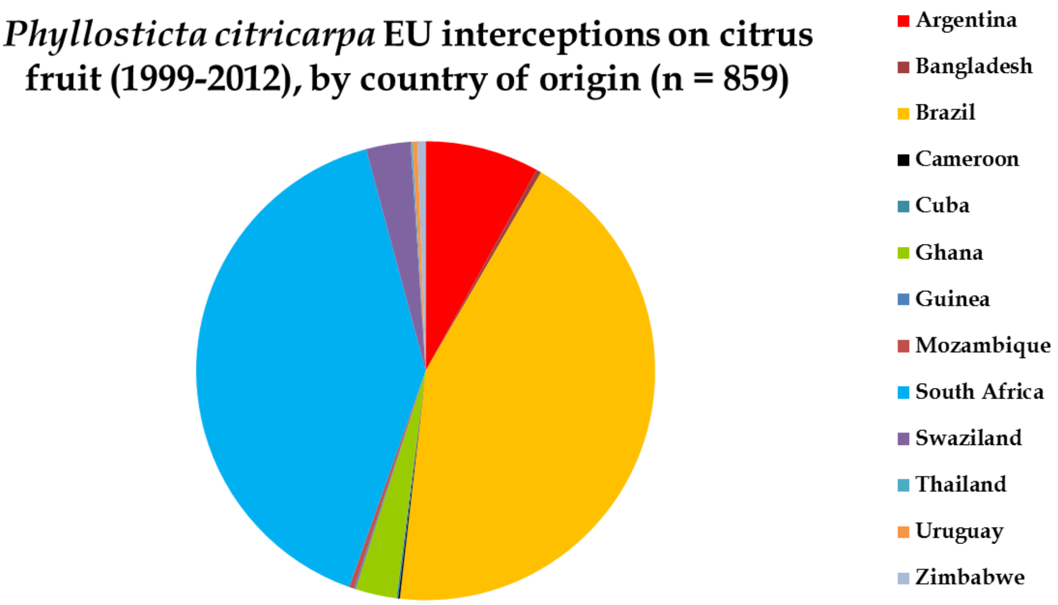


Figure 6: Distribution by country of origin of the 859 *Phyllosticta citricarpa* EU interceptions on citrus fruit consignments, excluded pomelo (*C. maxima*), imported from Third Countries between 1999 and 2012

Association with the pathway at origin

The association of the pathogen with the citrus pathway varies with the citrus species: lemons and late-maturing sweet orange cultivars are generally considered to be more susceptible (Kotzé, 1981), mostly because they hang on the tree for a longer period and are therefore more exposed to pathogen inoculum during periods when environmental factors are suitable for disease development and have more time for symptom development. Early-maturing sweet orange cultivars are considered less susceptible as they are harvested earlier (Timmer, 1999; Spósito et al., 2004; Sousa and de Goes, 2010). Results from the meta-analysis indicate that, under field trial conditions, disease incidences when using the best fungicide programmes ranged from 0.6 % to 7 % of CBS-affected fruit and from 7 % to 32 % with the least effective fungicides. Data from Sao Paulo state, Brazil, indicated that the incidence of CBS disease in fruits from commercial orchards intended for export was less than 2 % on arrival at the packing house, whereas in fruits harvested from orchards intended for domestic markets the disease incidence ranged from 19.3 % to 64.1 % (Fisher et al., 2008).

