GUIDANCE

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Guidance 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 EU. Phase one consists of pest categorisation to determine whether the pest has the characteristics 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 resources available and the needs of risk managers, pest entry, establishment, spread and impact steps may be assessed directly, using weight of evidence and quantitative expert judgement (first tier), or they may be elaborated in substeps using quantitative models (second tier). An example of an application of the first tier approach is provided. Guidance is provided on how to derive models of appropriate complexity to conduct a second tier assessment. Each assessment is operationalised using Monte Carlo simulations that can compare scenarios for relevant factors, e.g. with or without RROs. This document provides guidance on how to compare scenarios to draw conclusions on the magnitude of pest risks and the effectiveness of RROs and on how to communicate assessment results.

Keywords: guidance, quantitative pest risk assessment, risk reduction option, model, uncertainty, risk communication, expert knowledge elicitation

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Summary

The European Commission requested the European Food Safety Authority (EFSA) to evaluate the status of a number of plant pests listed in the Annexes of Council Directive 2000/29/EC[1] 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 (EU). 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, 2018b) 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 or 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 Annex A.

The Guidance aligns with the International Plant Protection Convention (IPPC) International standards for phytosanitary measures (ISPM) 2 (FAO, 2016a) and ISPM 11 (FAO, 2017a) and is consistent with EFSA Guidance documents (e.g. EFSA PLH Panel, 2011, 2012; EFSA Scientific Committee, 2012, 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 (EKE) and modelling. Depending on the data and other available 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 quantitative expert judgement (first tier), or they may be elaborated in substeps using quantitative models (second tier). Guidance is given for the development of quantitative models for assessing entry, establishment, spread and impact of the target organism. The models should contain sufficient detail to enable the quantification of key processes and address questions of the requestor on the effectiveness of RROs, but should be simple enough to remain transparent and suitable for parameterisation with the data and available resources.

The Guidance provides a framework within which a quantitative assessment can be performed. The framework is adaptable 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 and 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 goal 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, 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 EKE in a way that is transparent, rigorous and time efficient. Uncertainties are expressed quantitatively when possible, and in 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.

[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.

Appendices and annexes 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 that would facilitate the communication of results for each step in the particular assessment, 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 together 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 geographical 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 scales.

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, appendices and/or annexes. The Guidance advises on what form of expression best suits the results for each section of a published risk assessment opinion. As a reader progresses from the abstract to the summary and to the main body, the level of detail increases, while maintaining a consistent message.

In conclusion, this Guidance provides a framework built upon agreed principles of pest risk assessment and includes flexibility, which allows assessors to design conceptual and formal models at appropriate levels of sophistication and resolution to suit the needs of each assessment. When there are time or resource constraints, a first tier approach is proposed in which a base level quantification is carried out that directly assesses the uncertainty distribution of the result for all or some of the main steps (Entry, Establishment, Spread and Impact). 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 other users of this guidance as well as the needs of those requesting pest risk assessments.

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1. Introduction

1.1. Background

The current European Union (EU) 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[2] on protective measures against pests of plants, was adopted on 26 October 2016 and will apply from 14 December 2019 onwards, repealing Council Directive 2000/29/EC.

With mandates from European Commission DG SANTE (ARES 2014 970361 – 28/3/2014; ARES 2015 1418918 – 31/3/2015; ARES 2017 1111340 – 02/3/2017), the European Food Safety Authority (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 Council 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 of delivering scientific advice that replies to the needs of the risk managers, a dedicated Working Group of the EFSA PLH Panel was 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 a quantitative risk assessment as far as possible (EFSA Scientific Committee 2009, 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–d, 2017a–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 and assess the effectiveness of RROs. 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 the effectiveness of RROs. Such Guidance, which should include a description of the step-based risk assessment approach, should be delivered by June 2018.

In line with EFSA's policy on openness and transparency, EFSA is also requested: (i) to organise public consultation after the endorsement of the draft Guidance by the PLH Panel to invite comments from the scientific community and all interested parties; and (ii) to publish a technical report on the outcome of the public consultation on the draft Guidance.

1.3. Scope and objectives of quantitative risk assessment

1.3.1. Context of risk assessment in plant health and the quantitative approach

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 assessments provide the scientific basis for the evaluation of risks posed to cultivated and wild plants by plant pests. They involve the systematic synthesis of knowledge and characterisation of

[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, pp. 4–104.

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, 2017a). 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).

This Guidance explains an approach to risk assessment of plant pests using quantitative methods. Following the Guidance allows 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, 2018b; FAO/WHO 2015). It avoids qualitative expressions of risk or components of risk, which 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 RROs. An 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’ (EFSA PLH Panel, 2012). An RRO may become a phytosanitary measure, action or procedure according to the decision of the risk manager. Many risk management decisions involve selection 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 EU by the EFSA Panel on Plant Health (Panel) has been based on a qualitative approach, although both qualitative and quantitative approaches were recommended (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. So, 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. Importantly, this allows the incorporation of the effects of RROs at the place in the sequence of events where they have an effect on the pest abundance. In specific cases, the assessment can be carried out without the need for substeps. For these reasons, this Guidance recommends the use of a process-based mechanistic approach.

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

The Guidance provides a flexible approach and allows a variety of quantitative methods to be used at different levels of complexity, from relatively rapid semiformal expert knowledge elicitation (EKE) to more sophisticated quantitative modelling, 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. In fact, statistical models, based on data, are of great value in risk assessment, for instance to assess the area of potential establishment on the basis of climate variables as is performed in climate envelope models. While 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 PLH Panel, 2016a–d, 2017a–d) and stakeholder feedback was sought via public consultation (EFSA, 2018).

1.3.2. Key users and audience

This Guidance is principally designed for assessors when 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 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) 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 that responds 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,b; EFSA Scientific Committee, 2009, 2012, 2014, 2015, 2017), international standards (FAO, 2016a, 2017a), regional pest risk analysis methods (e.g. EPPO, 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:

- Communication with risk managers on the interpretation of the Terms of Reference (ToR) set by risk managers and the translation of the 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 substeps (i.e. any subdivision of the steps) in the risk assessment, as well as standardised descriptions for RROs.
- A method for quantifying and evaluating the effectiveness of RROs that is integrated within the risk assessment methodology.

1.3.4. Two-phase approach

Phase 1: Pest categorisation (see Annex A)

Plant protection organisations and authorities need to prioritise which pests require detailed risk assessment (Devorshak, 2012; Baker et al., 2014). To efficiently use the resources available, an early section within the risk assessment process involves pest categorisation (FAO, 2017a). Pest categorisation 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 to be a preliminary assessment and can be conducted with a limited amount of information (ISPM 11 – FAO, 2017a).

Within the EU, the EFSA Panel on Plant Health developed a pest categorisation template designed around the criteria, within the remit of EFSA to assess, that are used to identify a pest as an EU quarantine pest, or as a regulated non-quarantine pest (Regulation (EU) 2016/2031, Annex 1 Section 1 and 4) (see Annex A of this Guidance). The pest categorisation template provides guidance to the assessor in the form of explanatory text within 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.

Knowledge gaps that contribute significantly to uncertainty in the categorisation phase are highlighted in the template. This helps risk managers to identify which parts of categorisation are most uncertain.

Following a pest categorisation the European Commission might request a pest risk assessment and the EFSA PLH proceeds to phase 2. If a risk assessment is requested, the results of the categorisation inform which aspects of an assessment might need a particular focus or where research may be requested.

A pest risk assessment can also be requested without a pest categorisation.

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 (Annex B), indicating for each assessment the relevant questions and data requirements. A guidance for the identification and evaluation of RROs at substep's level is also given.

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

- a standardised check list of RROs (RRO information sheets – see Appendix A).
- a procedure for systematic identification of the RROs relevant to a particular pest problem.

- a linkage between the substeps in the risk assessment methodology and the different RROs, including the assessment of the effectiveness of combinations of RROs.

1.3.5. Advantages of the quantitative approach

In developing the Guidance, the principles and the methods of this quantitative approach were applied to eight case study pests (EFSA PLH Panel, 2016a–d, 2017a–d). The case studies reveal that the anticipated advantages are real and that it is possible to develop fit-for-purpose assessments using this quantitative approach.

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

1) The assessment outcome (expression of risk, or component of risk from a partial assessment) is expressed in quantitative units with a defined relationship to real world processes and outcomes. This provides risk managers with a clearer understanding of the assessment result allowing for a more informed basis for decision-making.
2) Expressing risk quantitatively avoids the risk management connotations associated with many qualitative expressions, e.g. 'high' can imply action is needed while 'low' implies the opposite. Quantification therefore facilities clear separation between risk assessment and risk management which is fundamental to the legal remit of EFSA.
3) Choosing a target quantity for assessment that is measurable in the real world allows mechanistically based explicit linkages between subsequent steps in the assessment process and comparison or validation with measured data when available.
4) The effect of RROs can be assessed quantitatively and fully integrated in the risk estimations. 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.
5) Risk estimates and associated uncertainty can be updated transparently when new data become available.
6) Risk is expressed in quantitative terms facilitating comparison between pests allowing possible ranking and prioritisation provided that units of measurement are the same or similar.
7) Although expression of the risk in monetary units is not within the remit of EFSA, results from quantitative risk assessments can generate estimates of risk in term of costs and cost functions. Quantitative risk assessment can also generate estimates to feed into cost-benefit analysis for different options (e.g. MacLeod, 2007).

1.3.6. Challenges of the quantitative approach

1) Quantitative risk assessment is data intense (see Section 3.4). However, in many instances, there is a shortage of empirical data. EKE procedure (EFSA, 2014a) may be used to overcome this constraint.
2) Although some very relevant data may exist, there can be challenges around obtaining access to them. Maintaining an inventory of accessible databases (Kenis et al., 2009) and appropriate models for use in quantifying step-specific, or substep-specific processes (Rossi et al., 2009) could help address this challenge.
3) The use of quantitative modelling approaches may require increased resources and the development of skills on quantitative estimation (Soliman et al., 2015). However, with learning and experience, the production of assessments will become more efficient. When time and resources are limited, the methodology also makes it possible to apply more efficient possibilities to select the appropriate level of detail in the assessment, as a first tier approach (see Section 3.1).
4) The proposed approach requires the assessor to make their interpretation and evaluation about the events and processes involved in the assessment explicit. This is a step-change from a qualitative risk assessment and can be a challenge for assessors who are more familiar with previous approaches. However, being clear about the meaning and interpretation of results greatly enhances transparency and exposes the uncertainties that a risk assessor may have around their estimates.
5) 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 substeps. Assessors should aim to develop a parsimonious model (see Section 3.1).

6) There may be challenges in explaining the details of quantitative assessments to risk managers. Intensifying communication between risk assessors and risk managers will improve mutual understanding of the risk expressions. The use of quantitative terms will avoid any interpretational bias that results from the use of linguistic terms.

1.4. Guiding principles

This Guidance aligns with the IPPC International Standards ISPM 2 (FAO, 2016a) and 11 (FAO, 2017a), 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:

1) 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 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 when proposing a quantitative approach and incorporating the RROs directly into the assessment. This Guidance replaces entirely the PLH Panel Guidance on a harmonised framework for risk assessment (EFSA PLH Panel, 2010).

2) 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 RROs;
- 1.9. Quantitative pathway analysis and other quantitative tools for assessing RROs.

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

3) 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 adds the important novelty of assessing the impact on ecosystem services and biodiversity in terms of continuous uncertainty distributions, as carried out for the impact on crop yield and quality and includes the assessment of RROs.

4) 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 MS 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, 2014).
- EFSA Guidance on Statistical Reporting (EFSA, 2014a,b).
- 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 flexibility to enable assessors to develop an assessment appropriate to the data and resources available. 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 clarifying the objectives of the assessment, the definitions that are specific for the assessment, the pathways that are to be considered, the different scenarios to evaluate e.g. different RROs or removal of RROs (see Section 2.2), the conceptual model and the tools (in particular any models) to be used. For example, it may be necessary to consult with risk managers on which scenarios (in particular pathways, RROs) and which steps of the risk assessment are of most interest to them.

1.4.2. Assessment based on scenarios

Pest risk assessment, for a quarantine pest, refers to the probability of its introduction and spread and to the magnitude of potential consequences that result with regards to a defined spatial and temporal frame, i.e. the pest risk assessment area and the time horizon for the assessment. Pest risk assessment is performed on a scenario basis; therefore, the assessment is based on plausible and often simplified descriptions of how the future might develop, starting from a coherent and internally consistent set of assumptions about key driving forces and relationships. When designing 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 in which the pest is deregulated and RROs are removed. By constructing different scenarios for a pest, the probability distribution of the expected impacts can be estimated and compared, so 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 (Gilioli et al., 2017b).

As 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 (Gilioli et al., 2017b). 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.

As stated by Gilioli et al. (2017b), 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, the current situation consisting of relevant pathways and existing RROs. To account for the assessments' time horizon, the current situation is projected to a certain time point into the future. Changes in the pathways or RROs represent alternative scenarios (A_1 to A_n) and can be compared against each other and against A_0, the baseline. Clear units and values assigned to the assessed variables and parameters increase the transparency of the assessment, in this way the assessment, including the assumptions being made and the procedures being applied, can be checked using dimensional analysis (factor-label method) (Stahl, 1961).

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 by the Working Group and it has been ascertained that they are suited to answer the questions of the risk managers, 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 that are relevant to the assessment, their interactions and interdependencies, either relying on data and existing models or on expert judgement. 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 substeps, which are all characterised 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 relevant to 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 or without RROs in place (Gilioli et al., 2017b).

1.4.4. Weight of evidence approach

Weighing of evidence is an intrinsic part of the scientific process and occurs at many points in any assessment, including defining relevant scenarios, developing conceptual models, specifying appropriate quantitative or qualitative models (when used), specifying model inputs, identifying and evaluating uncertainties and deriving conclusions.

When a quantitative or qualitative model is not used, the whole assessment may be conducted by a weight of evidence process, in which expert judgement is used to reach conclusions by evaluating and reasoning from the relevant evidence. EFSA's Guidance on weight of evidence assessment defines it as 'a process in which evidence is integrated to determine the relative support for possible answers to a question' (EFSA Scientific Committee, 2017). The conclusion of a weight of evidence assessment should specify the range of possible answers to the assessment question and how probable they are. It is important to express this quantitatively when possible, to avoid the ambiguity of qualitative expression (EFSA Scientific Committee, 2017). The guidance includes an overview of qualitative and quantitative methods that can be used in weight of evidence assessment and a framework for selecting and applying them in practice.