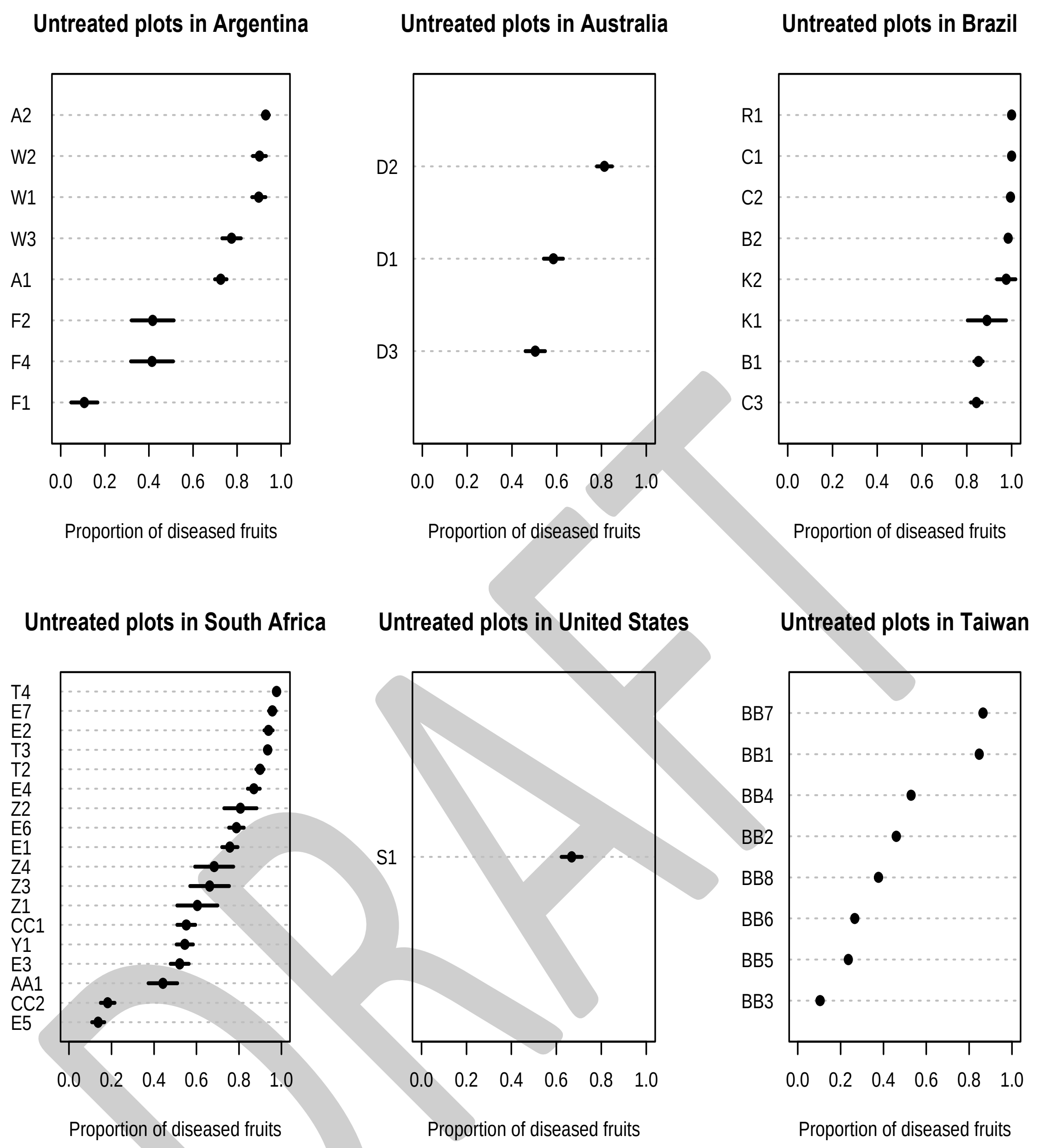


Figure 7: Proportion of CBS-affected fruits in untreated plots in Argentina, Australia, Brazil, South Africa, the USA and Taiwan. Plot names are given on the y-axis. Bars indicate 95 % confidence intervals (missing for Taiwan) (from EFSA PLH Panel, 2014a)

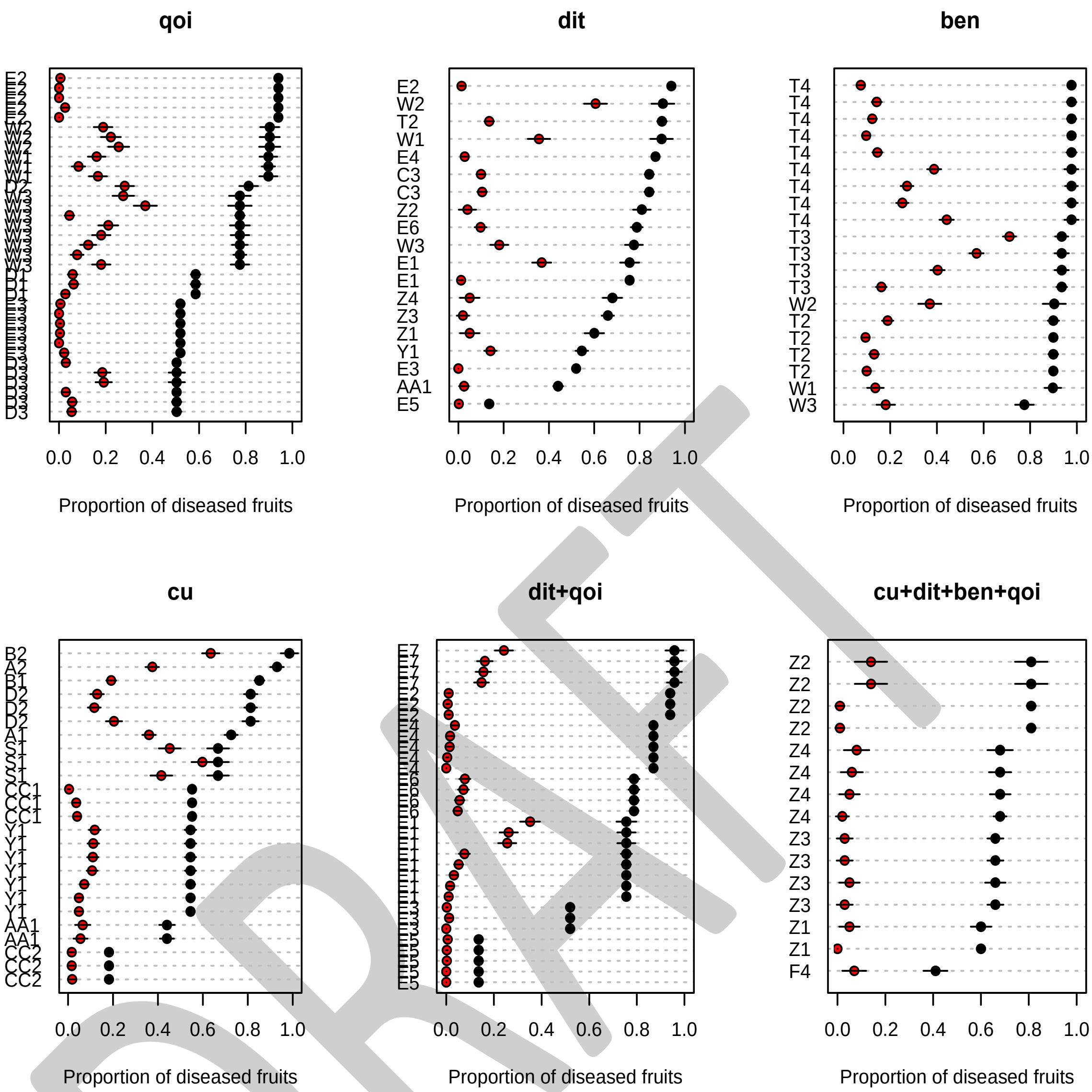


Figure 8: Observed proportions of CBS-affected fruits in untreated (black) and treated (red) trees for different types of fungicide (qoi, dit, cu, ben, dit+qoi, cu+dit+ben+qoi) and different plots. Bars indicate 95 % confidence intervals. Plot names are given on the y-axis (from EFSA PLH Panel, 2014a)

ANNEX A -

Tool kit for identification and evaluation of risk reduction options

The Excel file "tool kit for RRO assessement.xls" (available from: https://zenodo.org/record/1170121#.Wn2ya2eGOUk) contains three worksheets for aiding the risk assessor in the identification and evaluation of risk reduction options (RRO) combinations that are relevant for the risk assessment:

i. RRO identification tool
ii. Scenario design tool
iii. RRO evaluation tool.