The present guidance on pest risk analysis refers to weight of evidence assessment at several points, most importantly as an approach for first tier assessments, in which a combination of weight of evidence assessment combined with quantitative expert judgement is used instead of quantitative modelling. When time and resources are limited, e.g. for rapid assessments, both the weight of evidence and expert judgement procedures can be streamlined accordingly.

1.4.5. Quantitative reporting of risk

Probability distributions are used to describe both knowledge and uncertainty about the results of the assessment and, when quantitative modelling is used, about the parameters in the model. 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 real world. This contrasts with alternative methods expressing pest entry in terms of probability of entry without revealing the magnitude of entry (i.e. the number entering), 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 (Gilioli et al., 2017b). 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 reduction measures and the number of spatial units or area representing the endangered area – each under the different scenarios.

1.4.6. 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. So, 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. This does not mean that variability is ignored: the variability of data influences the uncertainty of parameters estimated statistically from the data. Variability should also be taken into account when assessing parameters by expert judgement (Section 3.5). Where differences between specified alternative scenarios or regions, for example, 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 both variability and uncertainty within a single assessment, but this is more complex, requiring two-dimensional probabilistic approaches (EFSA Scientific Committee, 2018b) and better left until the simpler approach is well established.

1.4.7. Consistent communication

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

- the assessment should focus on issues within the ToR;
- the results should be presented in a clear and understandable way;
- 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;
- the degree of uncertainty shall be primarily expressed by reporting an appropriate probability distribution or uncertainty interval associated with the risk estimates;
- assessments should be reported without implying any value judgements;
- 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. The objective of the pest risk assessment is to provide advice that will inform pest risk management decision-making. It is therefore 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 project (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.

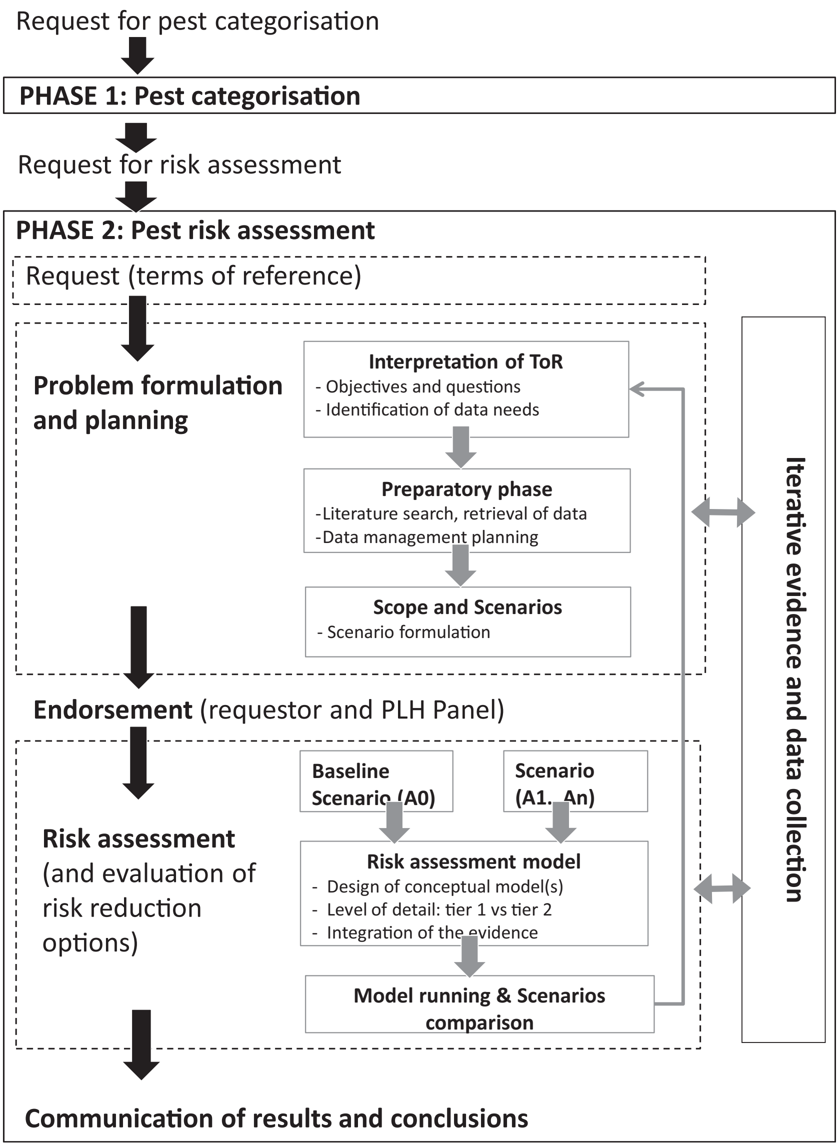


Figure 1: Conceptual framework for the pest risk assessment process and its relationship to pest categorisation

2.1.3.1. Problem formulation

The problem formulation phase is essential to provide a fit-for-purpose deliverable that focuses 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.

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 broken down into:

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

Before starting any activity of data collection and/or risk assessment, in the interpretation of the ToR, 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 ToR:

Reasons for the initiation of the risk assessment

It is recommended to scrutinise 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 ISPM 11 (Pest risk analysis for quarantine pests, 1. Stage 1: Initiation) (FAO, 2017a) and suggests that the risk assessment process may begin as a result of:

1) the identification of a pathway that presents a potential pest hazard (for example a new commodity or a new origin of the commodity, like e.g. packing material, mail, garbage, passenger baggage or natural spread);
2) the identification of a pest that may require phytosanitary measures;
3) 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?

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?

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 subquestions. 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 addressing the different subquestions can already be identified.

Scope

Depending on the specific questions of the ToR and the scope of the assessment and available knowledge and data, substeps 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 substep.

The quantities (variables and parameters) to be assessed increase proportionally with the number of risk assessment steps and substeps 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 substeps 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 substeps 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, two case studies involving partial risk assessment were conducted by the EFSA PLH Panel. The assessments considered Grapevine flavescence dorée phytoplasma (EFSA PLH Panel, 2016a) and *Atropellis* spp. (EFSA PLH Panel, 2017c). The assessment of Grapevine flavescence dorée phytoplasma did not assess entry into the EU because the organism is not known to occur outside of the EU (EFSA PLH Panel, 2016a). The partial assessment of *Atropellis* only addressed entry because there was no uncertainty regarding the ability of the pest to establish, spread or cause impact 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.

As 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 in which there is a change to the risk managers' concerns during the conduct of the risk assessment, it is possible to add additional scenarios and to modify or delete existing scenarios. Once scenarios are confirmed, the risk assessment is carried out for the selected scenarios (Gilioli et al., 2017b). 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 substeps 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/substeps (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 minimising the complexity (e.g. number of substeps 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 Working Group 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 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 Working Group, 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 focused 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 substep 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 partial or full risk assessment is carried out. 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

According to the interpretation of the ToR, only the relevant pathways of introduction should be considered. Pathways can be distinguished in a variety of ways, for example based on the host range and geographical distribution of the pest, trade flows, plant parts traded and method of transport. Pathways can be defined very broadly, for example plants for planting from countries where the pest is present. A pathway can also be defined more narrowly, for example for a specified commodity, from a specified area processed in a specified manner and shipped at a specified time of year arriving at a specified destination in the risk assessment area with a specified intended use. Additional pathway descriptors can add further complexity to the range of possible pathways (MacLeod and Baker, 2003).

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 when appropriate. For a list of examples of pathways see Table 1.

Table 1: Examples for pathways (from EPPO Express Pest Risk Assessment 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	
Fruits or vegetables	*Other possible pathways*
Grain	Other packaging material
Pollen	Soil/growing medium as such
Stored plant products	Conveyance and machinery
Natural spread	Passengers and passenger baggage
	Plant waste
	Manufactured plant products
	Intentional introduction (e.g. scientific purposes)

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 (although it might need to be considered in a precautionary way, if there is the chance that trade will be set up in the future).
- It may be worthwhile to first assess the risk of transfer before including the pathway in a risk assessment. If 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), when 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 EKE 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. 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.

Based on the data available and the needs of the assessment, the following units may be used 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 tonne 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 subunit: In some cases, it is necessary to consider that the pathway unit is composed by several elements. A pathway subunit 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 subunit may or may not be affected.

Transfer unit: A unit composed by one or more pathway units or subunits, which move as a cluster within the risk assessment area and carry 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. For 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 Member States, the LAU2 and 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. For example, 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. kilograms of olives per tree, tonnes 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 subunits 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 tonne of seed potatoes, the number of nematodes in 1 tonne of soil.
- For the subunit, a possible definition of the abundance is the number of individuals present on it, e.g. four thrips per rose, two nematodes per potato tuber.

The units for the abundance of the pest could be defined in different ways in different sections of the assessment. Risk assessors need to define units taking into account the information available, the nature of the processes of entry, establishment, spread and impact and the requirements 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 to be 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 should consider the time horizon in which the assessment is performed (e.g. consideration of a time horizon of 1 year, 5 years, 30 years, etc.), 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 1 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 1 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 1 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 commodity pathway can be characterised by different processes involved during the production and trade of the commodity. Understanding these processes can help the assessor identify when phytosanitary measures can be implemented.

For each process of the pathway, a 'critical point' can be identified when the commodity 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. Examples of generic processes are shown in Table 2.

Table 2: Example processes and critical points on a pathway

Production and trade process	Critical point (where and when RRO may be applied)
Ensuring a pest free environment	At origin or place of production; before and during production
Production of the commodity	At place of production; timing can depend on phenology of commodity and pest
Preparation of the consignments (packing, grading, culling)	At relevant sites of production and preparation; post-harvest, pre-export
Transport	Within conveyance or container; during transport
Storage	At storage site; during storage
Arrival in risk assessment area	Point of entry; before customs clearance
Intended use of commodity	Specified restricted areas or for restricted purposes at restricted times

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

The Panel recommends keeping the description of the processes as simple as possible, although 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

Risk reduction options contribute to reduction of the pest population abundance assessed at each step (see Section 3.2.1). A RRO may become a phytosanitary measure, action or procedure according to the decision of the risk manager. Tools were developed to guide the assessors in the systematic identification of the relevant RROs for the baseline scenario (and alternative scenarios, see Annex E). The result of this process is the identification of the model components corresponding to the risk assessment substeps for which the identified RROs have a combined effect on a same sub step of the risk assessment (e.g. cultural practices and waste disposal; roguing and pesticide treatment).

For detailing the RRO components of the baseline scenario (A_0), it is necessary to interpret the current EU-legislative requirements, 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 or more regulated pest. When formulating alternative scenarios the non-pest-specific RROs cannot be removed or altered.

Pest-specific requirements laid down in the EU legislation

In the EU legislation (Council Directive 2000/29/EC), pest-specific requirements for import and EU-internal trade are specified in Annex IV of this Directive. In accordance with 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.

Non-pest-specific requirements laid down in the EU legislation

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.

Standardised checklist of RROs

To harmonise the use of RROs across the forthcoming EFSA PLH opinions, a comprehensive list of specified RROs was compiled that should be used to select the relevant RROs for the scenarios in the assessment (Appendix A). For the specified RROs, information sheets are developed that contain the definition, description, examples and limitations of the RRO. The links to the latest versions of the information sheets are available in Appendix A. Some RRO information sheets are still under development and are not yet published.

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, 2017b), production places (Pest Free Place of Production (PFPP) ISPM 10: FAO, 2016b) and consignments (Pest Free Consignment (PFC) EPPO standard phytosanitary measures (PM) 3/72(2) (EPPO, 2009); ISPM 12 (FAO, 2017c) and ISPM 23 (FAO, 2016c)). 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 highest protection level is the PFA, then comes the PFPP and then the PFC, 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 PFA. A PFA may include many places of production. Within the EU the PFAs correspond largely to protected zones. By definition all places of production and commodities produced in an officially recognised PFA are free from the specified pest. A PFA is managed as a whole by the National Plant Protection Organization (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, 2016a), 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 (ISPM 10 (FAO, 2016b)).

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 PFCs 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 PFC 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, 2016d) (Integrated measures for plants for planting). See for example the *Diaporthe* opinion (EFSA PLH Panel, 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.

Prevention

Prevent pest introduction by importing from a pest free source or with pest free consignments

- **Establish a pest free environment before production of a host commodity**
  - Pest free area
  - Pest free place of production
  - Pest free production site
- **Establish pest free consignment**
  - 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

- **Delimit infested regions**
  - Eradication
  - Containment
  - Low pest prevalence
- **Delimit pest free regions (protected zones)**
  - Maintain pest free status

Correction

Figure 2: Overview of risk reduction options to prevent introduction, spread and impact of quarantine plant pests. From top to bottom, the emphasis shifts from prevention to correction or containment. Terminology is aligned with that of ISPM 11 (FAO, 2017a), 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 substep 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 substeps chosen for the risk assessment (Section 3.1). For each step (or substep), the RRO or RROs implemented at that substep must be specified. The set of RROs implemented at a substep is referred to as the 'RRO combination' for that substep. The effect on pest population abundance at that substep 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 substep reflect the effect of the RRO combination as implemented in current phytosanitary legislation.

The model output under the baseline scenario should be scrutinised 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 substep 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 substep 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 substep 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). 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 E, 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 organising 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 risk assessment is not to have a characterisation in full detail of all processes relevant to entry, establishment (including transfer), spread and impacts. Having a full characterisation is a never ending process and is not a fit-for-purpose aim of assessment. Risk assessors need to prioritise 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 RROs. 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 and in consideration of the related time and budget constraints this guidance proposes a tiered assessment approach.

A tiered approach is one in which a base level quantification (first tier) is carried out directly assessing the uncertainty distribution of the result for each step (Entry, Establishment, Spread and

Impact) or only some of these and scenarios without detailed modelling (quantifying only the endpoints of the relevant steps without considering the substeps). These first tier assessments should be based on the evidence normally considered in pest risk assessment, tailored to the time and resources available. Because of the benefits of quantitative expression, discussed in Section 1, it is recommended to quantify the result for each step and its uncertainty using expert elicitation. The first tier approach can be used in cases for which pest risk assessment needs to be developed in very short time and/or the details on the processes on the substep level are not required. The first tier approach is being applied by EFSA for the assessment of the impact step (in terms of yield and quality losses and needs for additional treatments with plant protection products) of the candidate Union quarantine priority pests, to support a multivariate economic analysis conducted by the Joint Research Centre of the European Commission,[3] with the aim of listing the pest as priority for the EU in accordance with Article 6 of the Regulation (EU) 2016/2031 (referred to here as the new Plant Health Law). An example of such an application is provided in Annex C of this Guidance).