This Annex describes the use of these tools for the risk assessor in:

i. the systematic identification of RROs that may affect the pest abundance at each distinguished step of the risk assessment for a specified scenario. This may be the baseline scenario or an alternative scenario, according to the request specified in the Terms of Reference,
ii. structuring the evidence and related uncertainties for facilitating the discussions of the experts when estimating the effect of the RRO combination as implemented for a step of the risk assessment.

1. Systematic identification of RROs

1.1. Preliminary identification of RROs

In the context of the definition of the scenarios, it is suggested to start with a preliminary identification of RROs that can potentially affect the pest at the level of risk assessment steps (Entry, Establishment, Spread, and Impact). RROs are briefly described in Appendix C of the guidance document. Further details for each RRO can be consulted in the corresponding RRO information sheet available at www.Zenedo.etc..

The Table 1 can be used for a preliminary RRO identification where for each RRO it could be indicated to which step of the Risk assessment the measures could apply to (Entry, Establishment, Spread and/or Impact).

Table 1: Aid for the preliminary identification of RROs (Excel sheet "RRO identification" https://zenodo.org/record/1170121#.Wn2ya2eGOUk)

N°	RRO Information sheet title	Entry	Establishment	Spread	Impact
CONTROL MEASURES					
1.01	Growing plants in isolation				
1.02	Timing of planting and harvesting				
1.03	Chemical treatments on crops including reproductive material				
1.04	Chemical treatments on consignments				

	or during processing				
1.05	Cleaning and disinfection of facilities, tools and machinery				
1.06	Soil treatment				
1.07	Use of non-contaminated water				
1.08	Physical treatments on consignments or during processing				
1.09	Controlled atmosphere				
1.10	Waste management				
1.11	Use of resistant and tolerant plant species/varieties				
1.12	Rogueing and pruning				
1.13	Crop rotation, associations and density, weed/volunteer control				
1.14	Heat and cold treatments				
1.15	Conditions of transport				
1.16	Biological control and behavioural manipulation				
1.17	Post-entry quarantine and other restrictions of movement in the importing country				
SUPPORTING MEASURES					
2.01	Inspection and trapping				
2.02	Laboratory testing				
2.03	Sampling				
2.04	Phytosanitary certificate and plant passport				
2.05	Certified and approved premises				
2.06	Certification of reproductive material (voluntary/official)				
2.07	Delimitation of Buffer zones				
2.08	Surveillance				

The resulting table can be used as a starting point for the design of scenarios.

1.2. Defining the RRO components of the scenarios

For defining the RRO components of the scenarios an Excel file has been developed by the Panel to guide the risk assessor in the scenario design (Excel file "tool-kit for RRO assessement.xls", worksheet "Scenario design" https://zenodo.org/record/1170121#.Wn2ya2eGOUk)

In this section the use of this Excel sheet is presented. However the Panel recognises that depending on the organism and the complexity of the related regulation, other more tailored approaches can be developed.

1.2.1. Required information

Prior to starting the design of RRO scenarios some essential information is required:

With regards to documentation

- Terms of Reference (ToR) should be available
- The Pest categorisation should be available to have the minimum knowledge about the biology of the pest, its distribution and the current regulatory requirements
- RRO information sheets
- scientific and/or technical literature
- knowledgeable expert(s) in the field

With regards to Risk assessment scenarios

- The time and spatial scales of the assessment need to be defined
- The ecological factors of the scenarios should be identified
- The pathways for entry need to be clearly identified
- The pathway units need to be defined
- The relevant steps and sub-steps of the risk assessment need to be selected

The number of RRO scenarios to be designed depends upon the request of the risk managers in the Terms of Reference. Each RRO scenario will describe and designate univocally the elements that contribute to the risk posed by the organism. Each RRO scenario is composed of the sequence of RRO combinations that act on each RA sub-step reducing the overall risk posed by the pest.

In this part of the assessment, the objective is to identify the relevant combinations of RROs that compose the different scenarios.

1.2.2. Phytosanitary strategy

The scenario is constructed based on the phytosanitary strategy under which the risk assessment is performed. This is where the dialogue with the risk managers is crucial for endorsing the scenarios before starting the actual risk assessment.