A second (more detailed) tier assessment using modelling is carried out when necessary and considering the time and resources available. The decision to proceed to tier 2 will also be based on the assessors' judgement as regards the extent to which the usefulness of the assessment result may be increased by additional detailing and quantification.

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 and how detailed it should be:

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 drawing up 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.

All models are necessarily simplified representations of the real world, focused on the most relevant pathways and processes. Assessors should make a list of other relevant pathways and processes that are potentially relevant to the assessment scenario but omitted from the model, so that their impact on the risk can be evaluated as part of the overall uncertainty assessment (see Section 3.7).

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 prepare 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 assessment aims at

[3] Request from European Commission DG SANTE to EFSA for technical assistance pursuant to Art. 31 of Regulation (EC) No 178/2002 in the field of plant health as regards the list of Union quarantine pests qualifying as priority pests under Regulation (EU) 2016/2013. The mandate can be consulted in EFSA Register of Question at http://registerofquestions.efsa.europa.eu/roqFrontend/ListOfQuestionsNoLogin?3&panel=ALL

quantification of the expected total entry, establishment, spread and impact over a specified time frame, for defined scenarios. The units are observable quantities in the real world. Uncertainty is explicitly accounted for; hence the final outcomes are given as distributions reflecting the confidence of the assessors in their estimates of the assessed quantities. These uncertainty distributions are constructed using a quantitative model with parameters that are specified by the assessors, including parameter uncertainty (see Section 1.4.5). The quantitative risk assessment framework is designed to estimate the following endpoints for the four steps:

Entry: Total number of potential founder populations in the EU within the chosen time horizon, 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, in which 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 total 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. Founder populations assessed in the entry step are potential founder populations. Conversely, founder populations assessed in the establishment step are realised (actual) founder populations. The potential founder populations derive from encounters between propagules and hosts. However, few encounters may result in an established population, for instance because the weather conditions are not suitable, or the initial population size is too small to be successful due to demographic stochasticity. Hence, there will be (much) fewer actual founder populations than potential founder populations.

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 (by natural means or human assistance) 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 (weight of evidence approach; EFSA Scientific Committee, 2017)) 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 (e.g. proportion of citrus fruit infected with *Phyllosticta citricarpa* for 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 with a host plant 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 characterised by specific substeps in which the abundance of the population is assessed and transitions in which a series of processes modify the abundance in the pathway units/subunits. The effects of these processes are represented by a multiplication factor changing the abundance of the population from one substep to the next. To account for uncertainties in the estimation of the multiplication factors, quantiles of their expected values are requested.

Five substeps 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 (substep E_1).
- Abundance when crossing the border of the exporting country (substep E_2).
- Abundance when arriving at the EU point of entry (substep E_3).
- Abundance when leaving the EU point of entry (substep 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 (substep E_5).

For the first substep, the initial conditions for the assessment are defined as the estimated pest abundance in the countries of origin or exporting countries (if they are different), 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 five 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 substeps are calculated, considering the estimated distributions for the multiplication factors. These distributions have to be estimated by the assessors. The values for the five 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.

If 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/subunit), 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. Overall entry is calculated as the sum of entry across all pathways. Based on the quantification of total entry and entry per each pathway, 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 establishment factor accounting for the number of actual founder populations across the EU, given the number of potential founder populations. The elicited establishment factor is defined as the overall average establishment probability per propagule entering the EU territory. The estimate for this probability should be made by expert judgement, based on the available evidence (weight of evidence approach; EFSA Scientific Committee, 2017) and should be expressed in the form of a 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 for establishment. 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 geographical 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 *Diaporthe vaccinii* (EFSA PLH Panel, 2017b). Niche modelling and mapping of areas of potential establishment take into account host or habitat presence and suitability of climatic conditions in the new territory. Such models take into account data from areas where the organism is present, including the native range (Fitzpatrick et al., 2007; Peterson and Nakazawa, 2008; Jarnevich et al., 2015; Kumar et al., 2015).

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 be established for the selected temporal and spatial scales (as selected in Section 2.2.1.4).

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

The first tier assessment of spread should give an estimate of the invaded territory or area of hosts or habitat affected as a result of entry, establishment and spread over the defined time horizon. This entails a direct assessment (weight of evidence approach; EFSA Scientific Committee, 2017) 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 were 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 *Ditylenchus destructor* (EFSA PLH Panel, 2016b), *Radopholus similis* (EFSA PLH Panel, 2017a), *E. lewisi* (EFSA PLH Panel, 2017d) and *Diaporthe 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 (*Diaporthe vaccinii*), plant to plant spread of the pathogen was also included in the spread model. Two opinions (*R. similis* and *E. lewisi*) considered that a larger unit (e.g. 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 *Ceratocystis platani* (EFSA PLH Panel, 2016d) used the NUTS-3 region, the one on *Cryphonectria 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 initialised 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. The opinions on *Ceratocystis platani* and *Cryphonectria 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 substeps 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. 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 in the numbers of spatial units occupied by the pest due to the spread is broken down 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 in the 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 five quantiles is given. The spread process can be modelled by cell occupancy model (a simple spatial implicit meta-population model) represented by a discretised differential equation describing the temporal dynamics of the spatial units occupied by the pest.

The quantification of spread takes into account both natural and anthropogenic mechanisms. The way in which these mechanisms are modelled and taken into account is tailored to the requirements of the assessment (see Section 3.3.3.3 for modelling options).

3.2.5. Impact

Two impacts need to be assessed: on the plant production system and on the environment. The first tier is a direct assessment (weight of evidence approach; EFSA Scientific Committee, 2017) 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 or area unit. This is straightforward. This was carried out in opinions on *Ditylenchus 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 impacts of pest introduction on crop yields and quality and environmental impacts e.g. impacts on ecosystem services or biodiversity components. The impact on crops, on ecosystem services and on biodiversity depends on factors such as the temporal and spatial abundance of the pest in the occupied spatial unit. It is important 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. Estimated impacts on crops should be based on expected yield loss under current production practices, recognising that existing practices might provide collateral protection against new pests.

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

The assessment of the impact on the crop is carried out considering the change in the production unit (relative impact). The assessment of the impact on the environment is carried out considering the level of provision of ecosystem services and components of biodiversity. As 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 performed 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 the 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 are set as 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 reduction measures (estimated as the number of spatial units occupied by the pest requiring additional risk reduction 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:

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

For each of the factors required a distribution over five 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. So, 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. Fundamental niche maps may be needed to inform where entry may result in establishment and further spread.
3) In the spread step, the template provides an option to account for spatial heterogeneity within the EU by applying 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. The grain size of the spatial unit (e.g. NUTS-2 vs. 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 (*Diaporthe vaccinii, Ditylenchus destructor, E. lewisi, 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 option makes the calculation of impact easier.
4) The impact step is again conceptualised 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 (*Diaporthe vaccinii, Ditylenchus destructor, E. lewisi, R. similis* – see EFSA PLH Panel, 2016b, 2017a,b, d), impacts in natural areas were not accounted for. Impact on the plant production system' 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 conceptualised in terms of the number of colonised administrative regions the risk assessors should assess the density of the pest within these areas (e.g. opinions on *Ceratocystis platani* and *Cryphonectria parasitica* - EFSA PLH Panel, 2016c,d). The issue of density is multiscale and concerns what proportion of fields within a given NUTS area would be infested. It would also be concerned with what proportion of the plants in infested fields would be infested. And finally, it would be concerned with the density of the pest or the severity of disease on the affected plants. Modelling these multiscale processes is extremely complicated and therefore beyond the scope of the risk assessment, but these multiscale issues are amenable to expert judgement. Risk assessors are advised to use expert judgement to assess any impact if they model spread on the basis of administrative regions.
5) In each step, it will be necessary for the assessors to choose from a range of possible models. There is no 'correct' model. Whatever model is chosen, assessors must take account of the uncertainties associated with it, i.e. how closely its results are expected to

represent real outcomes. This should be carried out as part of the assessment of overall uncertainty (see Section 3.7). In addition, sensitivity analysis will help the risk assessors to identify which sources of uncertainty have most impact on the assessment conclusions. If results are inconclusive this may trigger additional effort to reduce the uncertainties in a tiered approach (see Section 3.9.6).

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, etc.); A_0 represents the current scenario.

Different substeps are defined by an integer following the letter of the step, e.g. E1 is the first substep of the Entry step; B2 is the second substep of the Establishment step.

Variables

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

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

Y = represents an area, a letter (E, B, S, I) and a number (1, 2, etc.) in the subscript specify to which step and substep it refers to (e.g. Y_{S4} represents the area occupied in substep 4 of the Spread step).

I = represents an impact, a number (1, 2, etc.) in the subscript specifies to which substep of impact it refers to (e.g. I_1 represents the impact on crop yield in substep 1 of the Impact step).

T = represents a time horizon.

Parameters

e = a generic parameter appearing in the model for entry (with a subscript 1, 2, etc., 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, etc., 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, etc., 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, etc., 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 the publications where they are reported, are given.

3.3.3.1. Entry

When the experts are interested in considering many subprocesses in the quantification of entry, they engage in what is called 'pathway modelling' (Douma et al., 2016). Pathway modelling is a formalisation 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 conceptual pathway model with substeps can be visualised as in Figure 3.

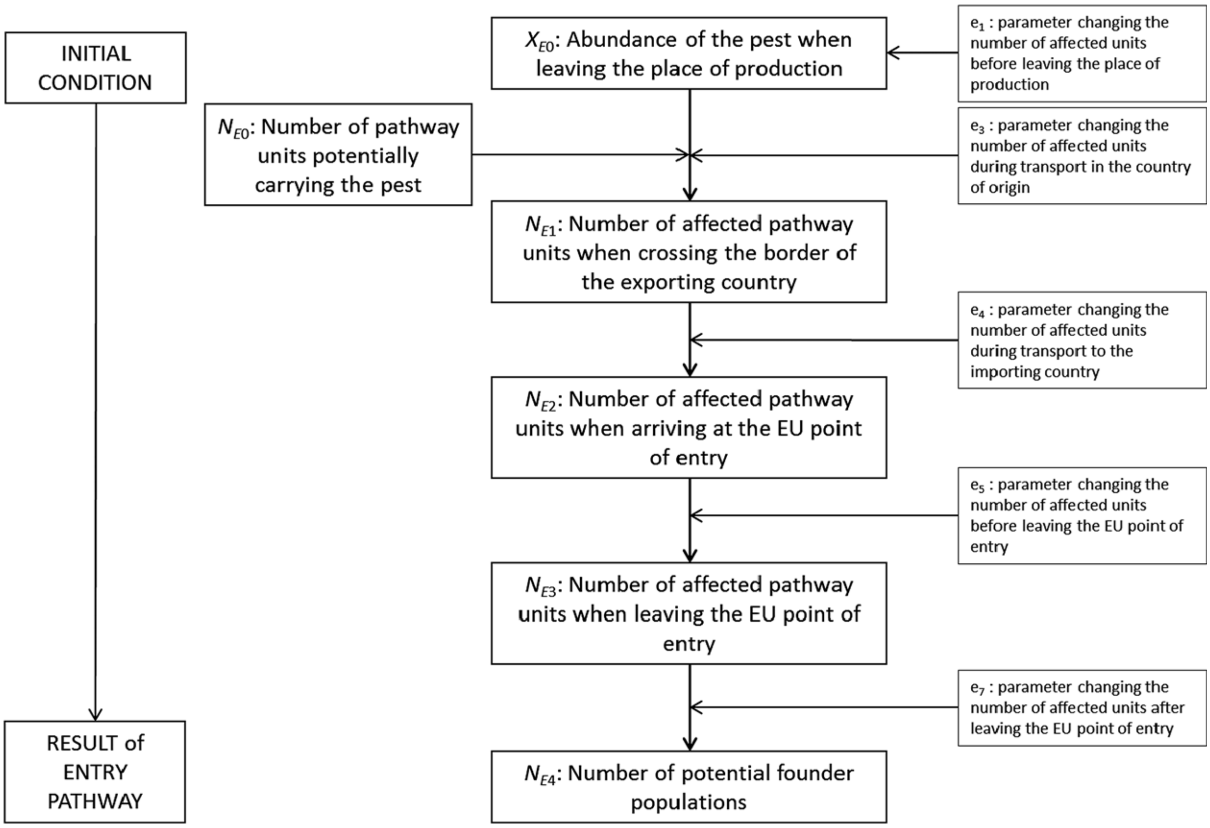


Figure 3: A conceptual pathway model with substeps

A full mathematical description, representing the formal model, is given in Appendix B.

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;
- the number of founder population they produce.

In many risk assessments published by EFSA in the past, a list was provided of countries of origin and the size of the trade flow from those countries. 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 (MacLeod and Baker, 2003). Risk assessors need therefore to find a way to prioritise and aggregate countries of origin in clusters that show similarity in the factors affecting abundance of the pest in the trade. Prioritisation can be carried out 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 by 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 prioritised 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 3 may be helpful in prioritising pathways.

Table 3: 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 3 already represents a simple pathway model, which can be specified formally as:

$$N_{transfer,i} = N_{import,i} \times p_i \times t_i$$

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 RRO 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,

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

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.

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 undertake 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. 1×, 2×, 3×) 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 albeit at a (very) low level of abundance (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 (Citrus black spot 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 pest population that will persist for the foreseeable future (see Figure 4). For the risk assessment, 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 localised 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 that 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 categorisation and pest risk assessment is based on using hardiness zones or Köppen–Geiger maps of climate (Rubel et al., 2017; http://koeppen-geiger.vu-wien.ac.at/). 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 et al., 2005). According to Kearney et al., 2010 correlative species distribution models (SDMs) are widely used to predict the spatial distribution of species and impacts of climate change on the potential area of establishment. Thomas et al. (2004) exploit the statistical association between spatial environmental data and occurrence records to capture implicitly processes limiting the distribution of the species. Techniques for fitting SDMs have developed rapidly over the past 20 years (Guisan and Thuiller, 2005; Elith and Leathwick, 2009). Correlative SDMs convey practical advantages over more mechanistic modelling methods due to the simplicity and flexibility of their data requirements, their relative ease of use within freeware packages, and the range of the interactions (biotic and abiotic) they can detect and characterise (Kearney et al., 2010). New methods for species distribution models are becoming available to estimate fundamental niche, e.g. SDM (Naimi and Araújo, 2016) and biomod2 (Araújo and New, 2007). Process-based (i.e. mechanistic) demographic models can provide meaningful information for 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 suited not only for assessing the establishment but also for the impact as the population abundance represents the main driver determining the pest impact on the cultivated plants and on the environment.

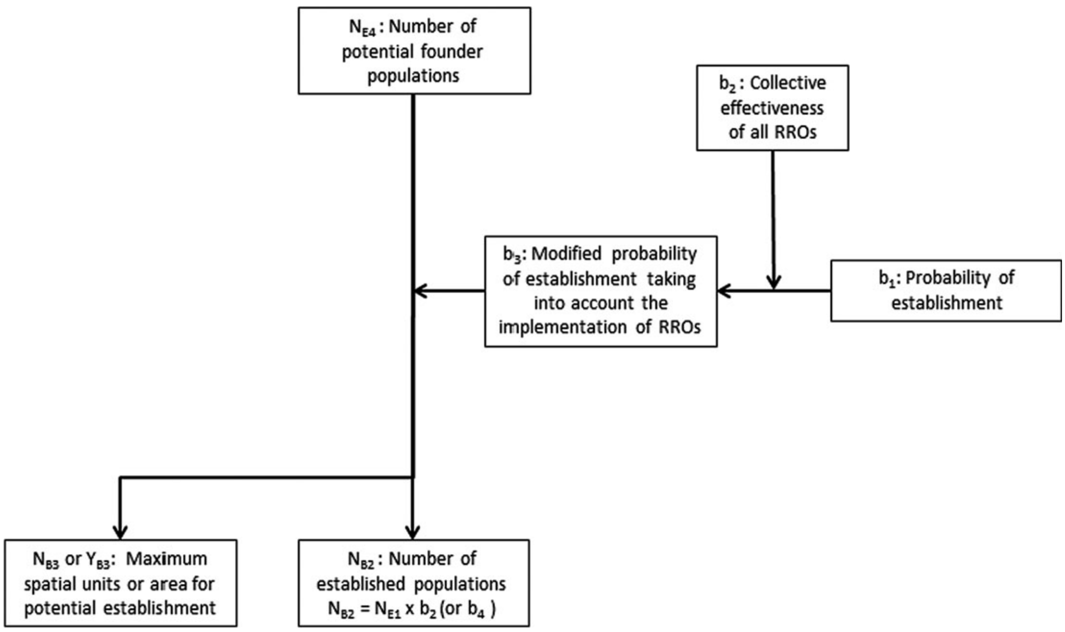


Figure 4: Information flow in a conceptual model of the establishment step

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. Conversely, 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 the absence of hosts or unsuitability of the climate, whereas 1 means that the area is highly suitable. It would therefore usually 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. Conversely, if logistic regression is used to predict the probability of establishment, the resulting model outputs can be directly used as probabilities.

Risk assessors may use maps of establishment potential in quantification of the expected number of founder populations by carrying out EKE 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 1 or close to 1 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 *Ditylenchus destructor* and *R. similis*, (EFSA PLH Panel, 2016b, 2017a), it was considered that the pest was introduced with a living host as planting material, resulting in a probability of (near) 1 that introduction would result in establishment of a local population that would persist. The same is probably true for fungi in wood that 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 *Ceratocystis platani* (EFSA PLH Panel, 2016d) and *Cryphonectria 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 of 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 decision support scheme 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, although it may be (partly) available in specific industries.

Approaches for spread modelling used in recent risk assessments by the 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) (*Ditylenchus 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, *Ceratocystis platani* – EFSA PLH Panel, 2016d and *Cryphonectria parasitica*- EFSA PLH Panel, 2016c) (details on this model are reported in the appendices of the above-mentioned EFSA opinions).
- Matrix modelling (*Diaporthe 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.

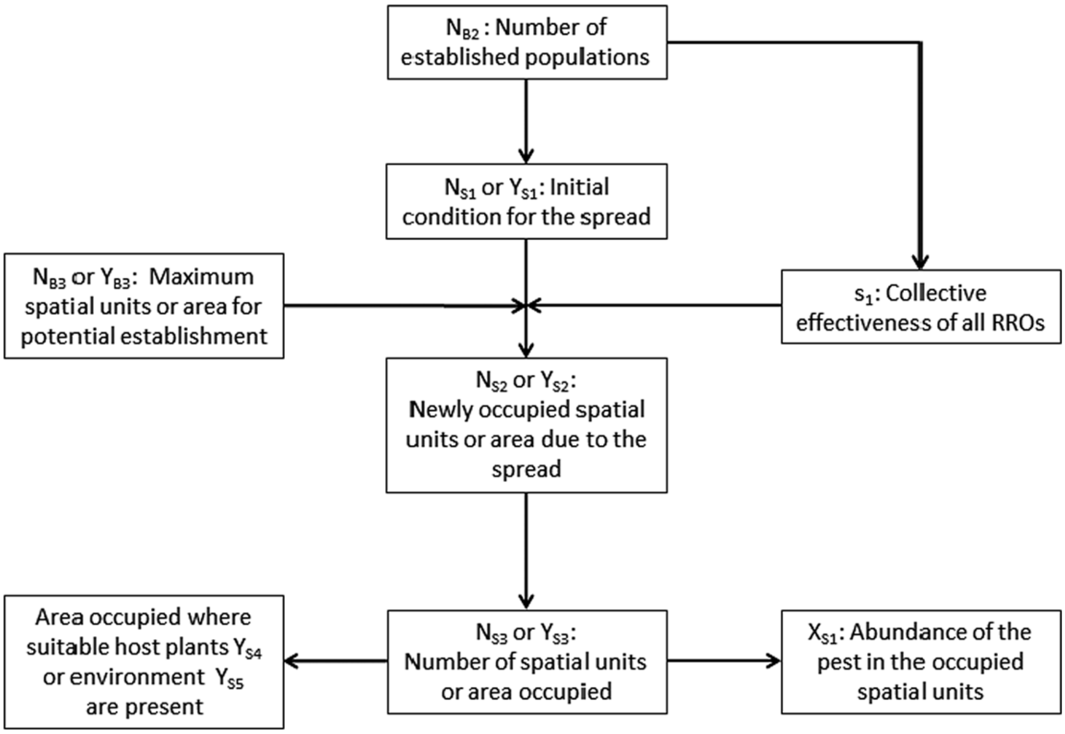


Figure 5: Information flow in a conceptual model of the spread step based on occupancy of spatial units, such as NUTS regions

3.3.3.4. Impact

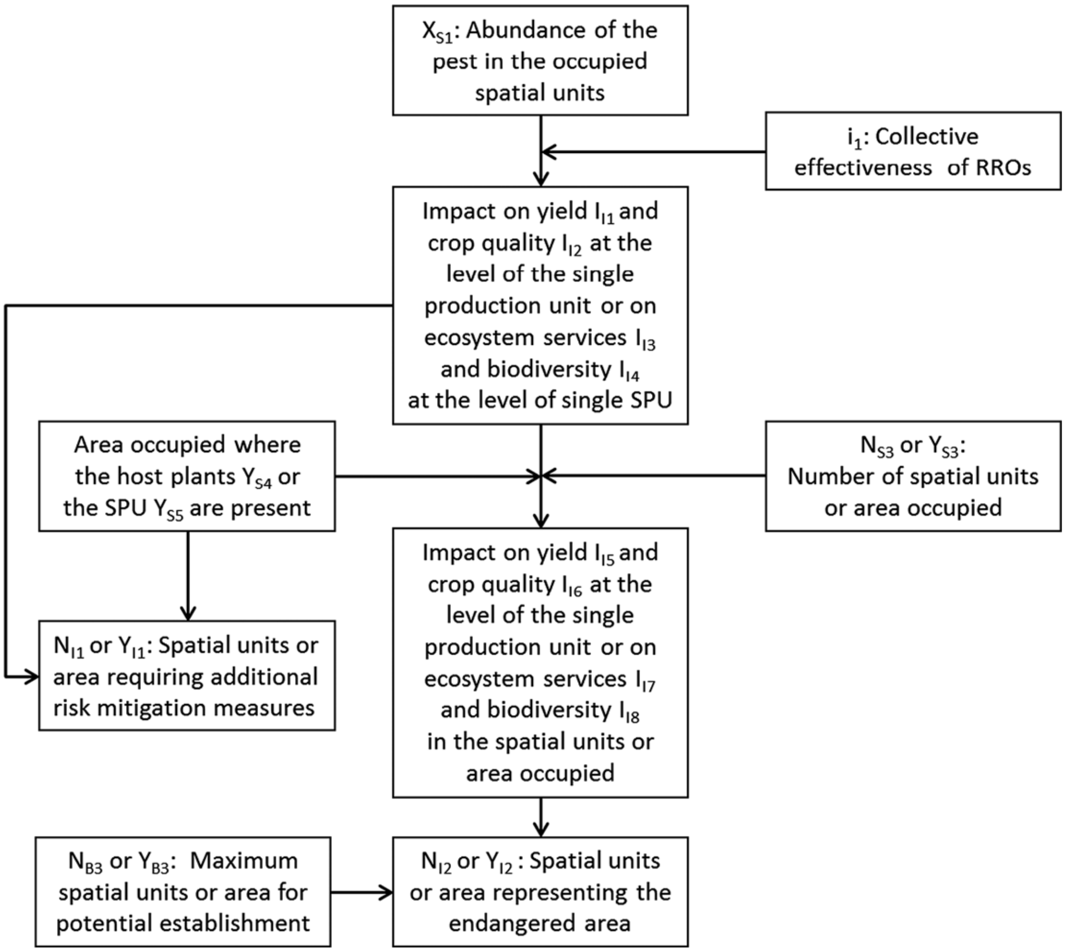


Figure 6: Information flow in a conceptual model of the impact step

Models for impact are usually simple dose–effect relationships, in which 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, 2017a,b). 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 materialise. 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 judgements required within the assessment process. The types of information required for pest risk assessment are outlined within the ISPM 11 (FAO, 2017a). The European and Mediterranean Plant Protection Organisation (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 and surveillance methods;
- 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;
- risk reduction options.

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 ToR.

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 applied (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 (MacLeod, 2015; FAO, 2017a). This information may not be publicly available although it could potentially be provided on request. Sharing information on 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, 1997). 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). 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 (FAO, 2017a) 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 the 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 on pest risk (Kolar and Lodge, 2001; Baker and MacLeod, 2005; Devorshak, 2012). In particular, there is often a lack of detailed information on events on pathways.

In many situations, risk assessors are constrained by data availability and need to use what information is available to inform judgements, for example extrapolating from partial historical data and data from where the pest occurs, to assess potential future events in a different geographical 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. When using information about a surrogate organism, assessors should justify the choice of the surrogate species.

Further guidance on making expert judgements due to the lack of specific information is discussed further in Section 3.5.

3.4.4. Transparency

The 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 Scientific Committee, 2009).

To ensure transparency in risk assessment, uncertainties should be identified, characterised 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 appropriate mathematical tools to represent uncertainty in a risk assessment (EFSA Scientific Committee, 2018b). Uncertainty about whether a specified event or outcome will occur can be quantified as a probability for that event or outcome, while uncertainty about the value of a quantity that has a single true value can be quantified as a probability distribution for that quantity. Probability distributions can also be used to quantify variability but are not used for that purpose in the approach taken in this Guidance, as is explained in Section 1.4.6.

This section provides guidance on how to obtain the probabilities or distributions that are needed. This should include statistical analysis, if relevant and reliable data are available (Section 3.5.1). If such data are lacking, or there is a mixture of quantitative data and other types of evidence to consider, probabilities or distributions may be obtained using expert judgement (Sections 3.5.2 and 3.5.3). The resulting probabilities and/or distributions are used as parameter inputs within the risk assessment models.

3.5.1. Obtaining probabilities and distributions from data

There exist in general two statistical approaches for obtaining probabilities and probability distributions from data, respectively Bayesian methods that provide a probability distribution directly and frequentist methods in which probability distributions are derived from confidence intervals, or from samples of possible values produced by bootstrapping. See Section 11.2 of EFSA (2018) for an overview of relevant statistical methods and 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 the text for consideration later, by expert judgement, as part of the overall uncertainty assessment (see Section 3.7).

3.5.2. Obtaining parameter distributions by expert judgement

Data to estimate the parameters needed in plant health risk assessments, e.g. on future trade imports, are commonly absent or of limited relevance and reliability. Therefore, parameters will frequently be assessed by expert judgement. Expert judgements must be based on evidence. The evidence may include quantitative data and/or estimates from statistical analysis as well as 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, 2014a,b). EFSA (2014a,b) Guidance on EKE describes formal methods that are designed to counter those biases: these maximise rigour, but require significant time and resource. EFSA (2014a,b) 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 Scientific Committee, 2018a).

The present Guidance uses a semi-formal approach to eliciting probability distributions for parameters, based on the Sheffield method (EFSA, 2014a), because this is more practical than other elicitation methods within the context of EFSA's pest risk assessments. 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. EFSA (2014a) recommends using 6–8 experts for the Sheffield method. In practice, pest risk assessments are often conducted by small groups of experts and, for some parameters, only one or two group members may have specific expertise. It is strongly recommended that at a 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. Consideration should be given to involving additional experts (from outside the Working Group, if necessary) for elicitation of the most critical parameters, especially if these have important consequences for decision-making. 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 plausible range for the parameter, then a median, then quartiles; this sequence is designed to counter over-confidence, anchoring and other potential biases (EFSA, 2014a). 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 relevant and reliable 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, Scientific Committee 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 is recommended 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. The experts should 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, in years and derive an annual 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.

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. Various software solutions are 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, in which the information in the uncertainty distributions are calculated by randomly drawing sample values by simulation. The uncertainty calculations require 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 specialised 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.