Different types of strategies can be distinguished as indicated in the Figure 1 below:

The sequence of Risk Assessment sub-steps corresponds with a hierarchy of prevention in strategies for risk reduction (in line with ISPM 11):

Prevention ↓ Correction

- Prevent Entry and Establishment of the pest via import in non-infested regions:
  1. Establish a pest free environment before production of a host commodity:
     - Pest free Area or Country (Protected zone in the EU)
     - Pest Free Place of Production
     - Pest Free Production Site
  2. Establish pest free commodity:
     - Absence of pest during crop cycle
     - Absence of pest during consignment preparation, export and transport
     - Absence of pest during import and arrival at area of destination
- Prevent Spread of established pests from infested regions and Impact in infested regions :
  3. Delimit infested regions:
     - Eradication
     - Containment
     - Low pest prevalence

Figure 1: Phytosanitary strategies from prevention to correction

When designing a scenario in terms of RRO combinations it is necessary to clearly indicate the corresponding phytosanitary strategy for reducing the risk choosing from Appendix C of the guidance document.

The correspondence between these strategies and the risk assessment sub-steps are indicated in the following Table 2.

Table 2: Example of a table to guide the risk assessor to establish the correspondence between phytosanitary strategies and the risk assessment sub-steps for the scenario design (Excel sheet "scenario design" https://zenodo.org/record/1170121#.Wn2ya2eGOUk)

RA step	ENTRY								ESTABLISHMENT	SPREAD				IMPACT	
RA sub-step or factor	E1				E2	E3	E4	E5		Human assisted	Vector spread	Natural spread			
Approach	pest free environment before production of commodity			Pest Free Commodity					Delimitation of infested regions						Delimitation of Pest Free regions
Fiches	Pest Free Area (ISPM)	Pest Free Place of Prod (ISPM)	Pest Free Prod. Site (ISPM)	Pest Free crop	Pest Free consignment	Transport	Entry	Transfer	Establishment	Containment			Eradication	Pest abundance	Protected Zone

Starting from the preliminary identification of RROs in Table 1, in line with a specific phytosanitary strategy it is now possible to discuss and select the specific measures that could be included in each scenario indicating on which risk assessment sub-step they have an effect.

2. Interpretation of Baseline Scenario

In the scenario design it is recommended to start with the definition of the Baseline Scenario in terms of its RRO components. This scenario is usually referred to as A0 and corresponds to the current measures laid down in the current legislation as officially implemented by phytosanitary legislation while the opinion on the pathway is developed (e.g: Regulation EU 2016/2031, Council Directive 2000/29/EC, EU Emergency measures, Control and Marketing Directives etc.). The complexity of the scenario design might vary depending on whether the phytosanitary measures could be specifically implemented for the pest being assessed or whether the phytosanitary measures could also affect one or more other regulated pests not being assessed.

For detailing the RRO components of the A0 scenario it is necessary to de-construct the current legislative requirements in risk reduction options and to 'translate' all phytosanitary measures into corresponding RROs, to identify specific and non-specific RROs for the pest being assessed.

The pest-specific RROs are subject to evaluation, modification or removal from the baseline Scenario when defining the alternative scenarios. The remaining RROs will not be evaluated and keep providing a baseline level of risk reduction.

Using the Table 2 each RRO in the current legislation can be linked with its RA sub-step (specific and non-specific) and for each RA sub-step a list of 'Combination of RROs' is provided.

3. Design of alternative scenarios

The Table 2 can be used to systematically identify RROs that could interfere with any of the (sub)processes by indicating for each measure its relevance by colouring the cell and by indicating in a second step in which scenario the measure would be considered. This would result in Table 3 presented below

Table 3: Example of a table to guide the risk assessor in the systematic identification of RROs for the scenarios design (Excel sheet "scenario design" https://zenodo.org/record/1170121#.Wn2ya2eGOUk)

RA step				
RA sub-step or factor		E1		
Approach		pest free environment before production of commodity		
Fiches		Pest Free Area (ISPM)	Pest Free Place of Prod (ISPM)	Pest Free Prod. Site (ISPM)
control measures				
1.01	Growing plants in isolation	A0		
1.02	Timing of planting and harvesting			
1.03	Chemical treatments on crops including reproductive material			
1.04	Chemical treatments on consignments or during processing			
1.05	Cleaning and disinfection of facilities, tools and machinery	A0/A1		A1