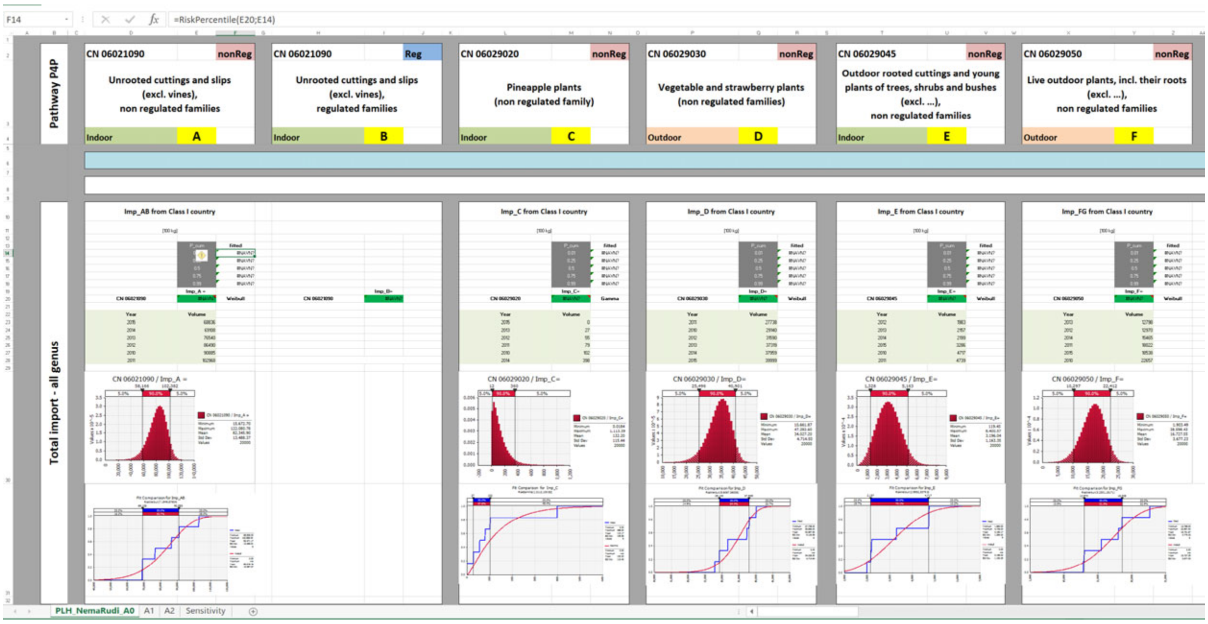


Figure 7: Screenshot of parameter specification for a part of a risk model using @Risk™ and Microsoft Excel™. The current example is taken from the EFSA risk assessment of *Radopholus similis* (EFSA PLH Panel, 2017a)

Figure 7 shows an example user interface where @Risk™ and Microsoft Excel™ are used to fit uncertainty distributions to quantile value estimates obtained by expert elicitation during work on the EFSA risk assessment for *R. similis* (EFSA PLH Panel, 2017a). 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. Some examples of risk model implementation and calculation are provided in Annex D.

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 on the model and its parameters that assessors did not 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 on 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 Guidance on Uncertainty (EFSA's Scientific Committee, 2018a) explains why it is 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 Scientific Committee (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). Further guidance on identifying uncertainties is provided by EFSA (2018), including tables listing common types of uncertainty affecting models and their inputs.
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 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 EKE (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 that the potentially unquantifiable uncertainties have no impact and address the latter through the approach described in the following section (Section 3.9).

The relationship 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 A_0 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 an underestimation of some risk factor, or exclusion of 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 a specified outcome 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 A_0 it is and likely (66–90% probability) that there will be more than 100 founder populations. EFSA's Guidance on Uncertainty analysis (EFSA Scientific Committee, 2018a) includes an approximate probability scale that defines a set of probability ranges for this purpose, including the examples given above and other ranges can be used if they better express the experts' judgement. Judgements of this type could be made for any outcome that was thought to be of interest for decision-making (e.g. more than zero founder populations, or exceeding some threshold of interest).

Adjustments or judgements of the types illustrated above should be reasoned expert judgements based on evidence (including expert knowledge) and the basis for these 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 Scientific Committee, 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 undertake 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 carried out 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 of which assessors are aware. It does not apply to 'unknown unknowns' – things that might change the assessment in the 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 for which 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 Panel opinions expressed pest risk in entirely qualitative terms (e.g. EFSA PLH Panel, 2011, 2013). In contrast, the current Guidance advocates the expression of risk in quantitative terms, by asking assessors to express (imperfect) knowledge and judgements 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 when interpreting risk information in such a way. Guidance is therefore provided here that aims to facilitate the communication of the quantitative aspects of the results from risk assessments and the evaluation of RROs. It is anticipated that harmonising 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 on how results are presented, outputs will be more consistent and users should come more quickly 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 aims to help to clearly present and communicate risk assessment results and to compare results between scenarios. As the purpose of risk assessment is to inform risk managers about the nature and potential magnitude of risk and so 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 the main body of text and appendix serve a different purpose and they should report results in a 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 70–200 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 that allows novel tools and techniques to be used and involves a terminology with which risk assessors and risk managers are perhaps unfamiliar. 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 carried out 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 in which 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, recognising 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 (Seynaeve and Verbeke, 2017) or may be estimated directly without substeps 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. When prohibition of a commodity is the RRO being considered, the pathway becomes closed and the number of founder populations being introduced will be zero. However, prohibition may incentivise smuggling activity of the prohibited commodity, giving rise to new pathways for assessment (NAPPO, 2014) and considered with additional uncertainties.
- 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 judgement, 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 Section 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 emphasised, when appropriate, by reporting the results in text form, provided that these have clear quantitative meaning. For example, the EFSA Animal Health and Welfare (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 Panel, 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 judgements (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).
   a) 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 substep (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 substeps 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).

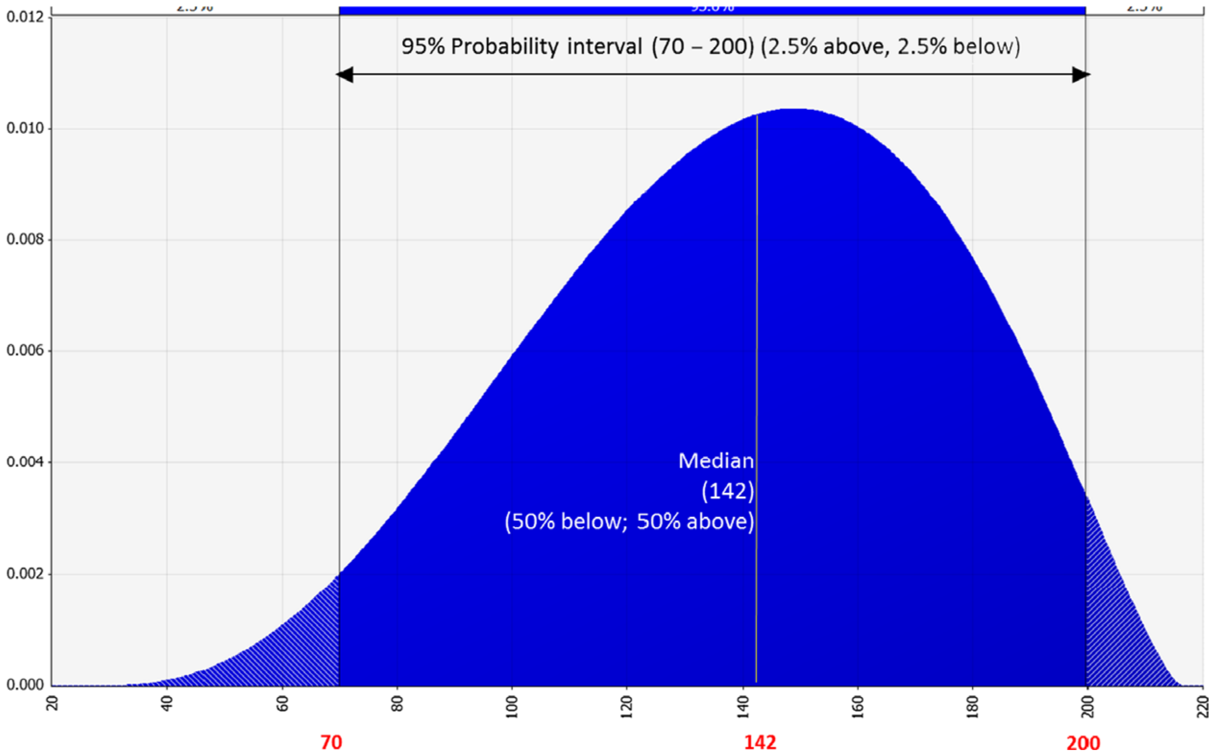
Additional uncertainties affecting the previous step should also be taken into account when assessing overall uncertainty for the relevant/current step, but can be listed as a single item in the uncertainty table for that relevant step, with a reference back to the table in the previous section.

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.

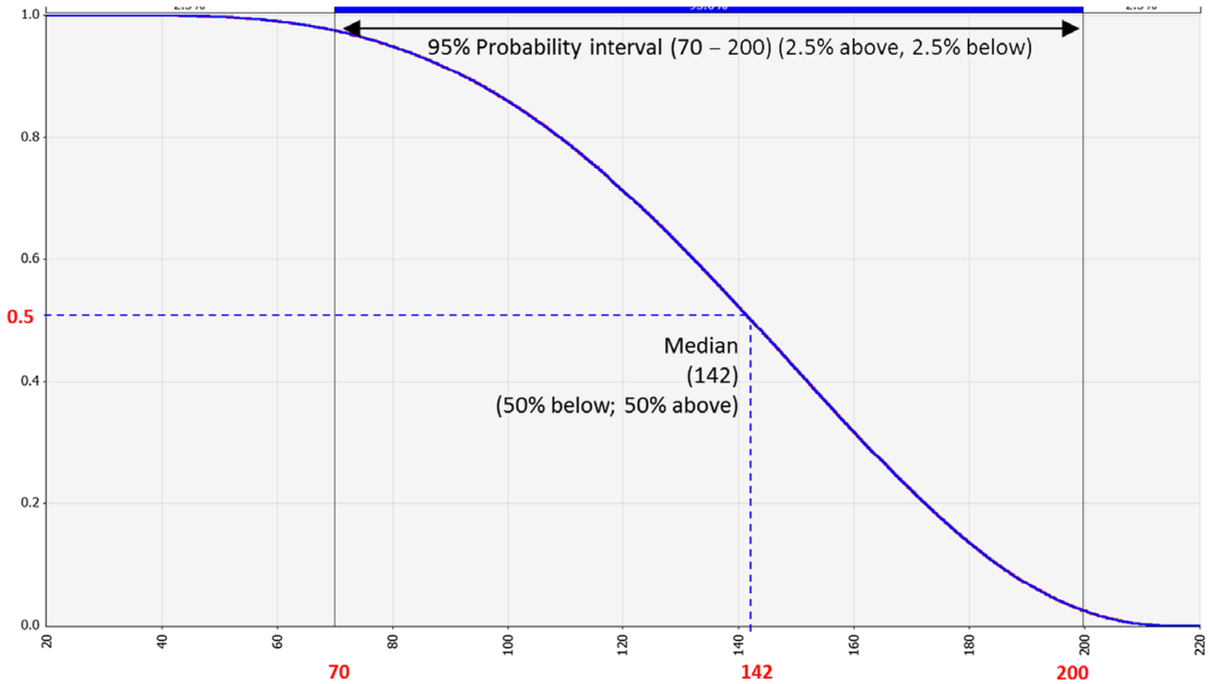
Much information can be obtained from such graphs. The curve describes the shape of the distribution. Rare or unlikely events (numbers) are represented at the shallow tails of the curve. The area between two points on the curve is the probability that an unknown value will fall between the two points. So 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 draft conclusions; they are not themselves the conclusions. Verbal terms and relevant numbers (rounding) should be used to reflect uncertainty.



X-axis label: Number of potential founder populations (Scenario A_0).
Y-axis label: Probability density.
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 A_0

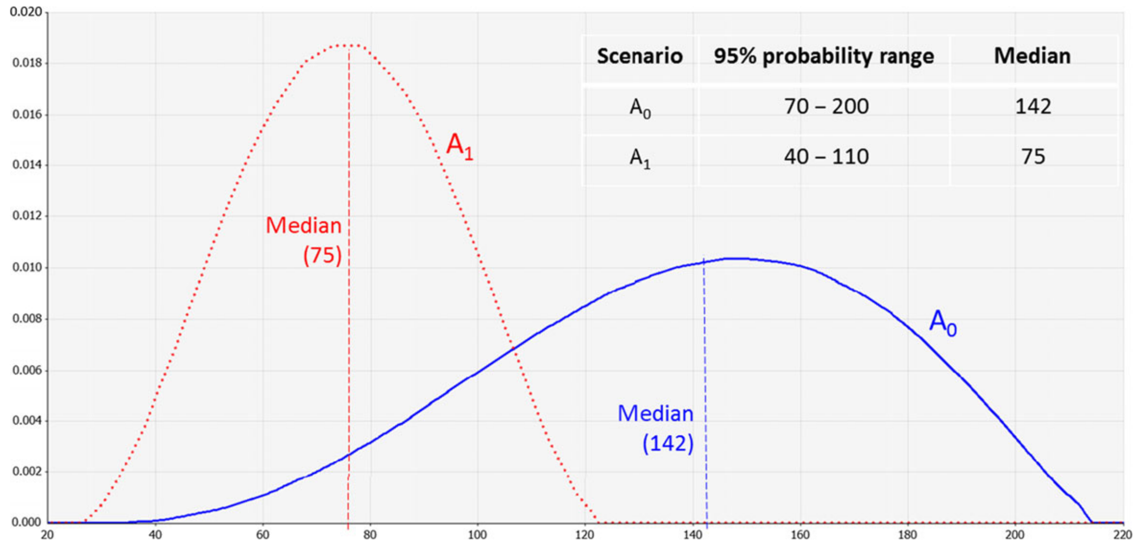


X-axis label: Number of potential founder populations (Scenario A_0).
Y-axis label: Cumulative probability.
Here the data from Figure 8 are shown as a descending cumulative probability plot. Reading across from 0.975 on the vertical axis, indicates that there is a 0.975 probability that the number of 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 A_0

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

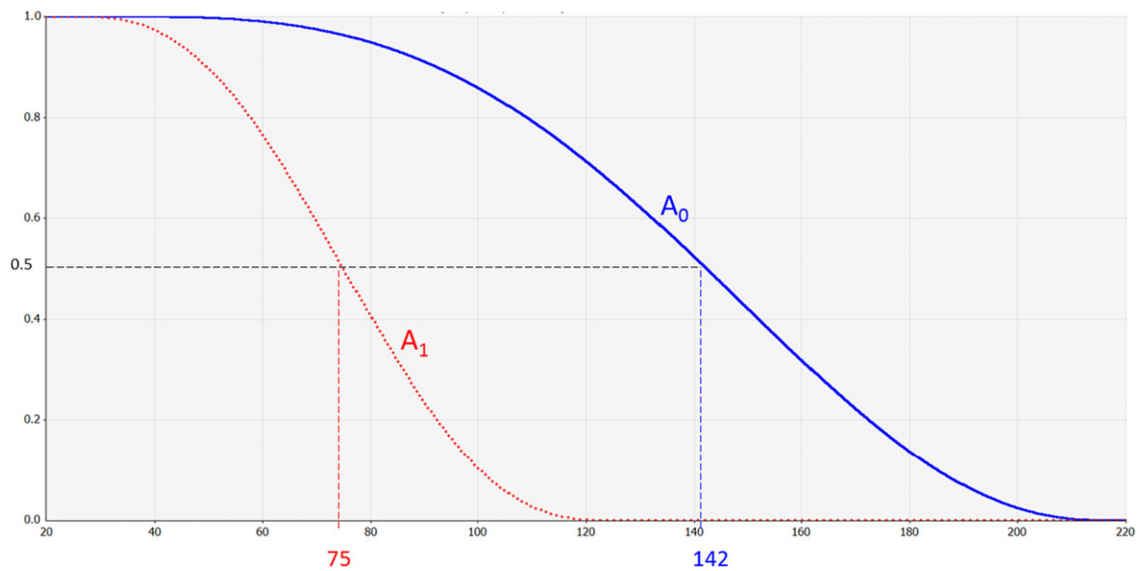
Overlaying the results of a distribution from one scenario on the results from another scenario may help communicate how scenarios compare (Figures 10, 11, 12) Comparison of the ranges in distributions should then be made. A default uncertainty range of 95% is suggested but the Commission can be asked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



X-axis label: Number of potential founder populations (Blue line Scenario A_0, Red Line Scenario A_1).
Y-axis label: Probability density.
A probability density plot for potential founder populations in scenario A_0, without RROs and A_1, with RROs. Note that the median for the number of potential founder populations in A_0 (142) is greater than the median for the number of potential founder populations in A_1 (75) although there is some overlap in the distributions.

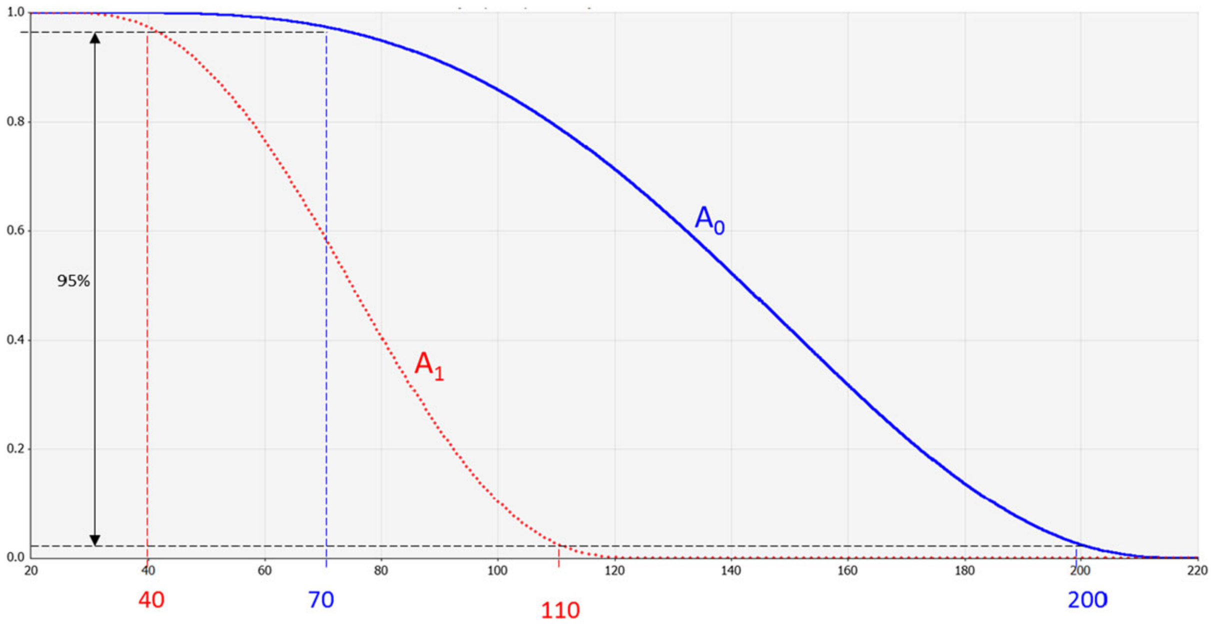
Figure 10: Probability density plots of the number of potential founder populations in scenario A_0 and scenario A_1

The results data used to generate the probability density in Figure 8 are expressed as cumulative descending probability in Figure 9 with the medians highlighted and in Figure 10 with the 95% probability range marked.



X-axis label: Number of potential founder populations.
Y-axis label: Probability.
Here the data from Figure 10 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 A_0 and A_1



X-axis label: Number of potential founder populations.
Y-axis label: Cumulative probability.
Here the data from Figure 11 are reproduced with the addition of the 95% probability range for each scenario. Scenario A_0 95% probability interval that the number of potential founder populations is between 70 and 200; Scenario A_1 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 scenarios A_0 and A_1

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 34–76 might be expressed as 30–80 and 462–878 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 if it conveys less precision than the assessors consider is merited.

Examples:

1,220 = Median: Approximately twelve hundred.

810–1,760 = 95% Uncertainty interval (interval between 2.5% and 97.5%): in the range of eight hundred 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 4 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 4: 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 A_0–A_n (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_n	50	120	180

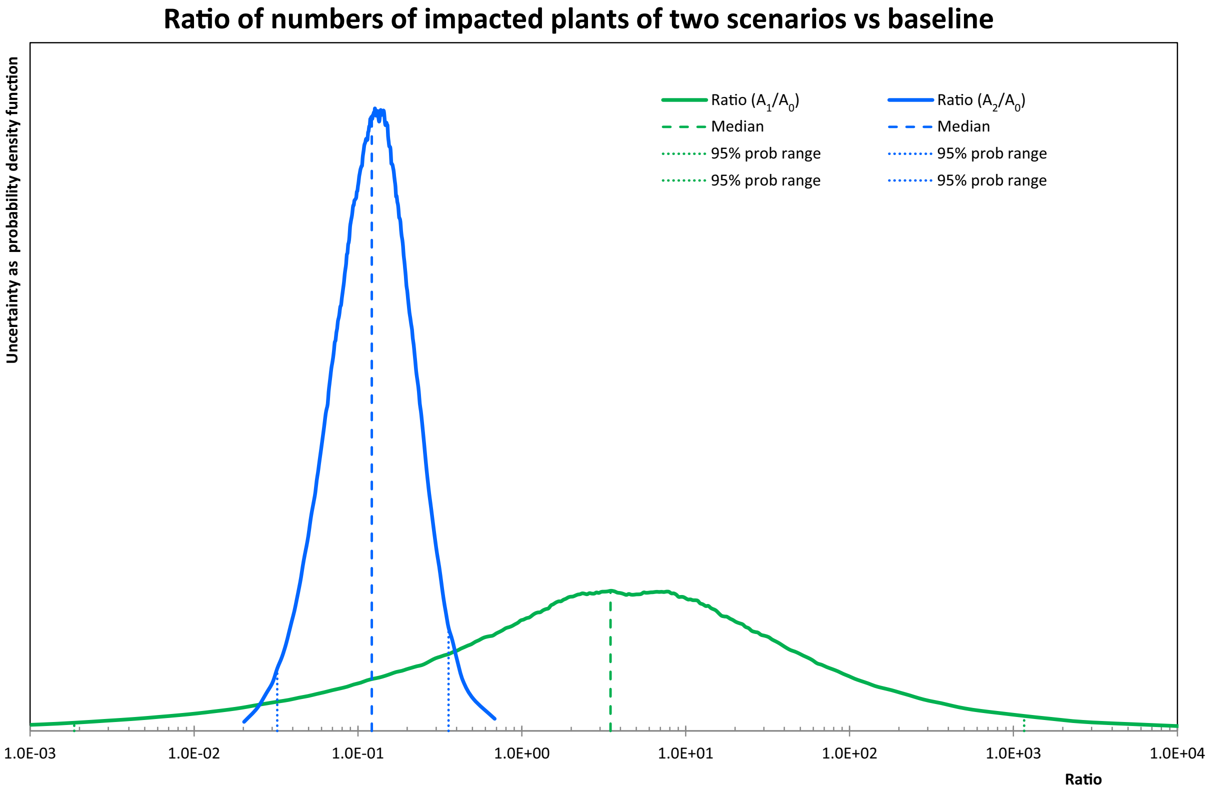
3.9.4. Comparing distributions

When an assessment results in distributions quantifying a measure of risk for different scenarios, A_0, A_1, etc., there will often be interest in comparing them. AS 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 A_0 from those of A_1) or a relative magnitude of effect (e.g. the ratio of the outcomes under A_1 and A_0). This is best carried out by Monte Carlo simulation, repeatedly calculating pairs of outcome values for A_0 and A_1 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 with a baseline scenario A_0, scenario A_2 represents stricter import inspection, whereas scenario A_1 represents less strict import inspection. In this example, the scenario A_2 has lowered each of the 10,000 stochastic simulation outcomes, such that the entire distribution of ratios of the outcomes under A_2 and A_0 is below 1 (denoted at 1.0E+00 on the figure x-axis). Conversely, scenario A_1 has increased most of the stochastic simulation outcomes compared with A_0 (ratios larger than 1), while it has lowered the stochastic simulation outcome in other instances (ratios smaller than 1). Figure 14 shows the same results as cumulative distributions. In this figure, it is easy to see that all ratios A_2/A_0 are all less than 1, whereas approximately 30% of the ratios A_1/A_0 are less than 1, while 70% are greater than 1. So, with a high level of confidence scenario A_2 reduces the risk, whereas scenario A_1 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 RRO is added as an additional substep 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 probability of an increase. However, if a risk reducing option is implemented in the risk model by eliciting a changed distribution for a substep 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 substep – with or without RRO – may result in some probability for either a reduction or an increase in the calculated outcome after the step.

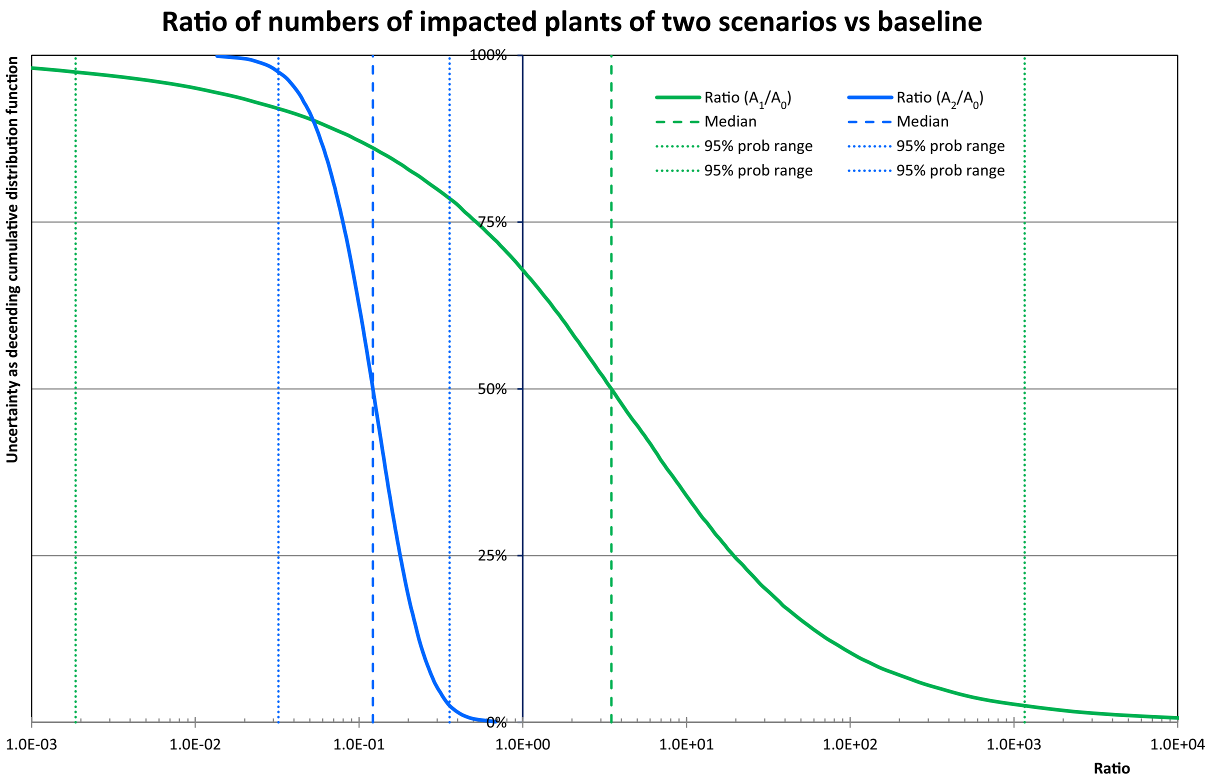
The choice between the two options (to implement the RRO as an additional substep or as a different elicited distribution for an existing substep) depends on whether the assessor considers the RRO to be an add-on or a replacement of an existing practice.

Advice may be requested from statistical support. The resulting distribution for the difference or ratio quantifies the impact of a change in risk management on the measure of risk and the uncertainty of that impact. 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.



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 with 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 Figure 14.

Figure 13: Comparison of scenarios by assessment of the ratio of the outcome variables under two scenarios (density form)



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 with 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 Figure 13.

Figure 14: Comparison of scenarios by assessment of the ratio of the outcome variables under two scenarios (cumulative form)

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 overprecise, then a more approximate quantitative expression should be found that appropriately communicates what the Panel is able to say about the conclusion, while minimising 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 the 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.