Each RRO can be implemented at various stages of the production and trade chain of a commodity. For example, a specified pesticide treatment of a growing crop may be applied in a foreign country (reducing the pest abundance at the step of Entry by reducing the rate of association of the pest with the pathway at the place of origin) or in the domestic country (reducing the rate of spread of established quarantine pests to non-infested areas of the country by reducing the association of the pest with the pathway, or reducing the impact of a pest on growth and yield of the treated crop by reducing the prevalence of the pest in the crop).

Hence, each RRO can be an element of various phytosanitary approaches or strategies, e.g. a special import requirement, the establishment of a pest free area, or an eradication programme.

The table also allows for smart selection of one or several RROs to be implemented at each sub-step in a scenario, for example by combining RROs with different 'modes of action', to establish the 'RRO combination' for each sub-step. The effect on pest population abundance at each sub-step must be assessed for the RRO combination rather than for each individual RRO. The aggregated list of RRO combinations over all sub-steps in the risk assessment scenario represents the RRO scenario.

4. Evaluation of the effect of RRO combinations

Once the A0 and alternative scenarios are designed and proposed by the risk assessor and endorsed following a dialogue with the requestor of the risk assessment, the effect of the RRO combinations on pest population abundance at each sub-step is expressed in terms of the quantiles of a probability distribution (see Section 3). The estimates for each quantile should be supported by a short text describing the justification of the probability distribution, based on the available scientific and technical data and/or expert knowledge. The new probability distribution includes both the effect and the related uncertainties of the RROs combination and represents the Panel's expectation of the pest abundance at the particular sub-step under the alternative scenario. It is meant to replace the quantile distribution for the sub-step in the baseline scenario (A0) when assessing the risk under the alternative scenario. If no other factors are considered, the difference in pest abundance between scenarios reflects the difference in effectiveness of the RRO combinations implemented in each scenario.

An Excel file has been developed (Excel sheet "RRO evaluation.xls" https://zenodo.org/record/1170121#.Wn2ya2eGOUk) to serve as an example for the risk assessors to structure the discussion on quantification of quantiles of the probability distribution representing the effect of the RRO combination, and to scrutinise the available evidence and related uncertainties for the combinations of measures under evaluation. No recommendations are provided for the use of the Excel sheet as its use is intuitive and self-explanatory.

When estimating the probability distribution for the population abundance at a sub-step of the assessment under the specified RRO combination, due consideration should be given to the level of pest reduction that is achieved by the RRO combination and to limiting factors that may reduce the attainable level, increase the uncertainty or cause variability. Information regarding the parameters to consider when assessing each RRO combination is provided in dedicated paragraphs of the corresponding information sheet.

It is acknowledged by the IPPC that absolute absence of a pest is not always attainable. The IIPC defines 'Free from (of a consignment, field or place of production' as 'Without pests (or a specific pest) in numbers or quantities that can be detected by the application of phytosanitary procedures' (ISPM No.5., FAO, 2017 - Glossary of phytosanitary terms). For example, a RRO combination may be implemented in a scenario to establish pest free production places in an area where the pest is present. Limiting factors for pest freedom may be that the RRO combination cannot fully prevent the entry of the pest on a production place (e.g. physical protection is lacking or not effective) resulting in a smaller number of pest free production places than aimed for. It may also be that the level of surveillance is insufficient for early detection of the pest on production places, resulting in increased uncertainty, or that chemical pest control in buffer zones is affected by weather conditions, resulting in increased variability of pest presence.

For each RRO component of a combination of measures, the risk assessor could identify and analyse such factors limiting its effectiveness. The importance of the limiting factors should be justified based on the scientific or technical literature, data on effectiveness of measures and expert knowledge. In preparation of the experts' assessment of the limiting factors, evidence and related uncertainties should be systematically listed. The related uncertainties need to be clearly formulated in this process.