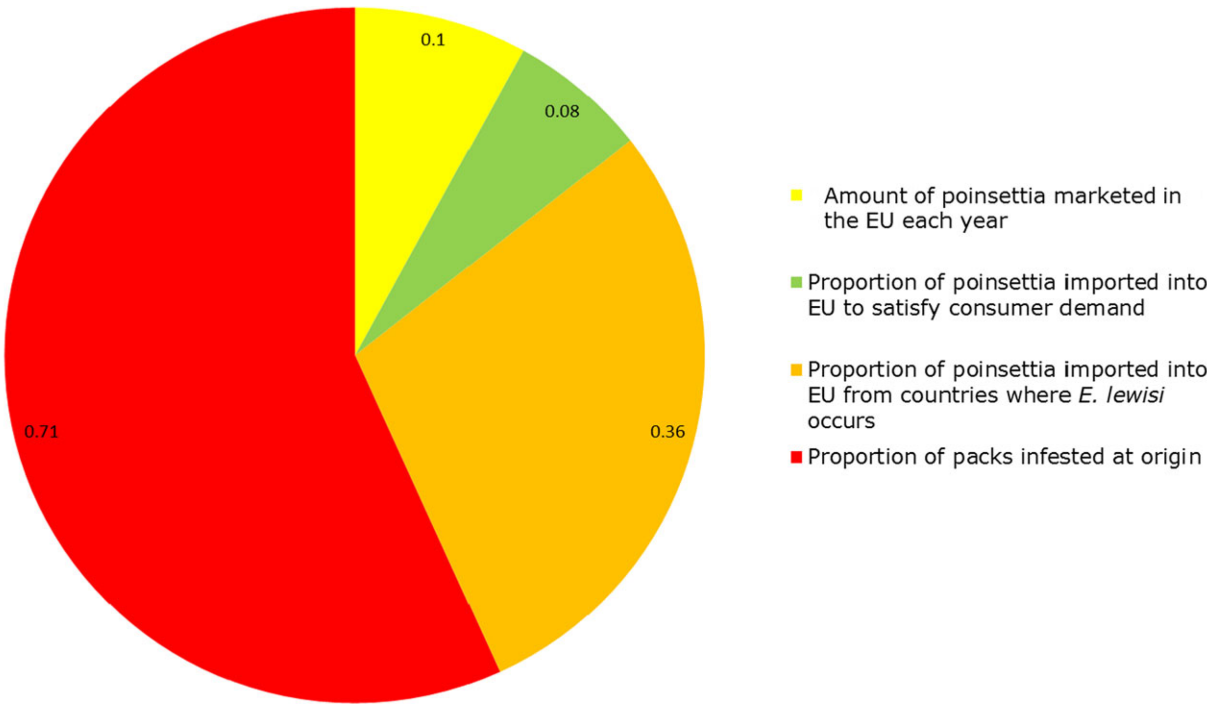
It should be identified which of the uncertainties contribute most to the overall uncertainty, including those quantified in the model and the additional uncertainties. Any actions that could be taken to try to reduce those uncertainties (e.g. further data collection or modelling) should be identified 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 – sensitivity analysis

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 performed 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 substeps 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 substeps 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 substeps with larger slices will have a greater effect on results.

Decomposition of the uncertainties provides valuable information for future refinement of the assessment, when needed. Obtaining and integrating new data are costly, so should be focused on those sources of uncertainty (whether model parameters or other parts of the assessment) that contribute most to the overall uncertainty. Decomposition can identify which of the uncertainties that are quantified in the model contribute most to the uncertainty of the model output; this needs to be considered alongside a review of the additional uncertainties that were not quantified in the model but included in the overall uncertainty assessment. If new data are obtained for one or more model parameters, they can be used to compare with the original estimates and either replace them, update them (by expert judgement or, preferably, Bayesian updating) or make new estimates based on the combined evidence (e.g. meta-analysis). Other types of new information might enable additional processes to be included in the model, or inform improvements in model structure.



Entry substeps whose estimates contribute the most to overall uncertainty on 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 substeps that contribute the most to uncertainty. Three of the four substeps 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 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 on entry is the level of infestation of the commodity at pathway origin.

Figure 15: Example on decomposition uncertainties from the EFSA opinion on *Eotetranychus lewisi* (EFSA PLH Panel, 2017d)

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 Section 3.9.8), why it is difficult to quantify, what assumptions have been made about it in the assessment and what could be carried out to reduce or better characterise it. If the assessors feel that they are able to use words that imply a judgement about the magnitude or likelihood of the unquantified sources of uncertainty when 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 on 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 (Section 3.9.5); 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. As 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 with which they are familiar (e.g. 95% confidence intervals). The purpose of this is to encourage the reader to 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 5 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.

Abstract

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 5. 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.

Summary

There is more space in the summary than in the abstract so assessors can go into more detail and be more precise on 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.

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 substeps 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 5: 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	EKE estimates of parameters and supporting information (evidence dossiers) used to inform estimates together with uncertainties and assumptions		

4. Conclusions

The 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 (EFSA Scientific Committee, 2018a).

This Guidance focuses 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 Annex A.

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 Panel 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. When there are time or resource constraints, a first tier approach is proposed whereby a base level quantification is carried out directly assessing the uncertainty distribution of the result for all or some of the main steps (Entry, Establishment, Spread and Impact).

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

Documentation provided to EFSA

1) ARES 2014 970361 – 28/3/2014. Request to provide a scientific opinion on the risk to plant health of 38 regulated harmful organisms, for the EU territory. Submitted by European Commission, Health and Consumers Directorate-General.
2) ARES 2015 1418918 – 31/3/2015. Request to complete the pest risk assessment (step 2) of seven regulated pests, following the analysis and exchange of views with Member States of the pest categorisations delivered (Ares(2014)970361). Submitted by European Commission, Health and Food Safety Directorate-General.
3) ARES 2017 1111340 – 2/3/2017. Request to provide a scientific opinion on the risk to plant health of 133 regulated harmful organisms, for the EU territory. Submitted by European Commission, Health and Food Safety Directorate-General.

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Glossary and Abbreviations

Additional uncertainties	Term used when some uncertainties have already been quantified, to refer to other uncertainties that have not yet been quantified and need to be taken into account in the characterisation of overall uncertainty (EFSA Scientific Committee, 2018a)

Area of potential establishment	The maximum number of spatial units or area for potential establishment of the pest in the risk assessment area for the relevant crops/habitats
Assessed variables	The variables object of the assessment. They are uniquely and unambiguously defined in terms of measurable quantity based on a clear question using empirical and physical data or evidence in the real 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) (EFSA Scientific Committee, 2018a)
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
Biodiversity component	Genetic, structural and functional components, which are represented at different organisational levels, from within organism to individual organism, species, population, community and ecosystem levels
Conceptual model	The reasoning developed by assessors in the course of a scientific assessment, which is then implemented as a narrative argument, a logic model or a combination of these. The conceptual model provides a general and qualitative description of the system to be modelled. It characterises the environmental and biological processes and their interactions and interdependencies. Documenting the conceptual model, e.g. as a bullet list, flow chart or graphic, may be helpful to assessors during the assessment and also for readers, if included in the assessment report (EFSA PPR Panel, 2014; EFSA Scientific Committee, 2018a)
Containment (of a pest)	Application of phytosanitary measures in and around an infested area to prevent spread of a pest (ISPM 5 (FAO, 2017d))
Control (of a pest)	Suppression, containment or eradication of a pest population (ISPM 5 (FAO, 2017d))
Control measure	It is a measure that has a direct effect on pest abundance. Control measures aim at suppression, containment or eradication of a pest population
Consignment	A quantity of plants, plant products or other articles being moved from one country to another and covered, when required, by a single phytosanitary certificate (a consignment may be composed of one or more commodities or lots) (ISPM 5 (FAO, 2017d))
Dependency	Variable quantities are dependent when they are directly or indirectly related, such that the probability of a given value for one quantity depends on the value(s) of other quantities (e.g. food consumption and body weight). Sources of uncertainty are dependent when learning more about one would alter the assessors' uncertainty about the other (EFSA Scientific Committee, 2018a)
Distribution	A probability distribution is a mathematical function that relates probabilities with specified intervals of a continuous quantity or values of a discrete quantity. Applicable both to random variables and uncertain parameters (EFSA Scientific Committee, 2018a)
Ecological niche models	They are models predicting the geographical distribution of a species on the basis of a representation of their known distribution in environmental space. The environment is usually represented by climate data (e.g. temperature, precipitation), but other environmental variables can also be used
Ecosystem services	Benefits that humans recognise as obtained from ecosystems that support, directly or indirectly, their survival and quality of life; ecosystem services include provisioning, regulating and cultural services that directly benefit people, and the supporting services needed to maintain the direct services (MEA, 2003; Harrington et al., 2010)

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
Emergency measure	A phytosanitary measure established as a matter of urgency in a new or unexpected phytosanitary situation. An emergency measure may or may not be a provisional measure (ISPM 5 (FAO, 2017d))
Endangered area	An area where ecological factors favour the establishment of a pest whose presence in the area will result in economically important loss (ISPM 5 (FAO, 2017d))
Entry (of a pest)	Movement of a pest into an area where it is not yet present, or present but not widely distributed and being officially (ISPM 5 (FAO, 2017d))
Eradication (of a pest)	Application of phytosanitary measures to eliminate a pest from an area (ISPM 5 (FAO, 2017d)). ISPM 9 (FAO, 2016e) lays down the requirements for pest eradication programmes
Establishment (of a pest)	Perpetuation, for the foreseeable future, of a pest within an area after entry (ISPM 5 (FAO, 2017d))
Evidence	Information that is relevant for assessing the answer to a specified question. In PROMETHEUS, a piece of evidence for an assessment is defined as data (information) that is deemed *relevant* for the specific objectives of the assessment (EFSA, 2015). In this Guidance, this is expanded to all *potentially relevant* information, i.e. all evidence identified by the initial search process, to recognise that the assessment of relevance in the search process is necessarily a preliminary one (e.g. based on keywords and titles alone). 'Evidence' can refer to a single piece of potentially relevant information or to multiple pieces (EFSA Scientific Committee, 2017)
Expert judgement	The judgement of a person with relevant knowledge or skills for making that judgement (EFSA Scientific Committee, 2018a)
Expert knowledge elicitation (EKE)	A systematic, documented and reviewable process to retrieve expert judgements from a group of experts, often in the form of a probability distribution (EFSA Scientific Committee, 2018a)
Formal model	The result of the formalisation of the conceptual model in which model variables and parameters are defined and linked together into mathematical equations or algorithms (EFSA PPR Panel, 2014)
Founder population	A viable population of a species which is able to successfully colonise and to establish in a new area
Fundamental niche map	A map of the areas characterised by set of conditions and resources that allow a given species to survive and reproduce in the absence of biotic interactions limiting its distribution
Hardiness zones	A geographical area defined by specific climatic conditions in which a plant species is capable to growth, including the ability to withstand the average annual extreme minimum temperature recorded in that area
Impact (of a pest)	The damage caused by a pest on the crop output and quality and/or on the environment
Introduction (of a pest)	The entry of a pest resulting in its establishment (ISPM 5 (FAO, 2017d))
Köppen–Geiger maps	Maps representing climate zones based on Köppen-Geiger climate classification (see http://koeppen-geiger.vu-wien.ac.at/)
Logistic model	A common model describing a population growth following the logistic function. It can also be used to describe the increase in the number of occupied spatial units in a spread model
Low pest prevalence	The ISPM 22 (FAO, 2016f) provides requirements for the establishment of areas of low pest prevalence

Mechanistic approach	An approach that states that the behaviour of complex systems is determined strictly by the interactions of the parts or factors of which they are composed. In mechanistic approach, process are described with model with lower-level derivation (Schoener, 1986). In this document, the term is equivalent to process-based approach
Model	In scientific assessment, usually refers to a mathematical or statistical construct, which is a simplified representation of data or of real world processes and is used for calculating estimates or predictions. Can also refer to the structure of a reasoned argument or qualitative assessment (EFSA Scientific Committee, 2018a)
Monte Carlo method	In this Guidance, only the one-dimensional Monte Carlo method is used. The one-dimensional Monte Carlo is a method for making probability calculations by random sampling from one set of distributions, all representing uncertainty about non-variable quantities or categorical questions (EFSA Scientific Committee, 2018a)
Occupancy model	A model describing the proportion of area, patches or sample units that is occupied (i.e. species presence)
Official	Established, authorised or performed by a National Plant Protection Organization (ISPM 5 (FAO, 2017d))
Overall uncertainty	The assessors' uncertainty about the question or quantity of interest at the time of reporting, taking account of the combined effect of all sources of uncertainty identified by the assessors as being relevant to the assessment (EFSA Scientific Committee, 2018a)
Parameter	Parameter is used in this document to refer to quantitative inputs to an assessment or uncertainty analysis, without specifying whether they are variable or not. In most places, a non-variable quantity is implied, consistent with the use of parameter in statistics. However, in some places parameter could refer to a variable quantity, as it is sometimes used in biology (e.g. glucose level is referred to as a blood parameter) (EFSA Scientific Committee, 2018a)
Pathway	Any means that allows the entry or spread of a pest (ISPM 5 (FAO, 2017d))
Pathway modelling	It is a formalisation 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
Pathway subunit	A pathway subunit 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 subunit may or may not be affected
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
Pest (population) abundance	It is the relative representation of a species in a particular habitat or spatial units (e.g. a sampling unit, an ecosystem). The term is here used in a broad meaning referring to any measures of the population presence in the unit (e.g. number of individuals, incidence/severity of symptoms, sign of activity)
Pest free area (PFA)	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 5 (FAO, 2017d)). ISPM 1 (FAO, 2016h) includes operational principles on recognition of PFAs. The establishment of a PFA involves both the exporting and the importing countries and is implemented by the National Plant Protection Organization (NPPO) of the importing country (ISPM 4 (FAO, 2017b). ISPM 8 (FAO, 2017e) provides guidance on the pest freedom declaration in pest records. ISPM 29 (FAO, 2017f) indicates the principles that apply for the recognition of PFAs)

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 5 (FAO, 2017d)). ISPM 10 (FAO, 2016b) 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 5 (FAO, 2017d)). ISPM 10 (FAO, 2016b) indicates the requirements for the establishment of pest free places of production and pest free production sites
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 (ISPM 5 (FAO, 2017d))
Plausible range	A range of a quantity defined by an upper limit and a lower limit assessed by expert judgement such that, although it may technically be possible for the true value to be above the upper limit or below the lower limit, the expert(s) would be extremely surprised if it were not somewhere between the limits, (Section 6.1.4 in EFSA 2014a)
Prevalence	It is a general term expressing how frequently something occurs. In the context of prevalence of pest in a trade, it may be thought of in terms of the proportion of units of the product that carry the pest (in this way the term is equivalent to pest abundance)
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 (EFSA Scientific Committee, 2018a). The latter definition applies to the probabilities used in this document. Probabilities are often expressed as proportions but in this document they are expressed as percentages
Probability judgement	A probability, approximate probability or probability bound obtained by expert judgement (EFSA Scientific Committee, 2018a)
Protected zones (PZ)	A protected zone is an area recognised at EU level to be free from a harmful organism, which is or not established in one or more other parts of the Union. In Council Directive 2000/29/EC, a protected zone is defined for a harmful organism: i) which is established in one or more parts of the Union, as a zone in the Community in which the organism is not present despite favourable environmental conditions for its establishment ii) which is not endemic or established in the Union, if there is a danger that the harmful organism will establish in that area, given propitious ecological conditions, for particular crops.
Product unit	A unit used to quantify the production (e.g. kg of olives per tree, tonnes 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
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%
Quantitative assessment	It can be regarded as the form of assessment in which the conclusion of an assessment is expressed in numeric terms (using a range of values and their relative likelihood), or to the methods used to reach the conclusion (involving calculations), or both
Quarantine pest	A pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled (ISPM 5 (FAO, 2017d))

Regulated pest	A quarantine pest or a regulated non-quarantine pest (ISPM 5 (FAO, 2017d))
Regulated non-quarantine pest	A non-quarantine pest whose presence in plants for planting affects the intended use of those plants with an economically unacceptable impact and which is therefore regulated within the territory of the importing contracting party (ISPM 5 (FAO, 2017d))
Risk assessment	A scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation (Regulation (EC) No 178/2002)
Risk management	The process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options (Regulation (EC) No 178/2002). The EFSA PLH Panel will not take part in the risk management activities as described in Regulation (EC) No 178/2002
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 (EFSA PLH Panel, 2012). An RRO may become a phytosanitary measure, action or procedure according to the decision of the risk manager
Risk reduction option combination	A set of RROs (control measures and supporting measures), for which the combined effect will be estimated, that reduce the risks posed by the pest on the same substep of the risk assessment
Risk reduction option scenario	The description of the complete sequence of RRO combinations for all substeps of the risk assessment reducing the overall risk posed by the pest
Scenario	In IPCC, 2000, a scenario is defined as 'plausible and often simplified descriptions of how the future may develop, based on a coherent and internally consistent set of assumptions about key driving forces and relationships'
Semi-formal expert knowledge elicitation	A structured and documented procedure for eliciting expert judgements that is intermediate between fully formal elicitation and informal expert judgements (EFSA Scientific Committee, 2018a)
Sensitivity analysis	A study of how the variation in the outputs of a model can be attributed to, qualitatively or quantitatively, different sources of uncertainty or variability. Implemented by observing how model output changes when model inputs are changed in a structured way (EFSA Scientific Committee, 2018a)
Service providing unit	For an environmental risk assessment of pests based on ecosystem services, it is necessary: (1) to identify the environmental components or units responsible for the genesis and regulation of the ecosystem services, the so-called 'service providing units'; they are regarded as functional units in which the components (individuals, species or communities) are characterised by functional traits defining their ecological role (EFSA PLH Panel, 2011)
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 LAU2 and the FAO GAUL
Spread (of a pest)	Expansion of the geographical distribution of a pest within an area (ISPM 5 (FAO, 2017d))
Statistical model	A probabilistic model of variability, possibly modelling dependence between variables or dependence of one variable on another, for example a family of probability distributions representing alternative possible distributions for a variable or regression or dose–response models. Usually have parameters which control the detail of distributions or dependence (EFSA Scientific Committee, 2018a)
Supporting measure	It is an organisational measure or procedure supporting the choice of appropriate risk reduction options that do not directly affect pest abundance

Temporal horizon	It is a fixed point of time in the future at which the outcome of certain processes will be evaluated. In the scenario-based approach adopted by the PLH Panel, for the risk assessment the current situation is projected to a certain time point into the future
Terms of reference	Statement of the background, objectives and purpose of a program, project, or proposal. (BusinessDictionary.com. WebFinance, Inc. 25 April 2018 <http://www.businessdictionary.com/definition/terms-of-reference.html>)
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
Transfer	Pest transfer has been defined as the movement of a pest from an imported commodity to a place where the pest can establish; see also ISPM 11, Section 2.2.1.5 (FAO, 2017a)
Transfer unit	A unit composed by one or more pathway units or subunits, 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
True value (synonym: real value)	The actual value that would be obtained with perfect measuring instruments and without committing any error of any type, both in collecting the primary data and in carrying out mathematical operations (EFSA Scientific Committee, 2018a)
Uncertainty	In this document, 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 (see separate definition) and sometimes to its impact on the conclusion of an assessment (EFSA Scientific Committee, 2018a)
Uncertainty analysis	The process of identifying and characterising uncertainty about questions of interest and/or quantities of interest in a scientific assessment
Uncertainty distribution	Technically, a mathematical function that relates probabilities with specified intervals of a continuous quantity or values of a discrete quantity (EFSA, 2018). Distributions are used in this document to quantify the uncertainty of model parameters and outputs
Unquantified uncertainty	An identified source of uncertainty in a scientific assessment that the assessors are unable to include, or choose not to include, in a quantitative expression of overall uncertainty for that assessment (EFSA Scientific Committee, 2018a)
Variability	Heterogeneity of values over time, space or other dimension characterising a set of data. It includes stochastic variability and controllable variability (EFSA Scientific Committee, 2018a)
Variable	A quantity that has multiple true values (e.g. body weight measured in different individuals in a population, or in the same individual at different points in time) (EFSA Scientific Committee, 2018a)
Weight of evidence assessment	A process in which evidence is integrated to determine the relative support for possible answers to a question (EFSA Scientific Committee, 2017). The conclusion of a weight of evidence assessment should specify the range of possible answers to the assessment question and how probable they are

AHAW	Animal Health and Welfare
CBS	Citrus black spot
EKE	expert knowledge elicitation
EPPO	European and Mediterranean Plant Protection Organization
ERA	environmental risk assessment
FAO	Food and Agriculture Organization of the United Nations
GAUL	Global Administrative Unit Layers
IPPC	International Plant Protection Convention
ISPM	International Standards for Phytosanitary Measures
LAU	Local Administrative Unit
NPPO	National Plant Protection Organization
NUTS	Nomenclature of territorial units for statistics
PAFF	EU Standing Committee of Plants, Animals, Food and Feed
PEQ	Post-entry quarantine
PFA	pest free area
PFC	pest free consignment
PFPP	pest free place of production
PLH	Plant health
PM	phytosanitary Measure
PPR Panel	EFSA Panel on Plant Protection Products and their Residues
PRATIQUE	Enhancement of Pest Risk Analysis Techniques – EU collaborative project
RA	risk assessment
RRO	risk reduction option
SDMs	species distribution models
SPU	service providing unit
ToR	Terms of Reference

Appendix A – Standardised checklist of risk reduction options

To harmonise the assessment of risk reduction options (RRO) across EFSA Plant Health scientific opinions, a list of specified RROs was compiled that could be used to select the relevant RROs for the scenarios in the assessment.

This appendix provides in Table A.1 the links to the information sheets characterising the RROs that have been developed with the aim to assist the risk assessor in the use of the RRO tool-kit (see Annex E) when performing:

i) the identification of the relevant combination of RROs in the development of the risk assessment scenarios;
ii) the evaluation of specific measures indicating the factors to consider in the process that limit the effectiveness of such measures.

The Panel has identified a collection of RROs that embraces 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, 2017d) as 'Suppression, containment or eradication of a pest population';
ii) the supporting measures that are organisational measures or procedures supporting the choice of appropriate RROs that do not directly affect pest abundance.

For some of these RROs, information sheets were developed; other RRO information sheets are still under development and are not yet published. In these documents, the Panel does not pretend to provide a monograph of the measures neither provide 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 information sheets should be revised when relevant and specific information on the characteristics of an RRO have been retrieved from the literature and used in the context of a pest risk assessment.

The RRO information sheets are all organised 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.

Table A.1: Standardised check list of risk reduction options

List of RRO information sheets			
Nr	**Information sheet title**	**RRO summary**	**Links to the documents**
Control measures: measures that have a direct effect on pest abundance. Control (of a pest) is defined in ISPM 5 (FAO, 2017d) as 'Suppression, containment or eradication of a pest population'			
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	https://doi.org/10.5281/zenodo.1175886
1.02[(a)]	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	https://doi.org/10.5281/zenodo.1310977
1.03[(a)]	Chemical treatments on crops including reproductive material		https://doi.org/10.5281/zenodo.1311010
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	https://doi.org/10.5281/zenodo.1175909
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	https://doi.org/10.5281/zenodo.1175928
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	https://doi.org/10.5281/zenodo.1175955

List of RRO information sheets			
Nr	**Information sheet title**	**RRO summary**	**Links to the documents**
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)	https://doi.org/10.5281/zenodo.1175965
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)	https://doi.org/10.5281/zenodo.1176194
1.09	Controlled atmosphere	Treatment of plants by storage in a modified atmosphere (including modified humidity, O_2, CO_2, temperature, pressure)	https://doi.org/10.5281/zenodo.1180170
1.10	Waste management	Treatment of the waste (deep burial, composting, incineration, chipping, production of bioenergy, etc.) in authorised facilities and official restriction on the movement of waste	https://doi.org/10.5281/zenodo.1181441
1.11[(a)]	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	https://doi.org/10.5281/zenodo.1311070
1.12	Roguing and Pruning	Roguing is defined as the removal of infested plants and/or uninfested host plants in a delimited area, whereas pruning is defined as the removal of infested plant parts only without affecting the viability of the plant	https://doi.org/10.5281/zenodo.1181435

List of RRO information sheets

Nr	Information sheet title	RRO summary	Links to the documents
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	https://doi.org/10.5281/zenodo.1181716
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 fiche are: autoclaving; steam; hot water; hot air; cold treatment	https://doi.org/10.5281/zenodo.1181639
1.15	Conditions of transport	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	https://doi.org/10.5281/zenodo.1181607
1.16[(a)]	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	https://doi.org/10.5281/zenodo.1311114
1.17[(a)]	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	https://doi.org/10.5281/zenodo.1311127

List of RRO information sheets			
Nr	**Information sheet title**	**RRO summary**	**Links to the documents**
Supporting measures: are organisational measures or procedures supporting the choice of appropriate RROs that do not directly affect pest abundance			
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, 2017d)) The effectiveness of sampling and subsequent inspection to detect pests may be enhanced by including trapping and luring techniques	https://doi.org/10.5281/zenodo.1181429
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	https://doi.org/10.5281/zenodo.1181212
2.03[(a)]	Sampling	According to ISPM 31 (FAO, 2016g), 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	https://doi.org/10.5281/zenodo.1311143
2.04[(a)]	Phytosanitary certificates 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, 2017d)): a) export certificate (import), b) plant passport (EU internal trade)	https://doi.org/10.5281/zenodo.1311158

List of RRO information sheets			
Nr	**Information sheet title**	**RRO summary**	**Links to the documents**
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	https://doi.org/10.5281/zenodo.1180844
2.06[(a)]	Certification of reproductive material (voluntary/official)		http://doi.org/10.5281/zenodo.1311164
2.07	Delimitation of buffer zones	ISPM 5 (FAO, 2017d) defines a buffer zone as ‘an area surrounding or adjacent to an area officially delimited for phytosanitary purposes in order to minimise 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, (FAO, 2017d)). 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)	https://doi.org/10.5281/zenodo.1180596
2.08[(a)]	Surveillance	ISPM 5 (FAO, 2017d) defines surveillance as ‘an official process which collects and records data on pest presence or absence by survey, monitoring or other procedures’	https://doi.org/10.5281/zenodo.1311184

(a): The information sheets are still in preparation.

Appendix B – Elaboration of a pathway model for entry (second tier)

This appendix provides in Table B.1 an example of a full mathematical description, representing the formal pathway model for entry (second tier).

Table B.1: Variables involved in the entry model

Variable	Explanation	Substep
P_1	Definition 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 Meaning/Example E.g. nematode-infested potatoes per tonne, proportion (%) of CBS-infected oranges in an orchard, proportion of thrips infested orchids in a box Value To be estimated by the experts Units Percentage of affected units or subunits, or number of individuals per units or subunits. To be operationalised by the risk assessor	E_1
P_2	Definition Abundance of the pest when crossing the border of the exporting country Meaning/Example See example for P_1 Value $P_2 = P_1 \times m_1 \times m_2 \times m_3$ Units Percentage of affected units or subunits, or number of individuals per units or subunits. To be operationalised by the risk assessor	E_2
P_3	Definition 5.1.1. Abundance of the pest when arriving at the EU point of entry Meaning/Example See example for P_1 Values $P_3 = P_2 \times m_4$ Units Percentage of affected units or subunits, or number of individuals per units or subunits. To be operationalised by the risk assessor	E_3

Variable	Explanation	Substep
P_4	Definition 5.1.2. Abundance of the pest when leaving the EU point of entry Meaning/Examples 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 substep E_3 to substep E_4 Value $P_4 = P_3 \times m_5$ Units Percentage of affected units or subunits, or number of individuals per units or subunits. To be operationalised by the risk assessor	E_4
N_0	Definition 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 Meaning/Examples Tonnes of seed potato per year, number of oranges per year, number of orchids (potted plants) per year Value To be assessed by the experts Units Units (tonnes, 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 Meaning/Examples 10 new founder populations in the risk assessment area per year Value $N_1 = P_4 \times N_0 \times m_6 \times m_7$ Units Number of transfers occurring per year in the EU	E_5

Variable	Explanation	Substep
m_1	Definition Multiplication factor changing the abundance of the pest before leaving the place of production in the different scenarios ($A_1, \ldots, A_n$) Meaning/Examples Proportion of the pest propagules that survive RROs applied before the product leaves the place of production Values In A_0, this is not assessed and is therefore put equal to 1 in the calculation tool. In a scenario in which additional measures are applied this factor could be ≤ 1. In a scenario in which measures are removed this factor could be ≥ 1 Units Dimensionless	E_1
m_2	Definition Units conversion coefficient. It changes the units from the abundance of the pest when leaving the place of production to the pathway unit/subunit along the pathway (i.e. it changes the way in which pest propagules are defined) Meaning/Examples 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 Values 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	E_1

Variable	Explanation	Substep
m_3	Definition Multiplication factor changing the abundance from substep E_1 (after having left the place of production) to substep 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 substep E_2 (after having left the border of the export country) to substep 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 substep E_3 (after arriving at the point of entry) to substep 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

Variable	Explanation	Substep
m_6	Definition Aggregation/disaggregation coefficient transforming the pathway units/subunits 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	E_4
m_7	Definition Multiplication factor changing the abundance from substep E_4 (after leaving the point of entry) to substep 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 substep E_4 to substep E_5 Values To be estimated by the experts Units Dimensionless	E_4

Annex A – Pest categorisation template

Annex B – Pest risk assessment template

Annex C – Example for application of tier one approach for pest impact assessment

Annex D – Examples of risk model implementation and calculation

Annex E – Tool kit for identification and evaluation of risk reduction options

Annexes A–E can be found in the online version of this output (in the 'Supporting information' section): https://doi.org/10.2903/j.efsa.2018.5350

Annex E can also be found on the Zenodo platform: https://doi.org/10.5281/zenodo.1170120